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*The law and practice of consent to medical intervention*

HEYWOOD, Robert James

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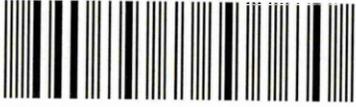
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# THE LAW AND PRACTICE OF CONSENT TO MEDICAL INTERVENTION

*Robert James Heywood*

*Sheffield Hallam University*  
*May 2006*

A thesis submitted in partial fulfilment of the requirements for the degree  
of Doctor of Philosophy.



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## DECLARATION

A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy.

I, Robert James Heywood, hereby declare that the material contained in this thesis has not been used in any other submission for an academic award.

Director of Studies:     Jim Hanlon (Law Department)  
1<sup>st</sup> Supervisor:         Kevin Williams (Law Department)  
2<sup>nd</sup> Supervisor:         Professor Ann Macaskill (Psychology Department)

*Rob Heywood.*

## DEDICATION

This thesis is dedicated, in its entirety, to my parents, Dave and Ann Heywood.  
Simply the best mum and dad anyone could ever wish for.

Work hard, play hard!

May 2006.

# ABSTRACT

## 'The Law and Practice of Consent to Medical Intervention'

*Robert James Heywood*

This thesis explores the challenging concept of informed consent. It is an empirical study investigated in a medico-legal context. The research combines the use of quantitative and qualitative research methods to analyse the different views of the parties who are actively involved in the consent process in both medical and legal settings.

The project provides a comprehensive review of the literature concerning the legal aspects of consent and information disclosure, critically analysing relevant case law and academic opinion. The problematic areas are highlighted and from these a number of research areas are identified forming the basis of the empirical inquiry. The thesis is then broken down into a number of individual studies incorporating a range of empirical techniques. These include:

1. A quantitative study employing a questionnaire to evaluate medical students' knowledge and to identify what is important to them in respect of consent.
2. A qualitative interview study exploring health care professionals' opinions on consent in primary care.
3. A qualitative interview study exploring health care professionals' opinions on consent in secondary care.
4. A qualitative interview study exploring patients' perspectives on consent.
5. A qualitative observational study to assess how consent procedures operate in practice in secondary care.
6. A qualitative interview study exploring consent litigation in practice from solicitors' perspectives.

Each project acts as a continuation of one another. The methodological position of the thesis is that knowledge is progressive and is accumulated as each study develops. This is achieved through the researcher being 'situated' in the work and through continuous legal and sociological reflections. Accordingly, the findings are analysed and provide for a critical assessment of the law pertaining to consent and information disclosure. The project is a collaborative venture between the law and the medical profession and seeks to develop a clearer understanding of consent issues in practice. In doing so a number of problems are identified which have previously gone unnoticed and, as such, future recommendations for improvement are provided at the end of this thesis.

# SUMMARY

## **Study Overview**

This thesis explores the challenging concept of informed consent. It is an empirical study investigated in a medico-legal context. It combines the use of quantitative and qualitative research methods to analyse the different views of the parties who are actively involved in the consent process in both medical and legal settings. The findings are then reflected upon from the author's own legal background to provide a critical assessment of the law pertaining to consent and information disclosure. The project is a collaborative venture between the law and the medical profession and seeks to develop a clearer understanding of consent issues in practice. In doing so a number of problems are identified which have previously gone unnoticed and, as such, subsequent recommendations are provided for at the end of this thesis.

## **Literature**

The study provides a comprehensive review of the literature concerning the legal aspects of consent and information disclosure. It critically analyses relevant case law and relies upon academic opinion to scrutinise and identify problematic legal areas. From this, a number of research areas are identified that form the basis of the empirical inquiry in this work.

## **Empirical Methods**

This is an empirical study. It provides evidence of research involving human participants who are actively involved in the consent process and explores the views and opinions of those who are faced with challenging issues in practice. The thesis combines quantitative and qualitative research methods to generate original data relating to a range of different participants' views in respect of consent. In turn, the views from all the different parties are combined and the contentious and problematic

areas are identified. The views are then reflected upon from the researcher's own legal background to provide a clearer understanding of the difficulties faced by those in practice, and to suggest a number of solutions to these problems in both a legal and sociological sense.

### **Individual Studies**

The study involves a range of different participants and combines the use of quantitative and qualitative research methods to investigate the issues identified above.

- 1) It employs quantitative research methods to evaluate medical students' knowledge of the legal issues relating to consent and attempt to gain a deeper understanding of how they are trained in communication processes.
- 2) It uses qualitative methods to interview medical practitioners in primary care about informed consent and relates this to the law.
- 3) It uses qualitative interview methods to explore consent from medical practitioners in secondary care.
- 4) It employs qualitative interview methods to explore informed consent from patients' perspectives.
- 5) It uses qualitative observational techniques to assess how consent is obtained in secondary care.
- 6) It uses qualitative interviews to investigate consent litigation in practice from solicitors' perspectives.

Although for the purposes of discussion and analysis the qualitative sections are presented as separate, and are broken down into smaller individual components, they are actually continuations of one another. The methodological position of the thesis is that knowledge is accumulated and combined as each study progresses. This is achieved through the researcher being 'situated' in the work and through continuous legal and sociological reflections. Thus, the knowledge is progressive throughout the study.

## **Ethics**

As this is an empirical study using human participants, the project was endorsed by the relevant NHS Ethics Committee and gained approval from NHS Research Governance.

## **The Major Research Findings**

- 1) The medical students in this study recognised the importance of informed consent in contemporary medical practice. They attached most importance to the ethical side of consent, yet acknowledged its importance from a legal perspective. Despite this, it is evident that they do not receive a lot of training in terms of informed consent at undergraduate level and therefore are not confident in dealing with these issues upon entering practice. The students in this study feel they have been trained ineffectively in terms of obtaining consent.
- 2) When asked to provide a definition of informed consent which was measured against the Department of Health's working description, the students in this study focus on three main components. These include risks, understanding and agreement.
- 3) Whilst recognising the overall importance of consent from an ethical point of view, in this study it seems medical practitioners in primary care engage in informal consent procedures. They are not concerned with the threat of the law and this does not affect their practice. In actual fact they seem to concentrate more on patient understanding. They focus less on risks suggesting that in primary care these are so trivial and infrequent that there is no need to disclose them. They perceive the most difficult part of their job as being the side-effects and risks associated with prescribing drug therapies and they state it is very difficult to keep up-to-date with the risks and to know what to disclose.

- 4) The Medical practitioners in secondary care within this study place emphasis on the importance of openness, disclosure and shared-decision making. However, they are more concerned with the threat of the law. They are involved in formal consent procedures which include written consent. There is criticism aimed at the bureaucratic nature of consent forms which stifles doctor/patient communication. The most important thing seems to be that informed consent is a relative concept and ought to be tailored to each individual patient. A great deal of significance is attached to risk disclosure. There is evidence that, in some situations, the clinicians in this study attempt to maintain clinical discretion in terms of what they disclose, yet feel this is being eroded by the law. It is unclear whether this is based on direct knowledge of the law or mere anecdotal evidence from colleagues. In all probability it is more likely to be the latter. What is clear is that the *perceived* threat of the law leads medical practitioners, in some situations, to engage in excessive disclosure where they bombard patients with risks. Also in this study, attention is paid to the importance of communication and understanding and how this can be improved in the consent process.
- 5) The patients in this study struggle to understand the true meaning of consent. They see it as something that is *necessary* in order to get to the next stage of their treatment. They value the provision of information and look favourably on receiving details about risks and alternatives. However, the process of disclosure seems to be viewed as independent of consent and patients struggle to make the link between the two. It is why they want information that is perhaps most interesting. It seems that they are not concerned with their right to self-determination. The patients here welcome additional information about treatment as it enhances and facilitates the healing process. They are more concerned with

the therapeutic benefits of enhanced disclosure prior to treatment rather than the need to receive information in order that they can make a decision. The patients involved in this project also see the value and importance of honesty and communication and suggest they would be unlikely to pursue a complaint unless the relationship of trust breaks down. It seems there is a marked reluctance to resort to legal action and they feel understanding can be improved by patient support-groups, patient volunteers and decision-aids.

- 6) The solicitors in this study suggest that the law has developed in an extremely paternalistic manner and that this has stifled consent and information disclosure cases. They indicate there are only a few cases and that not many of these are successful. It seems clients have difficulty in understanding exactly what they are claiming for and problems are identified in the way the law operates in terms of the battery/negligence divide. There are potential reforms suggested by the participants in this study in relation to the standard of care in information disclosure cases, the decision in *Bolitho* and the development of consent through professional guidelines and Patient Charters. Also, there is a call for greater training and awareness of the law and how it operates amongst clinicians to allow them to understand the true meaning of consent and that it is not just a medico-legal requirement.

### **Publications from this Thesis**

- 1) Heywood, R. "Re-Thinking the Decision in *Pearce*" (2005) 7 CIL 264.
- 2) Heywood, R. "Excessive Risk Disclosure: The Effects of the Law on Medical Practice" (2005) 7 Med L Int 93.
- 3) Heywood, R. "Informed Consent Through the Back Door?" (2005) 56 NILQ 266.

# 1 INTRODUCTION

'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs a operation without his patient's consent commits an assault'<sup>1</sup>

## 1.1 The Research Question

In order for medical practitioners to protect themselves against legal challenge, consent is required on behalf of the patient before any form of treatment that involves some kind of bodily contact is administered.<sup>2</sup> In terms of invasive procedures, consent is usually given expressly by the patient and this is usually evidenced in writing by means of a consent form. However, for lesser forms of treatment which involve physical contact, consent is often said to be implied. Conduct or verbal statements can evidence this. Many perceive consent to medical treatment simply as individuals giving medical practitioners permission to carry out treatment. However, the term "informed consent", first used in a medico-legal context in America, has come to mean something more.<sup>3</sup>

Informed consent is a process involving the communication of information and the making of a reasonable and co-operative decision by doctor and patient.<sup>4</sup> Still, the question of what constitutes a legally valid consent has been fraught with controversy. In order that the individual can make that decision and act as a truly autonomous agent, it is claimed that it must be made in an informed manner, free

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<sup>1</sup> Cardozo J. in *Schloendorff v Society of New York Hospital* (1914) 211 NY 125, 126.

<sup>2</sup> In some situations consent is not required because the patient does not have the specific capacity to consent. For example, if the patient is unconscious he may not be able to consent. Any medical treatment administered will then be legally excusable on the grounds of necessity. Similarly, if a patient does not have the mental capacity to consent due to their age or a mental disorder, then in some circumstances medical intervention may be justified without consent. This however, is outside the remit of this study. For discussion see Jones, M. "Justifying Medical Treatment Without Consent" (1989) PN 178; Skegg, P.D.G. "A Justification for Medical Procedures Performed Without Consent" (1974) 90 LQR 512.

<sup>3</sup> *Salgo v Leland Stanford Jr University* 317 P 2d 127 (Cal App, 1957).

<sup>4</sup> Gillett, G.R. "Informed Consent and Moral Integrity" (1989) 15 *Journal of Med Ethics* 117 - 123.

from prejudice and interference. That is, the patient must be given all the necessary information and understand that information, before they can make any decisions. The function of the law is to preserve the autonomous right of patients to exercise control over their own bodies by empowering them to bring a legal challenge where communication breaks down, bringing into question the validity of consent. This project delves deeper into the consent process to produce an intelligible understanding of some of the major issues that arise in everyday medical practice.

## **1.2 The Study**

The study is comprised of four elements:

The first part of the research concentrates on surveying medical students by means of a combined quantitative and qualitative questionnaire. This gives an insight into what they perceive as being important in the consent process. It assesses how effectively they feel they have been educated and prepared to deal with consent issues in practice and investigates how confident they feel about obtaining informed consent in a clinical setting. The survey also evaluates their understanding of the underlying ethical and legal principles behind asking a patient for their informed consent. This data is analysed and then any enduring legal issues are reflected upon.

The second component of the study will investigate informed consent in primary care. This is achieved by interviewing a number of GP's and practice nurses about what happens in terms of consent in primary care and their perceptions of informed consent. These findings are related to the law to reach an assessment of whether medical practitioners are doing enough to protect themselves from legal challenge in primary care. It will also look at the differences and similarities between this and consent in hospital settings.

The third part of the research focuses on gaining a clearer understanding of the consent process in a hospital setting. This involves interviewing the different levels of medical professionals from various surgical teams, and also a number of patients to develop awareness as to the wider issues faced by all parties concerned in the consent process. There is an observational element to this part of the study which scrutinises how consent is obtained, and to assess first-hand the problems faced by both medical practitioners and patients in clinical consultations. This includes analysing the uncertainty associated with understanding, communication, willingness to be involved in treatment, therapeutic privilege and defensive medicine.

The fourth element of the work involves looking at informed consent litigation in practice by interviewing a number of medical law solicitors. The aim of this element is to achieve an understanding of the frequency of claims, how they are dealt with, the problems faced by all parties in a legal case and how solicitors view the legal doctrine of informed consent.

The above data is analysed and then related to existing legal theory. This allows for a critical reflection of the law. The thesis highlights any potential legal problems and reforms. A number of future protocols are then advanced, which may be implemented for future use to improve the doctor/patient relationship.

### **1.3 Aims & Objectives**

- To investigate and evaluate the current law and practice of consent and information disclosure.
- To employ quantitative research methods to evaluate medical students' knowledge of the legal issues relating to consent and attempt to gain a deeper understanding of how they are trained in communication processes.
- To use qualitative research methods to interview medical practitioners about informed consent in primary care and relate this to the law.
- To use qualitative research methods to gather empirical data relating to how consent is gained in practice. This allows for an exploration of some of the wider issues faced by the medical profession when attempting to gain a patient's consent, issues which may not have been fully recognised by the law. These include questions of understanding, communication, willingness to be involved in treatment, therapeutic privilege and defensive medicine
- To use qualitative interview techniques to discuss informed consent litigation with practising solicitors to elicit their view on the law relating to informed consent.
- The above will highlight the differing perspectives on informed consent from a wide range of people involved in legal and medical practice. This is analysed within the prism of the doctor/patient relationship and in turn will be related to legal theory. This provides the basis for a number of future protocols to be constructed, which, it is hoped, will improve the doctor/patient relationship and reduce litigation.

## 2 LITERATURE REVIEW - PART 1

### 2.1 THE HISTORY AND CHANGING FACE OF THE LAW OF INFORMED CONSENT & INFORMATION DISCLOSURE

#### 2.1.1 *Introduction*

The purpose of this section of the literature review is to chart the historical development of the law relating to informed consent and information disclosure. The section begins by looking at the tort of battery and how, over the years, the courts have slowly eroded its use and application as a mechanism for enforcing patients' rights. It then proceeds to analyse how information disclosure cases have come to be understood within a negligence framework and discusses the major cases which have shaped and developed the law. The section provides an account of modern developments and addresses the significance and implications of recent case law in terms of advancing patients' rights and considers the potential impact of the Human Rights Act on informed consent. Finally, it assesses the difficulties associated with establishing causation in negligent information disclosure cases and consideration is given to the recent system implemented in New Zealand which seeks to give fuller all-round protection for patients' rights.

#### 2.1.2 *Categorising the Claim - Informed Consent & Battery*

The law states, that if a medical practitioner carries out a procedure that involves any kind of physical contact then, in the absence of a valid consent, or without some other justification<sup>1</sup>, that practitioner will be liable for a civil action in battery and may also face prosecution.

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<sup>1</sup> There are clearly some instances where clinicians will have to perform an operation on a patient where they are unable to consent. The most common example of this is where the patient is

Battery is a tort that requires a direct application of force.<sup>2</sup> Thus, conceptually, consent in law may be seen as a defence to the tort of battery, or alternatively, the absence of consent may be part and parcel of the tort itself.<sup>3</sup> The standard practice of the medical profession is to ask the patient to sign a NHS consent form before undertaking any kind of invasive procedure.<sup>4</sup> This is designed to safeguard the surgeon against any legal action by evidencing that the patient has expressly given permission for the operation. However, where the procedure is only minor or surgery is not involved, consent may often be given implicitly by the patient. This may be evidenced by oral statements or by the conduct of the patients themselves.

In American jurisdictions that operate an '*informed consent*' system, there is an obligation on the doctor to provide as much information as the reasonable (or prudent) patient would expect in the circumstances. In the case of *Canterbury v Spence* it was stated that:

'...True consent to what happens to one's self is the informed exercise of choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each...From these axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.'<sup>5</sup>

Accordingly, failure to provide adequate information about surgery negates the patient's consent and allows them to sue in trespass *or* negligence.

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unconscious and the procedure is necessary in order to save their life. The law justifies this on the grounds of necessity. See *F v West Berkshire Health Authority* [1989] 2 All ER 545 HL.

<sup>2</sup> *Collins v Wilcock* [1984] 3 All ER 374.

<sup>3</sup> Jones, M.A. *Textbook on Torts* Eighth Edition (Oxford: Oxford University Press, 2002) at 469. Jones suggests the issue revolves itself into the question of where the burden on proof lies. Must the claimant prove that he did not consent in order to establish his cause of action, or is it sufficient to prove a direct interference, leaving the defendant to assert and prove that the claimant consented? See for example, *Freeman v Home Office (No.2)* [1984] 2 WLR 130. Here it was held that the claimant has the burden of proof in this country.

<sup>4</sup> See standard NHS consent form. Copy available in "Good practice in consent implementation guide: consent to examination or treatment" (London: Department of Health Circular, 2001).

<sup>5</sup> (1972) 464 F 2d 772 at 774.

In England, this is not the case. In *Chatterton v Gerson* it was stated by Bristow J. that 'What the court has to do in each case is to look at the circumstances and say "Was there a real consent?"'<sup>6</sup> He then went on to suggest:

'In my judgment once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of action on which to base the claim for failure to go into risks and implications is negligence, not trespass.'<sup>7</sup>

Hence, it appears it will only be in exceptional circumstances where no adequate explanation was in fact given as to the *broad nature* of the operation that the consent will be invalid for the purposes of battery.<sup>8</sup> Similarly, if the operation performed was in fact different from that proposed<sup>9</sup>, or if consent was obtained by fraud or misrepresentation<sup>10</sup>, any purported consent would be nullified giving rise to an action in battery. This is because: 'the consent would have been expressed in form only, not in reality.'<sup>11</sup> In this situation, battery is applicable notwithstanding the fact that the surgeon feels the intervention is justified (in the sense that it will be of benefit to the patient) or that it was expertly performed.

Although the courts often refuse to accept it as an appropriate course of action, battery doubtless has a number of advantages for the claimant over an action in negligence. Firstly, the tort of battery is actionable *per se*. That is, it is actionable without proof of damage. As Teff asserts:

'In trespass, a failure by the doctor to tell the patient the nature of the proposed procedure would be all that was required. The unauthorised touching would

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<sup>6</sup> [1981] QB 432.

<sup>7</sup> *ibid* at 443.

<sup>8</sup> *Hamilton v Birmingham R.H.B.* [1969] 2 BMJ 456.

<sup>9</sup> *Murray v McMurchy* (1949) 2 DLR 442; *Cull v Butler* [1932] 1 BMJ 1195.

<sup>10</sup> *Appleton v Garret* [1996] PIQR P1. For an action to be successful it is generally thought that the misrepresentation or fraud must go to the nature of the procedure, rather than the risks involved. It has been argued that this distinction is unworkable as it pre-supposes an inherent difference in terminology and substance between the nature of the treatment and any risks involved. It is not difficult to envisage a situation where some risks may be so significant that they relate to the nature of the operation itself, so that non-disclosure would vitiate consent and lead to liability in battery: see Tan Keng Feng, "Failure of Medical Advice: Trespass or Negligence" (1987) 7 LS 149; Jones, *infra* n 17 at 110.

<sup>11</sup> *op cit* n 6 at 443.

itself constitute a tort, even if no harm were caused - the availability of redress for what would in effect be a dignitary injury further emphasising the rationale of self-determination.<sup>12</sup>

This is significant for the claimant as there will be no issues relating to differing standards of medical judgment. Thus the patient does not have to prove professional fault in the treatment itself and there will be no calling of expert evidence. Perhaps more importantly, the claimant will have less stringent requirements in regard to causation. All that would be needed was proof that there had been some unauthorised touching. There would be no examination needed of whether had the patient been adequately informed they would have rejected the treatment, a stringent rule of causation that often proves to be an insurmountable hurdle in any negligence action.<sup>13</sup> Similarly in some jurisdictions, in trespass, the doctor could well have the onus of proving consent<sup>14</sup>, although apparently not under English law.<sup>15</sup> Finally, the damages in a battery action would be more favourable to the patient as they would be able to recover for all '*direct damage*' caused by the unauthorised touching. In contrast, if the claim was in negligence recovery would be denied for '*unforeseeable*' medical complications.

This being the case, why do English courts seem reluctant to categorise claims relating to absence of consent as battery? In all probability, this is due to the very nature and roots of the tort itself, which is often associated with some form of hostile touching.<sup>16</sup> In the context on the doctor/patient relationship, it would be unusual to hold doctors so liable as the implication would be that they intended to harm patients, a concept that is wholly inconsistent with the principles of beneficence and

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<sup>12</sup> Teff, H. "Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance" (1985) 101 LQR 432 at 436.

<sup>13</sup> For a more detailed discussion see section 2.1.8.

<sup>14</sup> Teff, *op cit* n 12 at 439. See for example, *Aliter Ford v Ford* (1887) 143 Mass 577, 578, 10 NE 474, 475; *Latter v Braddell* (1880-81) 50 LJQB 448; the Canadian position is that the onus is clearly on the doctor to prove consent - *Kelly v Hazlett* (1976) 75 DLR (3d) 536 at 563.

nonmaleficence that are enshrined within the very foundations of the Hippocratic Oath. Irrespective of this, motive is irrelevant and as Jones states:

'...motive is not a defence and, though the medical profession may be dismayed to have it said, from the legal perspective the only difference between a surgeon and a mugger with a knife is the consent of the patient.'<sup>17</sup>

Thus, from a strictly legalistic point of view, the mere fact that the surgeon has not intended to harm the patient is irrelevant.

It is a consequence of the latter being classified in terms of negligence which has served to erode the historical importance of the tort of battery as a mechanism for enforcing patient rights. As Teff suggests:

'The very fact that negligence rather than battery is now the dominant basis for liability in surgical consent cases suggests a shift towards a rationale of good medical care and away from an exclusive focus on the right to bodily integrity and self-determination.'<sup>18</sup>

Nowadays, save in areas relating to police powers, trespass has been applied sparingly by the courts. Where there are grounds for bringing a successful claim under this heading, actions are met with hostility from the medical profession because, as Brazier states:

'A judgement in trespass for a failure in communication, an over-zealous desire to make the right decision for the patient, may be seen as putting the doctor on a par with a police officer who beats up a suspect.'<sup>19</sup>

Principally, the courts do not want to expose doctors to the stigma that attaches itself to a claim in battery, as the very wording of the tort itself may have a greater consequence on the career of a doctor than if a similar claim was levied in negligence. Also, it seems clear that the courts do not want to undermine the authority of health

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<sup>15</sup> *op cit* n 2.

<sup>16</sup> *Wilson v Pringle* [1986] 2 All ER 440.

<sup>17</sup> Jones, M.A. "Informed Consent and Other Fairy Stories" (1999) 7 Med L Rev 103 at 106. However, Jones points out that this may not be strictly accurate in that it is not merely the fact of the patients' consent which legitimises the doctor's act, but the fact that it is given within the context of the doctor/patient relationship: *R v Brown* [1993] 2 All ER 75 at 103, per Lord Mustill.

<sup>18</sup> Teff, *op cit* n 12 at 436.

practitioners by subjecting them to a risk of multiple legal actions. The purpose (as well as the effect) of *Canterbury*<sup>20</sup> may have been to give US patients access to a remedy where, if left to negligence alone, none would be available. Thus, English courts may be attempting to curtail litigation trends to discourage defensive practices.

As a result of the above, the circumstances in which the tort of battery is applicable nowadays are extremely rare and seldom successful. It was stated in *Kelly v Hazlett*:

'How the case is pleaded...is more than a matter of academic interest. It will have important bearing on such matters as the incidence of the onus of proof, causation, the importance of medical evidence, the significance of medical judgment, proof of damage, and most important, of course, the substantive basis of liability.'<sup>21</sup>

### **2.1.3 Categorising the Claim - Informed Consent & Negligence**

In switching the claim to the tort of negligence, in order for any action to be successful the patient must adhere to the ordinary requirements of a conventional negligence action. That is, the establishment of a duty of care owed by the medical practitioner to the patient, proof that this duty has been breached, and finally, that the breach of duty has *caused* some resultant harm that was reasonably foreseeable. Therefore when the claim is framed in negligence the emphasis is placed less on informed consent *per se* and more on information disclosure. This is demonstrated by in the following passage:

'In legal terms, the patient's consent to the treatment may be valid once he or she is informed in broad terms of the nature of the procedure which is intended. But the choice is, in reality, meaningless unless it is made on the basis of the relevant information or advice.'<sup>22</sup>

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<sup>19</sup> Brazier, M. "Patient Autonomy and Consent to Treatment: the Role of the Law?" (1987) 7 LS 169 at 180.

<sup>20</sup> *op cit* n 5.

<sup>21</sup> (1976) 75 DLR (3d) 536 at 538.

<sup>22</sup> *Rogers v Whitaker* (1992) 109 ALR 625 at 633.

In developing the above point, it is important to remember that the tort of negligence is not concerned with the presence or absence of consent, but rather the doctor's failure to comply with a legally imposed duty to take reasonable care to ensure the patient is adequately informed.<sup>23</sup> The law is concerned with what the doctor is obliged to do prior to acting. As a result the focus of any inquiry is on the *amount* and *type* of information a doctor is obliged to disclose.

The seminal case of *Sidaway v Board of Governors of the Bethlem Royal Hospital and others*<sup>24</sup> confirmed the existence of a duty of disclosure in English law. In this case, all of the judges sitting in the House of Lords acknowledged there was scope for developing a duty of disclosure under the common law which places an obligation on the doctor to communicate at least some information to the patient prior to any proposed treatment. Lord Scarman stated:

'...If it be recognised that a doctor's duty of care extends not only to the health and well-being of his patient, but also to a proper respect for his patient's rights, the duty to warn can be seen to be a part of the doctor's duty of care.'<sup>25</sup>

Thus, there is evidence that a duty of disclosure exists and, as Williams suggests, 'The doctor's duty arises out of the patient's right to make his own decision and not vice versa.'<sup>26</sup> This is interesting as it confirms that the doctor's duty derives from the right of the patient to decide what is done with their body.

Lord Scarman, dissenting, elaborated on this in the reasons he offered for developing a duty of disclosure:

'[the doctor] must acknowledge that in very many cases factors other than the purely medical will play a part in the patient's decision-making process...which may lead to a different decision from that suggested by a purely medical opinion. The doctor's duty...requires him...to provide information needed to enable the patient to consider and balance the medical advantages and risks

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<sup>23</sup> Kennedy, I. & Grubb, A. *Medical Law* Third Edition (London: Butterworths, 2000) at 677.

<sup>24</sup> [1985] AC 871.

<sup>25</sup> *ibid* at 885.

<sup>26</sup> Williams, K. "Pre-Operative Consent and Medical Negligence" (1985) 14 *Anglo-American LR* 169 at 172.

alongside other relevant matters, such as, for example, his family, business or social responsibilities.'<sup>27</sup>

This rationale looks beyond the immediate problem of the doctor/patient relationship and investigates further the problems faced by patients in the wider social context. The crux of the argument focuses on *why* the patient needs *all* the necessary information.

#### **2.1.4 Professional Negligence, Bolam and Information Disclosure**

On confirmation that a duty of disclosure exists in English law, what counts as actionable negligence? In order to answer this question we need turn our minds to the standard by which a doctor's disclosure is to be judged.

Although ordinarily the tort of negligence is based around the judicially defined concept of 'reasonableness', this standard changes when applied to the medical profession. In *Bolam v Friern Hospital Management Committee*.<sup>28</sup> McNair J. devised the following test for the professional standard of care:

'...where you get a situation which involves some special skill or competence, then the test as to whether there has been negligence or not is not the test of the man on top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill.'<sup>29</sup>

He then further commented that:

'A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.'<sup>30</sup>

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<sup>27</sup> *op cit* n 24 at 885-886.

<sup>28</sup> [1957] 1 WLR 582. The House of Lords in *Sidaway* confirmed that this test is applicable in the realms of both treatment and diagnosis. See *Whitehouse v Jordan* [1981] 1 WLR 246 (treatment) and *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634 (diagnosis).

<sup>29</sup> *ibid* at 586.

<sup>30</sup> *ibid*.

However, it is the second part of McNair J's judgment in relation to the standard of care to be applied to the medical profession that has come to mean something much more controversial:

'A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art...a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion taking the contrary view.'<sup>31</sup>

This has been the centre of intense debate since it effectively left the standard of care in negligence cases in the hands of the medical profession.<sup>32</sup> The practicalities of the test, one which is perhaps best described as the doctor's best friend, proclaim that a doctor cannot be held liable even if there are differing schools of thought as to what constitutes acceptable practice. As long as one body of responsible medical opinion views the conduct as within the range of acceptable practice at the relevant time then the doctor will not be negligent.<sup>33</sup> This is problematic. Amongst other things it tends to create a situation of closing of professional ranks, toleration for maverick practitioners who escape liability by employing procedures which gain minimal medical support<sup>34</sup>, and defences for those who lag behind the times by adopting out of date techniques.<sup>35</sup> Doctors are judges in their own case and set their own standards.

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<sup>31</sup> *ibid* at 587.

<sup>32</sup> Williams, K. "Informed Consent or a Duty to Inform" (1985) 129 SJ 195.

<sup>33</sup> One of the problems with *Bolam* is whether negligence itself is classed a sociological or ethical concept. See Montrose, J. L. "Is Negligence an Ethical or Sociological Concept" (1958) MLR 259. He asserts that although the standard of care *should* be an ethical concept, the problem with *Bolam* is that it can be interpreted in one of two ways. The ethical interpretation is to apply the normative requirement of reasonableness to the practice accepted by a respectable body of practitioners. If read in a sociological light, it is argued that once the body of professionals is accepted as responsible, then any act that body accepts cannot incur liability. This ambiguity is often associated with the blurring of normative and descriptive terminology within the case itself. See also, MacLean, A. "Beyond Bolam and Bolitho" (2002) 5 Med L Int 205 at 207; Teff, H. *Reasonable Care: Legal perspectives on the Doctor Patient Relationship* (Oxford: Clarendon, 1994) at 181.

<sup>34</sup> See for example, *De Freitas v O'Brien* [1995] 6 Med LR 108.

<sup>35</sup> Technically, and according to McNair J. in *Bolam*, *op cit* n 28 at 587 this should not be allowed to happen. He makes it clear the law does not condone medical men who fail to keep themselves updated with modern medical practice. However, in reality *Bolam* often provides a defence as most medical practitioners can find at least one body of medical opinion that is supportive of their techniques.

As has been said: 'The [Bolam] test became no more than a requirement to find some other expert(s) who would declare that they would have done as the defendant did.'<sup>36</sup>

Although there may be justifiable grounds for placing heavy reliance on accepted standards of the profession and expert evidence in terms of treatment and diagnosis, issues which are directly within the remit of doctors' professional expertise, these same grounds do not carry over to issues relating to disclosure. Arguably the courts should not adopt the same degree of leniency when judging what a doctor is obliged to tell a patient. This is not a matter of professional judgment *per se* but rather a process that the patient should be involved in so they can decide what level of information they require in order that they can make an informed decision about their treatment options. Ultimately, the only expert on the patient is the patient themselves and it should be for them to decide what is done with their bodies; not the doctor. Thus, arguably the law ought to implement a subjective standard of care tailored to each individual patient.<sup>37</sup>

In *Sidaway*<sup>38</sup> the House of Lords was invited to clarify the standard of care to be applied to medical disclosure cases. One of the major problems with *Sidaway* is that it provides no clear *ratio*. Each of the five judges agreed on the overall outcome but not so on the law and its application. Although three out of five of their Lordships explicitly referred to *Bolam* in one way or another, only one of them accepted the *Bolam* standard in its conventional format as being applicable to information disclosure cases.

Lord Diplock was the only Lord who endorsed the professional standard for disclosure. He stated:

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<sup>36</sup> Brazier, M. & Miola, J. "Bye-Bye Bolam: A Medical Litigation Revolution?" (2000) 8 Med L Rev 85 at 85.

<sup>37</sup> See section 13.9.3 later on in the thesis for further discussion on this assertion.

<sup>38</sup> *op cit* n 24.

'To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such a warning, if any, should be given, having regard to the effect that the warning may have is as much an exercise of professional skill and judgement as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated in the same way. The Bolam test should be applied.'<sup>39</sup>

Thus, he visualised one single comprehensive duty, which encompassed all aspects of the doctor's duty of care. The above quote suggests it is impossible to dissect the differing aspects of doctors' duties into component parts in order to develop individual tests to judge whether there has been a breach of duty. Lord Diplock's speech is a reflection of the law endorsing the paternalistic attitude of the medical profession. Although within his speech there seems little evidence to back it up, the rationale for his position seems based on the fact that patients often do not want extra information and if there was a legal obligation to provide more information than the doctor thought necessary, it may deter them from undergoing treatment that is best for them. Therefore, in his view at least, the professional standard of care should apply and *Bolam* employed to judge any questions centred on adequacy of disclosure. This approach is looking very much through the doctor's end of the telescope.

Despite Lord Diplock's speech being described by some as the '*locus classicus*'<sup>40</sup> for the nature of the doctor's duty of care, it is with great caution one should view his judgment as being an accurate portrayal of the law. Particularly in light of comments made by Lord Scarman in an extra-judicial lecture given to the Royal Society of Medicine. Here he goes to extreme lengths to point out that we can ignore Lord Diplock's opinion as he was in the 'minority of one'<sup>41</sup> (as of course was Lord Scarman himself).

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<sup>39</sup> *op cit* n 24 at 895.

<sup>40</sup> Hockton, A. *The Law of Consent to Medical Treatment* (London: Sweet&Maxwell, 2002) at 34.

<sup>41</sup> [1986] 79 J Roy Soc Med 697.

### 2.1.5 *The Prudent Patient Standard*

What then is the alternative to judging medical practitioners' disclosure by the proclaimed standard of their peers? One way is to impose a standard of care which places an obligation on the medical practitioner to disclose the relevant information that a reasonable patient would require in the circumstances, a test which has found favour with a multitude of jurisdictions.<sup>42</sup> This perhaps does not get to the very heart of what the informed consent debate is actually about. It fails to address what level of information the particular patient being treated would want to know in the circumstances (a purely subjective test grounded in the rights-based philosophy of a patient's right to self-determination).<sup>43</sup> However, arguably this test works as a compromise. On the one hand it seeks to promote autonomy by recognising a patient's right to be informed, whilst on the other it converts the actual patient into the hypothetical reasonable patient. Kennedy and Grubb warn of the dangers of this in suggesting: 'the particular circumstances of the patient are ignored...[and] at some point...the purported subjectivity of the test could evaporate into an objective examination of reasonableness.'<sup>44</sup>

The English courts however have not welcomed this approach. As we have already seen Lord Diplock flatly rejected this standard in *Sidaway*, but what did the other Law Lords make of it?

In complete contrast to Lord Diplock, Lord Scarman, a committed human rights activist, welcomed the doctrine of informed consent with open arms. His speech, which is generally regarded as the dissenting speech in this case, addressed

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<sup>42</sup> *Canterbury v Spence*, *op cit* n 5 (USA); *Reibl v Hughes* (1980) 114 DLR 3d (Canada); *Rogers*, *op cit* n 22 (Australia).

<sup>43</sup> The Australian case of *Rogers v Whitaker*, *op cit* n 22, contains this provision and is discussed in further detail below. See also section 13.9.3 later on in the thesis for further justifications for this approach.

<sup>44</sup> Kennedy and Grubb, *op cit* n 23 at 680.

the wider issues involved in doctor/patient relationship.<sup>45</sup> From the outset Lord Scarman summed up the *Bolam* test by saying: 'In short, the law imposes a duty of care; but the standard of care is a matter of medical judgment.'<sup>46</sup> This is significant, as it is evidence of judicial recognition that the medical profession have been allowed to dictate the standard to be applied in negligence and, in effect, the law has been shaped and developed around what the profession feels is right. Nevertheless, when it comes to issues regarding disclosure of potential risks, benefits, side-effects and alternatives to treatment, he felt it was time to depart from the *Bolam* test. This is due to the fact that these issues are concerned directly with human rights, a concept which the common law, through its adaptability, can be developed to protect. These views are exemplified in the passage below in which Lord Scarman signifies his distaste for the professional standard of care:

'The implications [of the professional standard] are disturbing...It would be strange conclusion if the courts should be led to conclude that our law, which undoubtedly recognises the right in the patient to decide whether he will accept or reject the treatment proposed, should permit the doctors to determine whether and in what circumstances a duty arises requiring a doctor to warn his patient of the risks inherent in the treatment which he proposes.'<sup>47</sup>

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<sup>45</sup> Lord Scarman clearly rejected the *Bolam* standard, thus it is *arguable*, though not *certain*, that his speech can be considered as the dissenting judgment. There is disagreement amongst academics as to what constitutes the majority opinion in *Sidaway*. Kennedy and Grubb, *op cit* n 43 at 691 seem to suggest that Lord Diplock may have been in the minority, thus his speech could have been classed as the dissenting judgment in that he was the only one who applied *Bolam* unequivocally. There is further support for this given by Lord Scarman in an extra-judicial lecture given to the Royal Society of Medicine [1986] 79 J Roy Soc Med 697. Here he suggests we can ignore Lord Diplock's opinion as he was in the '*minority of one*'. However, Hockton suggests that Lord Diplock's opinion provides the definitive opinion in *Sidaway* and is the '*locus classicus*' for the nature of the doctor's duty of care. Hockton, A. *The Law of Consent to Medical Treatment* (London: Sweet&Maxwell, 2002) at 34. However, it seems clear that most recently, Lord Woolf MR in *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118 certainly classed Lord Scarman's views as being in the minority at 123-124. Finally, there is a certain amount of ambiguity inherent in Lord Templeman's judgment where he seemingly rejected *Bolam* without explicitly referring to it. For discussion of this assertion and the rest of the Lords' views as to the doctrine of informed consent see Kennedy, *infra* n 50 at 195.

<sup>46</sup> *op cit* n 24 at 881.

<sup>47</sup> *ibid* at 882.

He went on to propose a test which is based on the prudent patient test as advocated in the American case of *Canterbury v Spence*.<sup>48</sup> He stated:

'English law must recognise a duty of the doctor to warn his patient of risks inherent in the treatment he is proposing; and especially so if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case, the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk.'<sup>49</sup>

Although he confined this only to '*material risks*' it is clear that this is still an autonomy-enhancing test as his definition of a material risk is centred on what the reasonable patient would want to know in the circumstances. In this sense he fell at the opposite end of the spectrum to Lord Diplock, and it is also apparent that his views did not rest easily with the other three judges in *Sidaway*.

### **2.1.6 Sidaway - Deciphering a Ratio**

Lord Bridge, in demonstrating signs of 'anguish and distress of being drawn one way by head and reason, and another by heart and tradition,'<sup>50</sup> rejected the prudent patient test for three principal reasons. Firstly, he opined that it gave insufficient weight to the doctor/patient relationship. Secondly, he felt medical evidence was not easily separable into the two component parts of primary medical factors and professional opinion on disclosure - to divide the two would be legally 'unrealistic'<sup>51</sup>, and finally, he stated that the *Canterbury* test is so vague and imprecise as to be almost 'meaningless'.<sup>52</sup> For these reasons he opted to retain the *Bolam* standard as the test for judging the adequacy of disclosure, albeit subject to a certain caveat. He preferred to state the law as follows:

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<sup>48</sup> *op cit* n 5.

<sup>49</sup> *op cit* n 24 at 889.

<sup>50</sup> Kennedy, I. "The Patient on the Clapham Omnibus Postscript: The House of Lords' Decision" In Kennedy, I. *Treat Me Right: Essays in Law and Medical Ethics* (Oxford: Clarendon Press, 1988) at 197.

<sup>51</sup> *op cit* n 24 at 889.

'Even in a case where, as here, no expert witness in the relevant field condemns the non-disclosure...I am of the opinion that the judge might in certain circumstances come to the conclusion that the disclosure of a particular risk *was so obviously necessary for an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it.* The kind of case I have in mind would be an operation involving a substantial risk of grave adverse consequences, as for example the 10% risk of a stroke from the operation which was the subject of the Canadian case of *Reibl v Hughes* (1980) 114 DLR 3d. In such a case, in the absence of some cogent clinical reason why the patient should not be informed, a doctor, recognising his patient's right of decision, could hardly fail to appreciate the necessity for an appropriate warning.'<sup>53</sup>  
[Author's emphasis]

The fifth speech was delivered by Lord Templeman. This may be described as judgment in its own right. Again, it is evident that he did not reject *Bolam* totally, but without referring explicitly to it, intimates that it should not be applied unequivocally. He works from the premise that the patient is not entitled to 'know everything' nor that the 'doctor is entitled to decide everything.'<sup>54</sup> It is clear that in his opinion the courts remain the final decision makers. He suggested: 'It is for the court to decide, after hearing the doctor's explanation, whether the doctor has in fact been guilty of a breach of duty with regard to information.'<sup>55</sup> In summing up he stated:

'At the end of the day, the doctor, bearing in mind the best interests of the patient and bearing in mind the patient's right to information which will enable the patient to make a balanced judgment must decide what information is to be given to the patient and in what terms that information should be couched. The court will award damages against the doctor if the court is satisfied that the doctor blundered and that the patient was deprived of information which was necessary for the purposes I have outlined.'<sup>56</sup>

Accordingly, although the doctor has clinical discretion as to how the information is phrased, the patient is entitled to as much information as is necessary for him to make a balanced judgment whether or not to consent to treatment.<sup>57</sup>

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<sup>52</sup> *ibid.*

<sup>53</sup> *ibid* at 900.

<sup>54</sup> *ibid* at 904.

<sup>55</sup> *ibid* at 903.

<sup>56</sup> *ibid* at 905.

<sup>57</sup> *ibid.*

The esoteric nature of the House of Lords' judgment makes it extremely difficult to say with certainty what was actually decided in *Sidaway* (apart from the fact that Mrs. Sidaway lost). Yet, the case left a test for judging the adequacy of a doctors' disclosure within the framework of the *Bolam* standard, albeit in a diluted form. This proclaims that, primarily, doctors' disclosure will be judged by the standards of the profession. However irrespective of this, a doctor may still be negligent if he fails to disclose risks that are so obviously necessary for a patient to make an informed choice, and these risks must be substantial in nature coupled with the potential for grave adverse consequences should they occur. This must mean that the views of the medical profession although persuasive, are by no means determinative of what a patient should be told. In addition, where patients specifically ask questions about the risks inherent in treatment, clinicians are obliged to answer truthfully and honestly.

The focus now turns on how the courts came to interpret *Sidaway* subsequently in an analysis of the modern developments of the law.

### **2.1.7 Modern Developments**

#### **2.1.7.1 Post *Sidaway* Case Law**

In addressing the question of whether the law has advanced since *Sidaway*, one may be met with a mixed response. Initially judges seemed to interpret *Sidaway* narrowly and as nothing more than authority for applying conventional *Bolam* to information disclosure cases. In *Gold v Haringey Health Authority*<sup>58</sup> the claimant brought an action for damages when she fell pregnant after undergoing a sterilisation operation. It was admitted that the operation was unsuccessful and that she had not been advised as to the possible risks of the procedure failing. At first instance her case was

successful. However, on appeal she lost. There was a responsible body of medical opinion that did not believe women should be warned that there was a chance of failure.<sup>59</sup> Kennedy has suggested in respect of this case that the Court of Appeal read *Sidaway* in an unnecessarily restrictive manner and seemed to only consider the speech of Lord Diplock as being the definitive judgment in the House of Lords.<sup>60</sup> This is somewhat puzzling. It appears obvious that none of the other Law Lords agreed wholeheartedly with his views. Clearly, it created an anomaly to suggest that women should be denied information as to the risks associated with sterilisation and should not be offered counselling as to any possible alternatives. For this reason, Kennedy further suggests that *Gold* should be 'speedily confined to the history books.'<sup>61</sup> Thankfully, the courts may also have recognised that *Gold* did not settle the law in England. For example, in the later case of *Thake v Maurice*<sup>62</sup> it was held that the surgeon had been negligent in his failure to warn of the possibility of the natural reversal of a vasectomy. Arguably this began to pave the way for a long-awaited departure from the mantra-like tones of the *Bolam* test.

### 2.1.7.2 The Australian Position

However, it was not until 1992 that real developments relating to patients' rights began to take shape.

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<sup>58</sup> [1988] QB 481.

<sup>59</sup> In a number of later judgments, the courts have appeared to consider the ruling in *Gold* as being authoritative on this issue. For example see *Palmer v Eddie* [18<sup>th</sup> May 1987, unreported]; *Blyth v Bloomsbury Health Authority* [1993] 4 Med LR 15; *Moyes v Lothian Health Board* [1990] 1 Med LR 463; *Abbas v Kenney* [1996] 7 Med LR 47. 'A doctor has a duty to explain what he intends to do and the implications of what he is going to do...The precise terms and emphasis on what he intends to do is a matter for the individual doctor based upon his clinical judgment. In this regard what has been called the "Bolam" test applied to this aspect of a doctor's duty in the same way in which it applies to diagnosis and treatment.'

<sup>60</sup> Kennedy, *op cit* n 50 at 210-211.

<sup>61</sup> *ibid.*

<sup>62</sup> [1986] QB 644.

In the seminal case of *Rogers v Whitaker*<sup>63</sup> the sweeping joint judgment of the majority of the Australian High Court<sup>64</sup> clearly rejected the *Bolam* standard as applicable to information disclosure cases.<sup>65</sup> Thus, while medical opinion is often relevant, it is not determinative of what should be disclosed. In Australia the doctor's obligation concerning what to disclose is grounded in the definition of what constitutes a material risk, the definition of which can be found in the following passage:

'A risk is material if in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should be reasonably aware that the particular patient, if warned of the risk, would be likely to attach significance to it.'<sup>66</sup>

Arguably, this test can be divided into two parts. The first limb of the test states the doctor is under an obligation to disclose all the material risks inherent in the procedure that the reasonable patient would consider significant in the circumstances. However, it is the second limb of the test that is open to interpretation and has the potential to create the biggest impact, representing a most notable departure from Lord Scarman's reasonable patient test which he sought to incorporate in *Sidaway*. On one view this second limb allows for a consideration of the idiosyncrasies of individuals because it takes into account the circumstances of the particular patient. Hence it has potential far to open the floodgates and increase litigation in this field. This is something English judges have been eager to prevent.<sup>67</sup>

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<sup>63</sup> *Op cit* n 22. In this case the High court relied upon the dissenting judgment of Lord Scarman in *Sidaway*, and the South Australian decision of *F v R* (1983) 33 SASR 189.

<sup>64</sup> Gaudron J dissenting.

<sup>65</sup> See also *Chappel v Hart* [1998] HCA 55.

<sup>66</sup> *op cit* n 22 at 633.

<sup>67</sup> This is evident from what are generally classed as the majority speeches in *Sidaway*. As previously stated Kennedy, *op cit* n 50 at 197 suggests that Lord Bridge (with whom Lord Keith agreed) showed signs of 'anguish and distress of being drawn one way by head and reason, and another by heart and tradition.' He further asserts the same signs can be seen from the speech of Lord Templeman.

### 2.1.7.3 The Post *Bolitho* Era

Can it be said that this advance in a patient's right to know has extended into English law? The subsequent House of Lords' decision in *Bolitho v City & Hackney Health Authority*<sup>68</sup> sought to restore the *Bolam* test to its original place by confirming that ultimately it was for the courts to define the legal standard of care and not the medical profession. This incorporated a new 'hard look' approach to the scrutiny of medical evidence. Lord Browne-Wilkinson stated that before medical evidence could be accepted under the *Bolam* test the body of opinion must be reasonable and responsible, 'but if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis'<sup>69</sup> then the judge will be entitled to reject that evidence. In deciding whether or not the body of medical opinion has a logical basis he emphasised the importance of assessing the relative risk/benefit ratio of any course of action:

'In particular, in cases involving, as they often do, the weighing of risks against benefits, the judge before accepting a body of opinion as being reasonable, reasonable or respectable, will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter.'<sup>70</sup>

It is actually difficult to ascertain the true effect of *Bolitho* on information disclosure cases in view of Lord Browne-Wilkinson's suggestion that 'I am not here considering disclosure of risk.'<sup>71</sup> However, Brazier and Miola warn about the dangers of reading too deeply into this apparently abstruse statement, suggesting:

'...his lordship was simply flagging up the fact that questions of information disclosure were simply not relevant on the facts of *Bolitho*, or, more probably,

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<sup>68</sup> [1998] AC 232. For discussion of this case see Teff, H. "The Standard of Care in Medical Negligence - Moving on from *Bolam*?" (1998) 18 OJLS 473; Grubb, A. "Case Note: *Bolam* in the House of Lords" (1999) 15 PN 42; Castle, N. "Applying *Bolitho*" (1998) JPIL 278.

<sup>69</sup> *ibid* at 243.

<sup>70</sup> *ibid* at 242.

<sup>71</sup> *ibid* at 343.

Lord Browne-Wilkinson considered that restraining *Bolam* in the context of information disclosure had already been achieved.<sup>72</sup>

The former theory is likely to be the more accurate and seems to carry more weight. This is because when looking at Lord Browne-Wilkinson's statement in context, it appears to be the kind of remark that is almost dismissive in nature and made in a way that seems casually connected to the facts of the case. Surely, if he had meant it to be read as a statement which was demonstrative, in his opinion at least, that restraining *Bolam* in terms of information disclosure had already been achieved, he would have stated this explicitly. Moreover, there was actually very little in terms of appellate court case law at the time to suggest that Lord Browne-Wilkinson would have been justified in reaching this conclusion.

Although it did not specifically concern negligent information disclosure, according to some academics, *Bolitho* has a positive outlook. Brazier and Miola suggest:

'...information disclosure and the supremacy of the "reasonable doctor test" may be the first *Bolitho* casualty...[as]...Attempting to analyse whether or not the doctors' justification for non-disclosure is logical and rational and will not be a task bedevilled by too much technical or scientific detail.'<sup>73</sup>

In further support of this Kennedy and Grubb suggest clinical judgements are much less likely to be at the heart of information disclosure cases. Risk/benefit calculations of the kind in *Bolitho* - which the courts are reluctant to disturb - will be less to the fore and more important questions will need to be considered such as respect for the patient's right to choose and decide what is done to his or her body. 'Reasons based upon "the need not to trouble the patient", the "desire to avoid worrying the patient

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<sup>72</sup> Brazier and Miola, *op cit* n 36 at 108.

<sup>73</sup> Brazier and Miola, *op cit* n 36 at 107-108.

unduly", or "the fear of refusal" will simply not stand up to analysis because they embody the wrong values.<sup>74</sup>

The realistic (or perhaps cynical) view is that *Bolitho* only really advanced the law on a theoretical basis and has done little to develop *Bolam* in practice. Any assessment of *Bolitho* should be made with the strongly worded and influential caveat of Lord Browne-Wilkinson in mind that:

'In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion...I emphasise that in my view, it will very seldom be right for a judge to reach a conclusion that views genuinely held by a competent medical expert are unreasonable.'<sup>75</sup>

In the early nineties there were some encouraging signs that courts of first instance, at least, were willing to look beyond mere conformity with professional practice when it came to disclosure. In *Smith v Tunbridge Wells Health Authority*<sup>76</sup> the judge concluded that although some surgeons may still not have been warning patients about the risk of impotence associated with an operation to repair a rectal prolapse, that omission was neither reasonable nor responsible. Therefore, the doctor was held liable for breaching his duty of disclosure. Also, in *McAllister v Lewisham and North Southwark Health Authority*<sup>77</sup> the defendant was held liable for failing to disclose the risks associated with a particular form of brain surgery despite the fact that the risk of leaving the condition untreated was high.<sup>78</sup>

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<sup>74</sup> Kennedy and Grubb, *op cit* n 23 at 709-710.

<sup>75</sup> *op cit* n 67 at 243.

<sup>76</sup> [1994] 5 Med LR 334.

<sup>77</sup> [1994] 5 Med LR 343.

<sup>78</sup> For discussion of this case see Grundy, P.M.D. & Gumba, A.P. "Bolam, Sidaway and the Unrecognised Doctrine of Informed Consent: A Fresh Approach" (1997) JPIL 211 at 217. For two further examples see; *Newell and Newell v Goldenberg* [1995] 6 Med LR 371 a case which involved the failure to warn the claimant of the reversal of a vasectomy. The undisclosed risk stood at 1:2,300 and the judge held the defendants liable as patients about to undergo elective surgery were entitled to be warned of its effectiveness. Similarly in *Williamson v East London and City Health Authority* (1997) 41 BMLR 85 non-disclosure of the full nature of the surgery to remove a breast prosthesis, which was effectively a full mastectomy, constituted negligence as it deprived the claimant of the opportunity to contemplate and agree that this might be the overall outcome of her surgery.

However, the major breakthrough was *Pearce v United Bristol Healthcare NHS Trust*<sup>79</sup> which adopted a standard of care not dissimilar from the Australian High Court in *Rogers*.<sup>80</sup> Finally, the concept of the reasonable patient entered the terminology of English case law, albeit via the backdoor.

#### 2.1.7.4 The Decision in *Pearce v United Bristol Healthcare Trust*

In this case the claimant was pregnant with her sixth child. The child was two weeks overdue. She was seen by her obstetrician who informed her that medical intervention by means of caesarean section or inducement was inappropriate. The consultant informed her of the risks to the foetus inherent in inducement and told her of the general risks to her as a mother associated with a caesarean section. He omitted to tell her of the increased risk of still birth if the baby continued to be delivered naturally. This risk stood at roughly 0.1-0.2%. The claimant, after listening to the advice of the consultant, reluctantly agreed to proceed with a natural delivery. Unfortunately the risk eventuated and the baby was stillborn. Mrs. Pearce alleged the failure to disclose the risk of stillbirth on the part of the consultant was negligent. In the first instance decision, the trial judge dismissed her claim, finding that there had been no negligence on the part of the consultant in not advising the claimant of the small risk attached to waiting for a natural birth to begin. The claimant appealed. Lord Woolf MR gave judgment in the Court of Appeal.

From the outset of his judgment he appeared to realign the standard of care in English law by introducing the concept of the reasonable patient, a standard which

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<sup>79</sup> (1998) 48 BMLR 118.

<sup>80</sup> Lord Woolf MR (in *Pearce*) attempted to fuse *Bolam* with the two House of Lord's decisions of *Sidaway* and *Bolitho* (at 122-214). However, whilst it was not specifically relied upon in *Pearce*, the Australian decision of *Rogers op cit* n 22 may have had an indirect influence on encouraging the concept of the reasonable patient to be implemented within English law. For discussion see Heywood, R. "Re-Thinking the Decision in *Pearce*" (2005) 7 CIL 264 at 266.

corresponds to the Australian position. The most important passage in his speech appears to be as follows:

'In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course of action he or she should take in relation to treatment, it seems to be the law...that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.'<sup>81</sup>

Leaving aside the omission of the subjective component which is dealt with at a later part of this thesis,<sup>82</sup> what then is to be made of the similarities and differences between the two reasonable patient tests which both *Rogers* and *Pearce* seem to support in one way or another? On a cursory read it appears that the only difference between Lord Woolf MR's speech and the approach adopted by the Australian High Court in *Rogers* is merely one of phraseology. Lord Woolf MR is effectively asking the question, what is the doctor obliged to disclose? The answer being what the reasonable patient would find significant.<sup>83</sup> As can be seen, in effect all he has done is supplant the word *material* with *significant*. With the practical difference between these two words being minimal, one can be forgiven for assuming that this is a definite move away from Lord Bridge's primarily (albeit diluted) *Bolam*<sup>84</sup> standard of disclosure in *Sidaway*, to a step closer towards Lord Scarman's judgment in the same case. A stance that was welcomed in Australia as being the only real way in which the courts can serve to protect a patient's right to self-determination by adopting a *legal* standard which runs synonymous with the concept of informed consent.<sup>85</sup>

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<sup>81</sup> *op cit* n 79 at 124.

<sup>82</sup> For discussion see section 13.9.3 later on in the thesis.

<sup>83</sup> Kennedy & Grubb, *op cit* n 23 at 709.

<sup>84</sup> See section 2.1.4 for discussion.

<sup>85</sup> See, for discussion, Chalmers, D. & Schwartz, R. "Rogers v Whitaker and Informed Consent in Australia: A Fair Dinkum Duty of Disclosure" (1993) 1 Med L Rev 139.

Kennedy and Grubb have suggested the decision in *Pearce* is a synthesis of the two House of Lords' decisions in *Sidaway* and *Bolitho*<sup>86</sup>, and further intimate that the Court of Appeal has moved into 'uncharted waters'.<sup>87</sup> It is uncertain to what extent courts will scrutinise medical disclosure in light of the *Bolitho* and *Pearce* decisions. However, it seems clear that ultimately it is for the courts to decide the standard of disclosure. Thus, doctors need to be aware that failure to disclose a risk or alternative can no longer be met with the standard response 'this is what we say'.<sup>88</sup> The courts are more likely to intervene and have their say in demonstrating a 'renewed appetite to set the standard of disclosure'.<sup>89</sup>

There were also further encouraging signs from the House of Lords in *Chester v Afshar*<sup>90</sup>, potentially one of the most influential case subsequent to *Pearce*.<sup>91</sup> Here the defendant neuro-surgeon was held negligent for failing to disclose the risk of cauda equina damage in routine back surgery. The risk of this injury occurring stood at 0.9 per cent. It was common ground that, in accordance with good medical practice, the claimant should have been warned of this risk.

However, the flip side of the coin is that there are movements of late which suggest that both the Australian Courts and the English Courts are conscious of developing the law too far. Thus, in two recent cases the courts have sought to clarify the situation. They advise on approaching the issue of information disclosure in a much less robust manner and are mindful of the fact that they should proceed with caution before judging the medical profession too harshly.

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<sup>86</sup> Kennedy & Grubb, *op cit* n 23 at 708.

<sup>87</sup> *ibid* at 709.

<sup>88</sup> *ibid* at 710.

<sup>89</sup> Grubb, A. "Negligence: Causation and *Bolam*" (1998) *Med L Rev* 378 at 384.

<sup>90</sup> [2004] UKHL 41; [2005] 1 AC 134.

<sup>91</sup> For further discussion see section 2.1.8 and 2.1.9 below.

### 2.1.7.5 A Sudden Retreat?

In *Rosenberg v Percival*<sup>92</sup> the defendant was a dental surgeon who had failed to inform the claimant of an inherent risk associated with proposed surgery. The risk materialised and the claimant suffered chronic pain and disability. Here, Gleeson C.J., although admitting that medical negligence cases were a matter for the judge to decide, suggested that 'in many cases, professional practice and opinion will be the primary, and in some cases it may be the only, basis upon which a court may reasonably act.'<sup>93</sup> Moreover, the judges in this case warned of the dangers of the expansive use of the concept of foreseeability suggesting that the correct approach was for the courts to identify only the *relevant* risk as opposed to *any* foreseeable risk. Amirthalingham makes the point that 'this can only be done when the matter is viewed through the prism of the doctor/patient relationship.'<sup>94</sup> This statement is unclear, but presumably means when determining the issue of relevance some consideration should be given to what medical practitioners have learnt, or ought reasonably to have become aware, about the individual circumstances of their patients. In *Rosenberg* the risk was relevant because the magnitude of the risk was foreseeable at the time of surgery, however on the facts it was found to be of such low probability that it could not be classed as material since no reasonable patient would be likely to attach significance to it.<sup>95</sup> As Amirthalingham further points out 'even

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<sup>92</sup> (2001) 178 ALR 577 (H.C.A).

<sup>93</sup> *ibid* at 579.

<sup>94</sup> Amirthalingam, K. "A New Dawn for Patient's Rights?" (2001) 117 LQR 532 at 534.

<sup>95</sup> Addison explains this point succinctly. In order that the risk be material the patient is required to 'attach significance to the risk'. In *Rosenberg* Gummow J. suggested this meant the patient must be likely to '*seriously consider* and weigh up the risk' before deciding to proceed with treatment. A rather more stringent approach than previously adopted in *Rogers* where 'likely to attach significance' refers to information that is '*relevant* to a course of action' and matters which 'might influence' a decision. Gummow J.'s approach is more favourable to the medical profession as there are more risks that may 'influence a decision' as opposed to those that the patient would be likely to 'seriously consider.' However, Addison reminds us these comments are only *obiter* and there is little evidence from the limited case law following *Rosenberg* to suggest this has been adopted. For further explanation see Addison, T. "Negligent Failure to Inform: Developments in the Law Since *Rogers v Whitaker*" (2003) 11 TLJ 165 at 180.

though the risk resulted in catastrophic injury to the plaintiff, it was not considered to be material because the relevant risk was narrowly defined. This is a much more restrictive interpretation of the *Rogers*'s test.<sup>96</sup>

If English courts adopt the persuasive precedent in *Rosenberg* to interpret a material risk in the narrow way that the Australian judges have done, *Pearce* will do little if anything to advance patient rights. Arguably it takes us no further than the definition of a 'substantial risk of grave and adverse consequences' in *Sidaway*.<sup>97</sup>

The willingness of the courts to depart from the accepted standards of the profession should take account of the remarks made by two other judges in *Rosenberg*. Gummow J. and Callinan J. both comment on the undesirability of imposing 'standards of perfection' on professionals, the dangers of hindsight reasoning, and remind us that the duty to warn, as part of the law of negligence, is a duty to take reasonable care only.<sup>98</sup> Only one of the judges, Kirby J., remained fully committed to the *Rogers* test, concluding that 'no reason has been shown to

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<sup>96</sup> Amirthalingham, *op cit* n 94 at 534.

<sup>97</sup> Worryingly, recent indications from a different division of the Court of Appeal in the case of *Burke v Leeds Health Authority* [2001] EWCA CIV 51; (Unreported elsewhere) suggest that *Bolam* is far from dead and buried. Lord Justice Schiemann stated (at para. 32) 'Clearly what a doctor must tell his patient or his parents at what point and with which force are matters of clinical judgment for the doctor.' See also *Abbas v Kenney* [1996] 7 Med LR 47; and more recently the first instance decision in *Newbury v Bath District Health Authority* (1998) 47 BMLR 138. Here the judge relied on *Bolam*, *Bolitho* and *Sidaway* in dismissing the inadequate disclosure claim. Ebsworth J. argued that the doctor was under no obligation to disclose the fact that it was an unusual choice of procedure. The duty would only arise when the technique was experimental or was one that had been condemned as defective.

<sup>98</sup> *Rosenberg v Percival*, *op cit* n 92. Per Gummow J. at 593 and Callinan J. at 631. Interestingly enough it has been suggested that, although historically English and Australian jurisdictions have operated different tests for judging medical practitioners' duty of care, in modern times the two systems are converging. Amirthalingham suggests that just as the English courts continue to affirm *Bolam*, but may in a restricted manner be watering down its application, the Australian High Court continues to affirm *Rogers*, but in a similar manner may be tightening up its application. Amirthalingham, K. "Anglo-American Law of Medical Negligence - Towards Convergence" (2003) 11 TLJ 117 at 128. Arguably, it is the restrictive application of *Rosenberg* that is responsible for the merge, rather than the expansive and more liberal use of the *Bolam* test.

reformulate more narrowly the rule stated or to apply it in a way that would be inconsistent with the rule stated in *Rogers*.<sup>99</sup>

Despite this, when seeking to develop the law of informed consent the Australian jurisdiction is where the English courts ought to direct their minds when seeking to improve the protection afforded to a patient's right to adequate information. Addison notes that of the fifty-seven cases examined since *Rogers* there are only seven in which the courts have held a risk not to be material. Thus, the courts are not slow to classify a risk as being material and are much more prepared to consider the individual circumstances of the patient paying particular regard to such things as medical history, the extent of the patient's inquiries and whether the procedure was elective or otherwise.<sup>100</sup> Indeed it is a sensible declaration that 'a slight risk of serious harm may satisfy the test [of materiality], while a greater risk of small harm may not.'<sup>101</sup>

### **2.1.8 Causation in Information Disclosure Cases**

The tort of negligence is a fault-based, actionable on proof of damage. Therefore, the claimant has to establish a link between the negligent act and the harm that has been caused. This requirement is particularly problematic in medical disclosure cases involving omissions as the courts are asked to answer the hypothetical question: what would have happened if the medical practitioner had not in fact breached their duty? In other words, if the patient was given the full information about the operation, would they have proceeded with it? The answer to this question is, in turn, compared to that of the known outcome so that if a patient would have agreed to the operation

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<sup>99</sup> Manning makes this point suggesting King J. also stressed this in *Chappel v Hart* [1998] HCA 55. See, for discussion, Manning, J. "Informed Consent to Medical Treatment: The Common Law and New Zealand's Code of Patients' Rights" (2004) 12 Med L Rev 181 at 189.

<sup>100</sup> Addison, *op cit* n 95 at 177.

<sup>101</sup> Per Gummow J. in *Rosenberg v Percival*, *op cit* n 92 at 595.

anyway, the breach of duty would have made no difference and is not, therefore, the cause of the harm.

Thus, the courts need to employ a test to assist them in answering this hypothetical question. In England the test remains a subjective one. However, this is clearly open to abuse as it asks what the individual patient would have done in those circumstances. Hindsight is an 'exact science' and patients who have suffered injury are likely to claim they would not have had the operation had they been informed of the risks. On the other hand, if the patient was suffering pain and discomfort, they may well have agreed to the procedure no matter what the dangers. Thus, English law has devised an approach which blends the subjective and objective approach and takes into account the wider social factors which may influence an individual's decision.

In *Smith v Barking, Havering and Brentwood HA*<sup>102</sup> it was held that the correct test for establishing causation was the subjective approach. Notwithstanding this, the trial judge stressed the point that it should be measured against an objective criterion which the courts should give 'particular weight'<sup>103</sup> in the absence of any 'extraneous or additional factors to substantiate'<sup>104</sup> the subjective view of the aggrieved party. Kennedy and Grubb<sup>105</sup> remind us that this judgment is only a trial court decision and should be treated with caution. It does not examine the merits of the alternative objective test<sup>106</sup> and is best supplemented by analysing the abundance

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<sup>102</sup> [1994] 5 Med LR 285.

<sup>103</sup> *ibid* at 289.

<sup>104</sup> *ibid*.

<sup>105</sup> Kennedy & Grubb, *op cit* n 23 at 728.

<sup>106</sup> The objective test for causation asks the question 'would the reasonable patient have proceeded with the operation in the circumstances.' Although it is often said this is offset against subjective criterion, in reality it is particularly disadvantageous to any claimant. It turns the *particular* patient into the *reasonable* patient in the patient's position. Thus, there is little scope for taking into account the circumstances of the individual. This test was applied in the Canadian case of *Reibl v Hughes* (1980) 114 DLR (3d) 1. Thus, although this jurisdiction operates a prudent patient standard of care, arguably what it has given in adopting this, it has taken away in implementing an objective approach for causation. This is their 'control-device' as opposed to the professional standard of disclosure. See also *Arndt v Smith* (1997) 2 SCR 539 (Can SC).

of Commonwealth authority on this issue.<sup>107</sup> Still, the current author submits that the hybrid method, which compares the subjective situation of the patient to the objective standard, is the most effective test to employ as it allows the law to balance the competing interests. On the one hand it allows for an examination of the particular circumstances of the individual patient, whilst on the other, it employs a mechanism which looks at the reasonableness of any decision. In effect safeguarding against biased testimony.

Recent developments in this area of law have shown a marked recognition in improving a claimant's chance of proving causation. Clearly, a problem arises when the claimant asserts that they may have not rejected the treatment totally, but would simply have postponed it until a later date in order to gain a second opinion. This was what happened in the case of *McAllister v Lewisham and North Southwark Health Authority*<sup>108</sup> Here the claimant contended she was not warned of the risks inherent in complicated brain surgery. Her argument was not that she would have never undergone the surgery, merely that she would have postponed the surgery to a later date because she had just started a new job which was important to her. Beyond this she declined to speculate as to what she would have done if given the relevant information. The judge concluded that she probably would have continued to decline the treatment and this was sufficient to prove causation.

The issue was not so clear cut in the recent House of Lord's decision in *Chester v Afshar*.<sup>109</sup> Here a distinction was drawn between when a judge can ultimately form an opinion on the claimant's future conduct (as in *McAllister*), and a situation where the judge is unable to decide what the claimant would have done after

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<sup>107</sup> For discussion see Kennedy & Grubb, *op cit* n 23 at 733-746. In particular the cases of *Ellis v Wallsend District Hospital* (1989) 17 NSWLR 553 and *Chappel v Hart*, *op cit* n 65 for a rejection of the previously mentioned objective approach.

<sup>108</sup> [1994] 5 Med LR 343.

postponing to obtain a second opinion. In *Chester*<sup>110</sup> the claimant stated that if she has known about the major complication inherent in the surgery she would have sought at least a second, if not a third opinion. The important issue here is that the claimant did not assert that she would never at any time or under any circumstances have consented to surgery. This being the case it was impossible to determine whom she would have seen, what advice would have been given, and how she would have acted in response to that advice. The House of Lords (by a majority of three to two) went on to conclude that there was a sufficient factual basis to establish causation as had the Court of Appeal, agreeing with the trial judge, and relying on the majority judgment in the Australian case of *Chappel v Hart*.<sup>111</sup> Here it was established that it was sufficient for the claimant to prove that had she been properly advised, she would not have consented to surgery *on that day*. Jones succinctly sums up the reasoning for this decision:

'...the materialisation of a small random risk...is the result of the particular time and circumstances in which the treatment was given (assuming that there is nothing which predisposes the particular patient to this risk), and therefore if treatment had been delayed to another occasion the probability is that the small inherent risk would not have materialised on that occasion, and thus the materialisation of the risk is causally linked to the negligent non-disclosure of risk.'<sup>112</sup>

The above judgment is pivotal in redefining a test for causation that is based on a more claimant-friendly approach. It could be argued that it is no longer a 'get out' mechanism for doctors. However, it is possible that the decision in *Chester* carries with it greater significance than a mere refinement of the causation test in medical disclosure cases.

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<sup>109</sup> *op cit* n 90.

<sup>110</sup> For a discussion of the facts of this case see *op cit* n 90. For an excellent critique of *Chester* see Devaney, S. "Autonomy Rules OK" (2005) 13 Med L Rev 102.

<sup>111</sup> [1998] HCA 55. For discussion see Cane, P. "A Warning About Causation" (1999) 115 LQR 21; Honore, T. "Medical Non-Disclosure, Causation and Risk: *Chappel v Hart* (1999) 7 TLJ 1.

<sup>112</sup> Jones, M.A. "But-for Causation in Actions for Non-disclosure of Risks" (2002) 18 PN 192 at 200.

### 2.1.9 The Symbolic Significance of Chester

In order that the claimant succeeded, it is evident that the in the House of Lords based their arguments on what they perceived to be a deviation from a straightjacket application of 'but-for' principles of causation. Effectively they looked beyond the immediate concern of establishing a causal connection to address the actual purpose and rationale behind the doctor's duty of disclosure. Lord Hope suggested:

'The function of the law is to protect the patient's right to choose. If it is to fulfil that function it must ensure that the duty to inform is respected by the doctor. It will fail to do this if an appropriate remedy cannot be given if the duty is breached.'<sup>113</sup>

The recommendation here is that for the law to achieve its purpose, and insofar as the duty of disclosure must have some meaningful content, it is desirable that if breached a remedy must be available to the patient by virtue of this very fact. Lord Hope further stated that: 'The scope of this duty...is unaffected by the response which the patient may give on being told of these risks.'<sup>114</sup> In acknowledging this and effectively condoning a versatile approach, Lord Hope confirmed causation is very much an ancillary consideration when placed in the wider setting of patient autonomy and the underlying purpose behind enforcing the duty of disclosure. However, a certain degree of perceived manipulation was needed in order to carry this to its conclusion. Some other justification was needed which was more persuasive than the tenuous argument that a causal link actually existed. Lord Steyn, a rather forward thinking judge who has a fondness for academic opinion, found this in Professor Honore's discussion pertaining to the Australian case of *Chappel v Hart*.<sup>115</sup> This was a case with more or less the same facts as *Chester* where the Australian High Court saw fit to find in favour of the claimant. Whilst conceding on the facts the doctor's

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<sup>113</sup> *op cit* n 90 at 153.

<sup>114</sup> *ibid* at 154.

<sup>115</sup> *op cit* n 111.

failure to warn was not the cause of the injury in the sense that he had not exposed the patient to a risk she need never run nor increased the risk she was bound to run in any event, he suggested:

'Dr Chappel violated Mrs Hart's right to chose for herself, even if he did not increase the risk to her. Judges should vindicate rights that have been violated if they can do so consistently...Dr Chappel did cause the harm that Mrs Hart suffered, though not by the advice he failed to give her...Morally he was responsible for the outcome of what he did...Do the courts have power in certain cases to override causal considerations in order to vindicate a plaintiff's rights? I believe they do though the right must be exercised with great caution.'<sup>116</sup>

Thus, in *Chester* Lord Steyn concluded that as a result of the doctor's failure to warn the patient, she had not given a true informed consent in a legal sense. Accordingly 'her right of autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles.'<sup>117</sup> This is where it becomes evident that the crux of the decision was based on policy considerations regarding justice and fairness taking precedence over traditional negligence principles so that the courts could reach a fair outcome for the patient. This is reinforced by Lord Steyn's further comments where he said:

...I am glad to have arrived at the conclusion that the patient is entitled in law to succeed. This result is in accord with one of the most basic aspirations of the law, namely to right wrongs. Moreover, the decision announced by the House today reflects the reasonable expectations of the public in contemporary society.'<sup>118</sup>

This, of course, begs the question that in *Chester* there is no 'wrong', or at least no actionable negligence, without damage caused. The majority were prepared to overlook this so as to give the duty of disclosure substance. Moreover, the final reference to the 'reasonable expectations of society' may carry most significance in the

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<sup>116</sup> *op cit* n 90 at 145 quoting from *Honore*, *op cit* n 111 at 8.

<sup>117</sup> *ibid* at 146.

<sup>118</sup> *ibid* at 146.

medico-legal environment. Therefore it is necessary to analyse this statement through the prism of the potential effect of the case on the domain of patient rights.

*Chester* is a case where policy arguments have prevailed over and above fundamental legal principle. This has happened before, yet it is the first time we have seen this in a disclosure case.<sup>119</sup> Jones notes that in the six previous medical negligence actions to come before the House of Lords, the score stood at Claimants 0; Defendants 6.<sup>120</sup> Historically the law has taken the view that the doctor knows-best, more or less allowing the medical profession to dictate the standard of care in negligence. Thus, in respect of risk disclosure, the courts have become embroiled in an almost unquestioning acceptance of medical decision making, thereby creating a paternalistic environment within law. This has now changed somewhat as a result of this case which represents the first decision by the House of Lords in which the patient has been successful. It is possible to view the judgment as encouraging evidence of a paradigm shift re-enforcing the notion that we are on the precipice of a new dawn for patient rights.<sup>121</sup>

On the other hand, after the more recent House of Lord's decision in *Gregg v Scott*<sup>122</sup>, this assertion may no longer carry the same weight. Here, again by a majority of three to two, the House of Lords declined to continue the expansive approach to causation, refusing to recognise liability for the loss of a chance of a more favourable outcome in clinical negligence actions. Arguably, the courts are taking one step forward and one step back. Maskrey and Edis suggest the two decisions are very difficult to reconcile. In both cases the breach was capable of causing the harm,

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<sup>119</sup> See *Fairchild v Glenhaven Funeral Services Ltd*, *Fox v Spousal (Midlands) Ltd*, *Mathews v Associated Portland Cement Manufacturers (1978) Ltd* [2002] UKHL 22; [2003] 1 AC 32.

<sup>120</sup> Jones, M.A. "The Bolam Test and the Reasonable Expert" (1999) *Tort Law Review* 226 at 236.

<sup>121</sup> See, for example, Heywood, R. "Informed Consent Through the Back Door?" (2005) 56 (2) *NILQ* 266.

<sup>122</sup> [2005] UKHL 2; [2005] 2 AC 176.

in neither could it be shown to have done so, yet the House of Lords came to different conclusions in each.<sup>123</sup> *Gregg* in itself raises some very interesting questions that remain open, elaborate discussion of these is beyond the scope of this thesis.<sup>124</sup> However, it is possible to view the differences between the two cases in one of two ways. Firstly, the subject matter of the two duties is very different. *Gregg* is about (non) treatment and diagnosis, *Chester* on the other hand concerns disclosure. The distinction between the two could be based on the importance the courts attach to the right of autonomy. This being the case, is it possible that a hierarchy of rights is being established whereby the courts are more willing to attach prominence to the right to be informed over and above the right to be diagnosed and treated correctly? Whilst this may demonstrate a renewed commitment towards patient rights, it does seem strange. Maskrey and Edis pose the question, 'why should the 'Right' (sic.) to decide whether to accept a treatment be accorded greater protection and value by the law than the chronologically prior right to be told that such treatment is available and could be beneficial?'<sup>125</sup> In explaining the rationale behind this they further suggest:

'It is difficult to see that there is any coherent difference between the right to decide whether to accept a particular treatment modality and the right to be made in the first place aware of its existence and the possibility of its need. Indeed, unless the patient is independently aware of the need for further investigation or treatment, the former right cannot, of course, be invoked unless the patient has gone through the gateway of the latter.'<sup>126</sup>

There is an alternative way to view the difference. In *Gregg* the fundamental concern for the courts may have been the policy considerations pertaining to the nature of the claim itself. A change in the law allowing claimants to recover for a loss of chance

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<sup>123</sup> Maskrey, S. & Edis, W. "*Chester v Afshar and Gregg v Scott: Mixed Messages for Lawyers*" (2005) 3 JPIL 205 at 222.

<sup>124</sup> For extensive discussion on the technical points this case raised relating to causation see Stapleton, J. "Loss of the Chance of Cure from Cancer" (2005) 68 MLR 996. In particular see pages 1003-1006 for analysis of the open questions left by *Gregg*. In addition, see Hoffmann, L. "Causation" (2005) 121 LQR 592.

<sup>125</sup> Maskrey and Edis, *op cit* n 123 at 222.

<sup>126</sup> *ibid.*

has potentially far-reaching consequences for the general law of negligence. It is possible that if the courts had taken the same liberal approach in *Gregg* as they did in *Chester*, this would allow nearly all clinical negligence claims to be reformulated as loss of chance cases. It seems this prayed heavily on the mind of Baroness Hale and has been suggested by some academics as the true reasoning behind the House of Lord's decision.<sup>127</sup> This being the case, it is possible the right of autonomy did not figure greatly in any of the Lords' thinking in *Gregg* and this weakens somewhat the first justification for the difference between the two cases.

Undoubtedly *Chester* is a case that can be confined to its own facts to a greater extent than *Gregg*, and the courts have gone to great lengths to stress this.<sup>128</sup> The apparent commitment towards patient autonomy in *Chester* may be a human rights inspired development, or a pragmatic recognition that selectively relaxing the cause rules will not flood the NHS with disclosure/consent claims, whereas doing the same for treatment and diagnosis errors might. The true significance of the decision is bound up in its symbolic nature. The law is supposed to be prescriptive; laying down guidelines for future conduct. Thus, its real power is to be found in the indirect influence that it may have on the medical profession in years to come, where consent may be taken more seriously as a result of the new found judicial recognition of respect for patient's rights. In a continuation of this there are encouraging signs of late from the recent Court of Appeal decision in *Wyatt v Curtis*.<sup>129</sup> In this case a rather liberal interpretation of Lord Woolf MR's test in *Pearce* allowed Sedley J. to conclude that the defendant

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<sup>127</sup> *op cit* n 122 at para 226. For discussion see Stapleton, *op cit* n 124 at 1002.

<sup>128</sup> See, for example, *Beary v Pall Mall Investments* [2005] EWCA Civ 415; [2005] PNLR 35. Here the Court of Appeal firmly rejected the attempt to extend the policy considerations in *Chester* from medical to financial advice. Dyson L.J. at (para. 38) stated the extension would be 'breathhtakingly ambitious, contrary to authority and...wrong.'

<sup>129</sup> [2003] EWCA Civ 1779; [2003] WL 22827037.

had breached her duty of disclosure. In doing so he appeared to concede that the significance of a risk is not wholly objective and therefore placed emphasis on the particular patient's perception of what is 'substantial' and 'grave'. Again this demonstrates is an increased willingness by the appellate courts to consider patients' rights in a much broader context. This case will be explored in greater detail in a later part of this thesis.

### **2.1.10 The Human Rights Act 1998 and Informed Consent**

It is with great caution that issues of human rights and the change that they may have on issues of informed consent should be addressed. It is difficult to predict how the European Court of Human Rights may interpret consent cases. However, there are a number of pertinent points, which may in time, need to be considered by the courts.

The Convention which may have the biggest impact on consent issues is undoubtedly the *European Convention on Human Rights and Biomedicine, 1997(ECHR)*. There are a number of relevant articles.

Firstly, Article 4 deals with professional standards and healthcare, this provision requires that any intervention in the medical field must be carried out in accordance with the relevant professional obligations and standards. This is particularly pertinent in light of the professional guidelines in relation to informed consent. The upshot of this provision may be that if guidelines are not adhered to then it may be a lot easier to mount a legal challenge. Secondly, and more importantly, Article 5 governs consent. It requires in respect of individuals who are able to consent:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as its consequences and risks.

The person may freely withdraw consent at any time.

This is of interest as Article 5 clearly expresses that consent should be truly informed in order to be legally effective. On closer inspection this is not really that different from the current English law. Whilst it talks about the idea of informed consent and the provision of adequate information about risks, it does not explore other components of the doctrine such as alternatives and patient understanding. Irrespective of this, as yet, the UK has not signed or ratified the Convention. However, even if the UK had ratified the Convention its practical effect may be limited by the fact that there is no right to individual petition. Individuals who feel they have suffered a violation of a right protected by the Convention have no right to obtain a remedy from the European Court of Human Rights. Instead, the European Court may give an advisory opinion on the interpretation of the Convention, but only at the request of a government party to the *ECHR*. This seems to rule out petitions from domestic courts on behalf of individuals who feel they have suffered at the hands of the state. Hence, in a practical sense, the *ECHR* would appear to be of limited value to lawyers.<sup>130</sup>

Notwithstanding this, the rights in the Convention may still be indirectly enforceable by individuals who seek to assert one or several rights in the main treaty. Article 29 of the *ECHR* confirms that any infringement of rights under this Convention may be considered in proceedings under the European Convention on Human Rights if they also constitute a violation of rights contained in the latter Convention. Thus, although a direct challenge would not be allowed for a breach of

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<sup>130</sup> Plomer, A. "Medical Research, Consent and the European Convention on Human Rights and Biomedicine" in Garwood-Gowers, A., Tingle, J., Lewis, T. *Healthcare Law: The Impact of the Human Rights Act 1998*. (London: Cavendish, 2001) at 314.

Article 5, a challenge could be brought under Article 8 of the *ECHR* which protects individual's right to respect for his private and family life, which encompasses physical and moral integrity of the person.<sup>131</sup> A similar claim may be made under Article 10 which protects the right to individual's freedom of expression, including the right to receive information.

It is argued by Plomer that the fragility of the *Bolam* test in protecting the patient's rights to self-determination has been in part due to the absence of a constitutionally entrenched right to informed consent.<sup>132</sup> Article 5 of the *ECHR* provides a legal framework in the form of an entrenched right, which ensures that too great a dependence on the medical profession by domestic courts and resilient paternalism can now be replaced by clear recognition of the primacy of patients' right to know. Brazier and Miola have opined 'the entry into force of the Human Rights Act 1998...will require that judges pay much more attention generally to claimants' rights.'<sup>133</sup> Thus, we may be faced with a subtle paradigm shift which places a patient's right to be informed at the forefront of medico-legal litigation and de-emphasises the significance previously attached to medical paternalism. Accordingly, Brazier and Miola have further suggested:

'...deference to the medical profession should be replaced with legal principles which recognise the imperative to listen to both doctors and patients and which acknowledge the medical professional is just as much required to justify his or her practice as the architect or solicitor.'<sup>134</sup>

### **2.1.11 Recent Developments in New Zealand**

Assessing the New Zealand position in respect of patients' rights is also worthwhile.

Since 1996, New Zealand has developed a Code of Health and Disability Services

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<sup>131</sup> *X and Y v The Netherlands* (1986) 8 EHRR 235.

<sup>132</sup> Plomer, *op cit* n 130 at 321.

<sup>133</sup> Brazier and Miola, *op cit* n 36 at 114.

<sup>134</sup> *ibid.*

Consumers' Rights. This Code places heavy emphasis on information disclosure and shows a commitment to an enshrined regulatory system, enforceable under the law, which seeks to protect patients' rights.<sup>135</sup>

The Code of Rights adopts a test of what the reasonable consumer would want in the consumer's circumstances and is thus similar to the *Rogers* test for judging information disclosure. The duty canvassed by the Code of Rights is to provide 'fair and balanced information' in the circumstances which, of course, extends not only to risks, but also alternatives to treatment and other possible useful information such as success rates and levels of aftercare that may be required. This is also supplemented by a separate duty to answer questions honestly and truthfully. For example, in one case it was held that a reasonable patient would expect to be advised that the majority of practitioners in the field would not perform the procedure which that doctor was offering at that time.<sup>136</sup> It has also been suggested that the doctor may be under a duty to correct unrealistically high expectations of what treatment can achieve.<sup>137</sup>

Moreover, in allowing for an assessment of the individual patient's circumstances, the Code of Rights recognises the limits and dangers of attaching statistical probability to the definition of expected risks. Right 6 (1) (b) refers to a right to an assessment of the expected risks. It has been made clear that this term attaches no statistical probability. Thus the probability of a risk transpiring must be weighed against the magnitude of potential harm and the availability of other options. It follows that where the potential harm of the risk eventuating is very serious the

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<sup>135</sup> For a very interesting and recent discussion on the Code of Rights see Manning, *op cit* n 99.

<sup>136</sup> Case 01HDC05619 *Hepatobiliary Surgeon* (31.07.02) - In this case the surgeon overstated risks that a simple cyst might be cancerous but did not advise that the majority of other surgeons would recommend another procedure.

<sup>137</sup> Manning, *op cit* n 99 at 198.

reasonable consumer can expect a warning of this regardless of what the statistical probability of the occurrence rate is.<sup>138</sup>

However, the advance into patients' rights can be seen in the recognition that where a risk is too unusual to require a warning in the normal course of events, the provider may still be required to disclose this if it is elevated in the circumstances of the individual patient.<sup>139</sup> Clearly this open-minded approach represents a significant departure from the English position in terms of both recognising, and advancing patients' rights. Manning has suggested that although the ordinary principles of negligence should be considered in deciding whether a risk is material and hence disclosure is necessary,<sup>140</sup> these have to be weighed against the wider social factors and considerations which may affect the individual patient. These should include such things as the how much the patient needs the operation, whether there are any reasonably available satisfactory alternatives and the fact that a patient may be more likely to attach significance to a risk if the procedure is elective rather than life-saving.

Early indications suggest the Code of Rights is having a positive influence.<sup>141</sup> Accordingly, problems begin to surface in England because of the way our law may be perceived. Medical practitioners may well view English law as doing nothing more than placing a duty on them to 'carpet-bomb' patients with often irrelevant (and

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<sup>138</sup> Case 01HDC13700 *Oral and Maxillofacial Surgeon* (29.4.03) A patient would expect advice about recognised risk of permanent nerve damage during wisdom tooth extraction, even though less than one per cent, as loss of sensation in the tongue would be a major concern to most patients.

<sup>139</sup> Case 98HDC13693 *Neurosurgeon/Hospital and Health Service* (6.12.00) Failure to advise of greater risk of post-operative complications and worsening of neurological deficit in circumstances of particular patient after a second investigatory operation.

<sup>140</sup> Manning, *op cit* n 99 at 200. Manning suggests these should include such things as the magnitude of the risk and the degree of probability of its occurring; the severity of the potential injury decided in reference to the patient; and the expense, difficulty and inconvenience of taking alleviating action.

<sup>141</sup> Manning, *op cit* n 99 at 190.

perhaps sometimes detrimental<sup>142</sup>) information about risks, coupled with a barely articulated duty to take some superficial steps to ensure the patient has understood what has been said. Thus, when equated with the New Zealand scheme it becomes evident that, over time, this may well prove to be a much more successful method of regulation in terms of raising not only the standards, but also the awareness of the importance of informed consent in practice. This is because clinicians are perhaps more likely to be aware of professional regulatory regimes and are more likely to pay attention to them than legal rules in court cases.

### **2.1.12 Statistics<sup>143</sup>**

Since the decision of the House of Lords in *Sidaway* there have been thirty cases, reported or unreported, where informed consent was in some form an issue. This represents two cases a year over a 14-year period. There were only nine cases where informed consent was the *sole* basis of the claim. Of the thirty cases that involved informed consent, the claimant was successful on the informed consent issue on seven occasions. The seven successful cases comprised four which were solely informed consent cases, and three of these concerned allegations about failure to warn about the risks of sterility treatment. In only eleven of the thirty cases did the claimant succeed

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<sup>142</sup> If these risks are not placed in context by the doctor in explaining the procedure in terms of a risk/benefit analysis, regimental disclosure may well be harmful to the patient in putting them off treatment that is necessary and clearly in their best interests.

<sup>143</sup> Both sets of statistics provided derive from insightful papers by Professor Jones and Doctor Maclean. See Jones, *op cit* n 17 at 122; Maclean, *op cit* n 33 at 211. Professor Jones's figures are gathered from an automated search of *Lexis*, together with a manual search of the *Medical Law Reports* and the *Butterworths Medical-Legal Reports*. Dr. Maclean's figures are generated from manual searches of *Lloyd's Medical Law Reports and Butterworths Medical Law Reports* and automated searches of *Casetrack, Lexis, Lawtel and Westlaw*. His figures are accurate up to 13<sup>th</sup> November 2001. However, both authors concede that drawing conclusions from such limited data is dangerous. This is because it only looks at cases that have gone to trial and that have been reported or recorded in the relevant law reports. Clearly many cases will be settled out of court and these are more likely to be the cases that are favourable to the claimant, and some cases will simply not be picked up by the searching. Recent findings by Amirthalingam, *op cit* n 98 at 127, 129-132 suggest the levels of disclosure cases are markedly higher in Australia. Particularly in high-risk areas, such as cosmetic surgery and obstetrics. This will be the subject of further discussion later in the thesis with worked case examples demonstrating the findings of the empirical research.

on breach of duty. In the remaining nineteen cases, the claimant failed to convince the court that there had been a breach of the doctor's duty to inform and failed to establish causation.<sup>144</sup>

Maclean's more recent figures suggest that since *Bolitho* there have been sixty-four cases of medical negligence which at least one of the issues was the standard of care. Eighteen of these were in the Court of Appeal and forty-six were in the High Court or County Court. In the Court of Appeal, four cases involved allegations of non-disclosure and the defendant was liable in two of these. In one case, the court applied the *Bolam* test and in the other explicit reference was made to neither *Bolam* or *Bolitho*. In courts of first instance, eight cases involved non-disclosure allegations; the defendant was liable in only one of these and in that case the *Bolam* test was applied.<sup>145</sup>

As a result of these figures, Jones has suggested that 'the law of informed consent does not work'.<sup>146</sup> Although case law may well fill in some areas of doubt it can never be a comprehensive framework.<sup>147</sup> Therefore, although conceptually the purpose of the legal rules governing informed consent may be to redress the balance of power within the doctor/patient relationship, the practical purpose of the law is to provide compensatory redress for breaching the rules of disclosure. The above figures indicate the law is falling short of its objectives in terms of this, as the majority of patients do not succeed in their claims. It follows from this point that in order to understand the true meaning of informed consent Jones suggests one must look at the concept beyond the courts.<sup>148</sup> It is the purpose of this thesis to draw on the work of Jones by investigating the realities of the consent process in practice. It

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<sup>144</sup> Jones, M.A. "Informed Consent and Other Fairy Stories" (1999) 7 Med L Rev at 122.

<sup>145</sup> MacLean, A. "Beyond Bolam and Bolitho" (2002) 5 Med L Int 205 at 211.

<sup>146</sup> Jones, *op cit* n 144 at 107.

<sup>147</sup> *ibid* at 106.

explores both medical practitioners' and patients' perceptions of what is important to them in the consent process and relates this to the legal concept of consent in an attempt to create a better understanding of how things operate in practice. One of the central themes of the work will be to appraise the statement that:

'...the law is not widely known and probably even less well understood by the medical profession...It seems probable the few doctors have heard of *Sidaway*, and if they have they have probably failed to understand its rather limited requirements, since they appear to be more afraid of the law, or rather of the prospect of litigation, than *Sidaway* realistically warrants.'<sup>149</sup>

The following chapter sets out the major research questions and themes that will be addressed throughout the project.

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<sup>148</sup> *ibid* at 123.

<sup>149</sup> *ibid* at 106.

## 3 LITERATURE REVIEW - PART 2

### 3.1 THE EFFECT OF THE LAW ON INFORMED CONSENT IN PRACTICE: THE SUBSTANTIVE RESEARCH QUESTIONS

#### 3.1.1 Introduction

One of the aims of this thesis is to explore the effect of the law on consent in practice and to bridge the gap between legal theory and medical practice. Can an optimum balance be struck between protecting and enhancing patients' rights without placing an unworkable duty on medical practitioners, which may have a detrimental effect on medicine?

The theoretical significance of English law adopting a professional standard of disclosure cannot be underestimated; the practical effect of this is debatable. Almost twenty years ago Kennedy highlighted the problem with this. He 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.'<sup>1</sup>

The extent to which this statement remains a fair reflection on contemporary medical care is uncertain. However, a problem with *Sidaway* was its apparent support for a non-existent professional standard of disclosure. This is compounded by the fact that, in an occupation where there is such diversity of practice and division of professional opinion, any suggestion of harmonisation of consent processes is impractical, and may be unworkable.

As noted, the statement made by Kennedy may only be of importance in a historical context. Mason, McCall Smith and Laurie suggest there are signs that consent practices are becoming more standardised. This is evidenced by the fact that

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<sup>1</sup> Kennedy, I. 'The Patient on the Clapham Omnibus' (1984) 47 MLR 454 in Kennedy, I. *Treat me Right - Essays in Medical Law and Ethics* (Oxford: Clarendon Press, 1988) at 189.

professional standards are developing in a manner which is similar to the prudent patient standard, and the gap between what *is* revealed and what *should* be divulged is closing.<sup>2</sup> As Jones has stated:

'...as professional attitudes to the question of information disclosure change (whether through gentle persuasion or the threat of litigation) patients will become 'entitled' to more information under the Bolam standard.'<sup>3</sup>

The purpose of this section of the literature review is to identify the major research questions this study addresses by discussing the implications of the legal rules and the effect that they have on informed consent in practice.

### **3.1.2 The Research Areas**

This project explores the following issues:

1. Informed consent in medical education.
2. Informed consent in primary care.
3. Types of risks that clinicians disclose.
4. Information provided about alternatives.
5. The inquiring patient.
6. The role of therapeutic privilege.
7. Defensive medicine in respect of consent.
8. Patient understanding.
9. Doctor/patient communication.
10. Professional guidelines and consent.

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<sup>2</sup> Mason, J.K, McCall Smith, R.A., Laurie, G.T., *Law and Medical Ethics*. (London: Butterworths, 2002) at 363.

<sup>3</sup> Jones, M. "Informed Consent and Other Fairy Stories" (1999) 7 Med L Rev 103 at 125.

### **3.1.3 Informed Consent and Medical Education**

A major issue, which arises in the consent process, is centred on who actually gains a patient's consent and where it takes place. Arguably for any consent to be valid and for the rules to serve their purpose, the consent should be obtained by the most senior person who is performing the operation i.e. the consultant, or at least somebody who has the relevant knowledge and experience of the procedure which is proposed.

However, Jones states:

'...Far too often the most inexperienced member of the surgical team is 'consenting' the patient, a term which itself suggests that consent is something which is done to the patient, usually for the purposes of avoiding liability, not a process that the patient participates in or indeed controls.'<sup>4</sup>

It is also apparent that the medical profession has recognised this is a problem. It has been suggested that the standards of consent achieved on the wards fall short of what lawyers would expect. This is because the task of obtaining the consent is often left to the more junior medical staff, who are themselves ignorant of the adverse effects treatments may have on patients.<sup>5</sup> American-based empirical evidence suggests that the vast majority of surgical residents are ill-equipped to obtain informed consent.<sup>6</sup> Jones suggests the reason for delegating consent procedures is directly linked to the way in which doctors perceive consent, that is they feel it is sufficient to get the patient to merely sign a form, when they themselves have little understanding of the procedure in question.<sup>7</sup> It has been suggested by Sedgwick and Hall that in a profession where the curriculum is concerned primarily with scientific fact and, coupled with the sheer volume of information students are expected to take in under

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<sup>4</sup> *ibid.*

<sup>5</sup> Kerrigan, D.D. *et al.* "Who's Afraid of Informed Consent?" (1993) 306 *BMJ* 298.

<sup>6</sup> Angelos, P. *et al.* "Residents Seeking Informed Consent: Are They Adequately Knowledgeable?" (2002) 59 *Current Surgery* 115.

<sup>7</sup> Jones, *op cit* n 3 at 130.

tight time constraints, issues such as patient communication, in the past, may have been overlooked or inadequately dealt with.<sup>8</sup>

Thus, the current study addresses issues of physician communication in relation to medical education and training. This research explores how medical students perceive the concept of informed consent, how they are educated in terms of it and whether they feel their training has been effective enough to give them confidence in obtaining informed consent in a clinical setting. Moreover, it investigates how senior doctors perceive consent, whether they delegate the process and, if so, why they feel this acceptable.

### **3.1.4 Informed Consent in Primary Care**

Very little, if any, research has been carried out into what consent systems are in place in primary care. It seems clear that, as any bodily touching requires some form of consent, both general practitioners and practice nurses will inevitably carry out procedures which require permission from the patient. For example, administering an injection is an invasive procedure for which consent should be obtained. However, is this written consent or implied consent? In a busy surgery, it is most likely to be implied. Would GPs feel more comfortable if it was written and how would this fit with the time constraints of a busy general practice? Perhaps, more importantly, how do you actually know if a patient is giving implied consent? Just because patients hold their arm out for an injection does not necessarily mean they have understood the consequences of what they are agreeing to.

Finally, what is the position with prescription drugs? Much of the informed consent debate has centred on invasive operations, yet with advances in modern drug therapies come increase in risks and side-effects that GP's surely must be under an

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<sup>8</sup> Sedgwick, P. & Hall, A. "Teaching Medical Students and Doctors How to Communicate Risk" (2003)

obligation to warn about. However, there may be risks that GP's simply do not have the time or do not actually know enough about them to adequately warn the patient, thus arguably, there is no informed consent.

One of the aims of this project is to explore GPs' and practice nurses' perspectives on informed consent and to investigate what procedures are in place in practice for obtaining a patient's consent and if this varies according to the procedure in question.

### **3.1.5 Types of Risk Disclosable**

#### **3.1.5.1 Substantial Risk of Grave Adverse Consequences**

It is an unfortunate consequence of the way the law has developed that so much emphasis is placed on the disclosure of risks. The legal definition of informed consent perceives medical practitioners mainly as agents of disclosure. However, perhaps the biggest problem with the consent rules is the law's vagueness about which types of risk actually have to be disclosed. The decision in *Sidaway* tells doctors that although they will be judged primarily by the standard of their peers, they must divulge necessary information to patients where there is a *substantial risk of grave adverse consequences*.

Brazier identifies the problem:

'The doctor is left to 'second-guess' the courts. In attempting to assess what level or nature of risk he must disclose in contravention of accepted practice of non-disclosure of risk, he has to judge the materiality of that risk by reference not to the patient before him, the patient he knows, but to the unknown judicial standard.'<sup>9</sup>

A further argument is centred on whether or not the two requirements have to complement each other for a claim to be successful. As Grubb notes, the test may be invoked rarely in practice if it means that both the chances of the risk materialising

are *substantial* and the *resultant* injury grave.<sup>10</sup> Indeed, if this were to be followed the test would be so stringent as to render it very difficult to succeed in establishing a breach. It seems clear that 'how likely' and 'how grave' depends on the condition of the particular patient.

This begs the question who decides what constitutes a substantial and grave risk? Although the most logical suggestion would be the patient, this has been rejected by the courts for being too subjective. However, surely it cannot be the medical profession as this takes us no further than conventional *Bolam* and the resultant paternalism. The only other option is for the courts to decide, after careful scrutiny of the medical evidence that is available at the time. However, the evidence has to be the subject of thorough examination by the courts if Lord Bridge's speech in *Sidaway* and Lord Browne-Wilkinson's speech in *Bolitho* is to have any effect other than endorsing medical paternalism.

This project seeks to discover what types of risk the medical profession perceives to be substantial and how they go about categorising risks. It may also be of importance to discuss with health care professionals under which circumstances they would be prepared to give evidence to the effect that a risk was so high that it should have been disclosed and under which circumstances they would support the non-disclosure of certain risks.

### 3.1.5.2 Percentages & Risks

The courts have given some guidance as to what they would classify as a serious risk. Regrettably, most of this guidance has centred on attaching percentage figures to the chances of risks occurring. In both *Sidaway* and *Pearce*, Lord Bridge and Lord Woolf

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<sup>9</sup> Brazier, M. "Patient Autonomy and Consent to Treatment" (1987) 7 LS 169 at 162.

<sup>10</sup> Grubb, A. "Negligence: Causation and Bolam" (1998) Med L Rev 378 at 382.

MR respectively both give the example of a 10% chance of a risk eventuating as a example of something a patient should be warned about.

This figure seems arbitrary, although it is a figure that most judicial scrutiny seems to focus on in terms of what should be disclosed. Yet with developments in modern medicine, it sets a noticeably high yard-stick for disclosure that may exclude 'most of the risks of serious permanent harm.'<sup>11</sup>

Kennedy demonstrates the danger of relying too heavily on percentages. Writing about the *Sidaway* case he suggests it was an unfortunate consequence of Lord Bridge's speech that he opted for a probability-based test to determine when a risk may materialise. This is because firstly, the law should not seek to produce a standard of care which substitutes mathematics for words such as '*reasonable*' and '*material*' which, by their very nature, allow the law to retain its flexibility and capacity for development. Secondly, there may well be disagreement as to the precise number to be assigned to the chance of a particular risk materialising.<sup>12</sup>

A practical aspect of this project investigates the willingness of medical practitioners to attach specific risk figures to certain procedures and to see how high these figures actually are.

### 3.1.5.3 'General' and 'Special' Risks

Historically the law has seemed to draw a distinction between general and special risks, with the suggestion being that the doctor is under an obligation to warn of the latter, but not the former.<sup>13</sup> This is dangerous. The difference between 'general' and 'special risks' may provide a basis for establishing what can be classed as

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<sup>11</sup> Maclean, A. "Beyond Bolam and Bolitho" (2002) 5 Med L Int 205 at 214.

<sup>12</sup> Kennedy, *op cit* n 1 at 200.

<sup>13</sup> There is evidence of this in both Lord Templeman's judgment in *Sidaway* [1985] AC 871 in the House of Lords, at 903, and Browne-Wilkinson judgment in *Sidaway* in the Court of Appeal [1984] 1 All ER 1018 at 1034.

material risks but they are not conclusive of it. For example, a 'general' risk may not be material as the patient is presumed to know it. Conversely, a 'special' risk may be material but does not necessarily have to be.<sup>14</sup>

What constitutes a 'general' or 'special risk' surely has to be decided with reference to the particular patient. It will depend on the circumstances of the patient and what effect any procedure may have on them as individuals. Again, this would mean that wider social factors involved in the patient's life must be taken into consideration when deciding which risks to disclose to them.

Lord Scarman recognised this in *Sidaway* when he suggested:

'With the world-wide development and use of surgical treatment in modern times the court may well take the view that the reasonable person in the patient's situation would be unlikely to attach significance to the general risks; but it is not difficult to foresee circumstances particular to the patient in which even general risks of surgery should be the subject of a warning by his doctor, eg. A heart or lung or blood condition. Special risks inherent in a recommended operational procedure are more likely to be material.'<sup>15</sup>

Legally speaking, although the distinction between 'general' and 'special' risks may still exist, it is only of relevance in determining whether the procedure in question carried with it a significant risk of which the patient should have been warned.<sup>16</sup>

Nevertheless, what the medical profession classes as general and special risks will have a bearing on the evidential issues that present themselves before the courts. If in the opinion of the medical profession the risk is only classed as a general one inherent in surgery, it will be extremely persuasive in allowing the courts to decide it was not substantial.

Some examples of general risks might encompass things such as risks associated with anaesthetic, sepsis, cardiac arrest etc.<sup>17</sup> It will be of interest to

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<sup>14</sup> Grubb, *op cit* n 10 at 384.

<sup>15</sup> *op cit* n 13 at 889.

<sup>16</sup> *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118.

<sup>17</sup> *op cit* n 13 at 889 *per* Lord Scarman.

discover whether these categories extend to other aspects of treatment such as general pain and bruising, bleeding, grogginess and nausea. Similarly, there may be some 'grey' areas such as warnings about levels of aftercare, scarring and the fact that some patients may need extra warnings about these side effects, as they have not realised the magnitude of them.

Therefore, a question that this project addresses is what medical practitioners class as 'general risks' and 'special risks', and indeed whether this distinction exists at all. Also, in deciding this, whether any thought given to the particulars of the individual patient?

#### 3.1.5.4 From 'Substantial and Grave' to 'Significant'

It was suggested earlier in this literature review that the decision in *Pearce* took us beyond the reasonable doctor test for judging adequacy of disclosure. This is supported by Brazier and Miola's assertion that:

'Even the cynic must concede that...the reasonable doctor test received a body blow in *Pearce*. It survives only if the reasonable doctor understands that he must offer the patient what the reasonable patient would be likely to need to exercise his right to make informed decisions about his care.'<sup>18</sup>

However, even though the emphasis is clearly on divulging what the reasonable patient would want to know in the circumstances, problems begin to surface when addressing the *type* of information that must be disclosed. Apparently this should include all significant risks the reasonable patient would want to know in the circumstances. Thus, the source of legal contention is centred on the definition of what constitutes a significant risk. The guidance given by Lord Woolf MR is as follows:

'When one refers to a significant risk, it is not possible to talk in precise percentages...the doctor...has to take into account all the relevant considerations,

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<sup>18</sup> Brazier, M. & Miola, J. "Bye-Bye Bolam: A Medical Litigation Revolution?" (2000) 8 Med L Rev 85 at 110.

which include the ability of the patient to comprehend what he has to say to him or her and the state of the patient at the particular time, both from the physical point of view and from the emotional point of view.<sup>19</sup>

There are a number of issues to consider here. Firstly, Lord Woolf MR is recognising what self-determination is actually about. His *dictum* emphasises the importance of looking beyond the mere blanket disclosure of risks to considerations such as comprehension and the ability of the patient to absorb and understand the information in order to reach a decision. Moreover, he argues that you cannot seek to quantify significant risks in terms of mere percentages. It is a pleasing facet of his judgment that 'the law must perforce be uncertain, and not seek to incorporate tests which have a spurious certainty but could be invoked against the interests of patients.'<sup>20</sup> Nevertheless, it is with great caution that one should analyse any theoretical judicial abstraction without looking at the actual outcome of the case. Judges have often sought to advance the law on a theoretical plane, but cynics will be mindful of the fact that on a practical level it is often best to look at what the courts did as opposed to what they said. This is may be true of *Sidaway*, is true of *Bolitho*, and in light of the fact that Lord Woolf MR seems to concentrate on the figure of 10% as being demonstrative of a significant risk, is also true of *Pearce*. In this sense Maclean suggests Lord Woolf MR's judgment is 'somewhat confused in that he continues to do exactly that against which he counselled.'<sup>21</sup> The real issue at stake is bound up in who decides what constitutes a significant risk that would affect the judgment of a reasonable patient. The answer appears to be, subject to the *Bolitho* logical scrutiny test<sup>22</sup>, the medical experts. Is this a recourse back to paternalistic traditions, the problems of which the courts were striving to avoid in the first place?

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<sup>19</sup> (1998) 48 BMLR 118 at 124.

<sup>20</sup> *Ibid.*

<sup>21</sup> Maclean, *op cit* n 11 at 214.

<sup>22</sup> See section 2.1.7.3

Accordingly Maclean suggests the standard becomes: 'A doctor must disclose those risks that the reasonable doctor believes the reasonable patient ought to find significant to a decision.'<sup>23</sup> When in reality the question in *Pearce* should have been 'whether the reasonable person, pregnant, post term and concerned to deliver a healthy baby, would find the risk significant.'<sup>24</sup> Had this been the case the outcome may have been very different.

Thus in adopting a *Pearce* type test for setting the standard of disclosure, although their views should not be conclusive, clearly the medical practitioners themselves are going to have a great deal of influence on deciding what counts as a significant risk. Accordingly, an aim of this study is to discover what risks are actually disclosed in practice and what types of risks medical practitioners classify as significant. In reality do medical practitioners rely heavily on percentages and to what extent, if at all, are the circumstances of the individual patient taken into consideration when deciding what to divulge in practice?

### **3.1.6 Information about Alternatives**

Kennedy and Grubb suggest that in *Sidaway* none of their Lordships referred to any duty to advise patients of alternatives to any suggested treatment.<sup>25</sup> With respect, this is wrong. Lord Scarman stated: 'I use the word advice to cover information as to the risk and options of alternative treatment.'<sup>26</sup> For the patient to be fully informed they need to be made aware of any possible alternative courses of action, for example non-interventionist therapies. However, there is a significant lack of legal authority in England that doctors are obliged to discuss alternatives with patients. In contrast,

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<sup>23</sup> Maclean, *op cit* n 11 at 214.

<sup>24</sup> Maclean, R.A. "The Doctrine of Informed Consent: Does it Exist and Has it Crossed the Atlantic?" (2004) LS 386 at 409.

<sup>25</sup> Kennedy, I. & Grubb, A. *Medical Law* Third Edition (London: Butterworths, 2000) at 680.

Kennedy and Grubb point us towards Canadian and American authority by way of example.<sup>27</sup> In *Haughian v Paine*<sup>28</sup> the Saskatchewan Court of Appeal held that failure to advise a patient of a more conservative treatment than was offered by the doctor constituted a breach of his duty to the patient. Similarly, in *Truman v Thomas*<sup>29</sup> the California Supreme Court found that failure to advise a female patient of the consequences of refusing a pap smear could constitute a breach of the doctor's duty when she subsequently died from cancer of the cervix. Kennedy and Grubb offer the only real English authority on this as the aforementioned case of *Pearce*. They submit that this case concerned the failure to disclose the increased risk of stillbirth if delivery was delayed. However, this may not be strictly accurate.<sup>30</sup>

The nature of Mrs. Pearce's risk was that of still-birth. Arguably, had she been informed about this she would have considered it significant, firstly because there was evidence adduced she was keen to have a caesarean section.<sup>31</sup> This may have served to tip the balance in favour of her rejecting the doctor's initial advice to proceed naturally, and resulted in her specifically requesting a caesarean section. In being given no information about the risks inherent in a natural delivery, she was denied the opportunity to weigh up the risk/benefit ratio concerned with the differing courses of action and to compare the two before making an informed choice about which treatment to opt for. It is with regret that no matter how creatively one reads Lord Woolf MR's judgment, there is nothing within his judgment to compensate for the lack consideration given to providing patients with information about alternatives to

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<sup>26</sup> *op cit* n 13 at 876.

<sup>27</sup> Kennedy & Grubb, *op cit* n 25 at 711.

<sup>28</sup> (1987) 37 DLR (4<sup>th</sup>) 624.

<sup>29</sup> (1980) 611 P 2d 902.

<sup>30</sup> Kennedy & Grubb, *op cit* n 25 at 712. Only in the sense that this is a creative interpretation at best. The alternative to a natural delivery, a caesarean section, was discussed with the patient and the relevant risks were highlighted. Thus, the case rested upon those inherent risks that were not disclosed in the doctor's preferred course of action i.e. the natural birth.

<sup>31</sup> *op cit* n 19 at 120.

treatment. Furthermore, and perhaps more worryingly, there is nothing to suggest the law should recognise this in the future.

Thus, although this requirement may be overlooked, in order for the objectives of self-determination to be fulfilled, advice about alternatives remains of central importance when seeking to enforce autonomy enhancing practices. Seemingly, this has been recognised in Australia where real in-roads have been made into the legal duty to advise of alternatives. Addison suggests 'in (non-emergency) situations where alternatives are available, the law expects 'fuller' disclosure of risks from medical practitioners.'<sup>32</sup> The medical profession themselves have started to recognise this as the standard NHS consent form includes a section which talks about the discussion of alternatives.<sup>33</sup> However, how much attention is paid to this in practice?

Accordingly, it will be an integral aspect of this project to identify how much information medical practitioners are willing to proffer regarding the availability of alternatives to the recommended treatment. For example, it may prove to be the case that once a surgeon has identified the problem, they may be unwilling to recommend any other course of action than surgery. Likewise there may be issues of professional pride to consider such as disagreements between physicians and the surgeons. The former endorsing non-interventionist techniques and hence making all options and therapies known to the patient, and the latter endorsing surgery at all costs leading to a reluctance to discuss alternative measures.

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<sup>32</sup> Addison, T. "Negligent Failure to Inform: Developments in the Law since *Rogers v Whitaker*" (2003) 11 TLJ 165 at 177.

<sup>33</sup> See for example appendix [5] 'I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment). *sic*. [See appendix 5].

### 3.1.7 *The Position of the Inquiring Patient*

Historically, the law has shown indifference to protecting the rights of the inquiring patient. Lord Denning set the scene in the early case of *Hatcher v Black*.<sup>34</sup> The claimant asserted that the doctor was negligent in failing to disclose the risk in the face of direct questioning. The question, as Lord Denning saw it, was what should the doctor tell his patient? He stated:

'...[the doctor] admitted that on the evening before the operation he told the plaintiff that there was no risk to her voice, when he knew that there was some slight risk, but he did so for her own good because it was of vital importance that she should not worry. In short, he told a lie, but he did it because he thought in the circumstances it was justifiable...so far as the law is concerned, it does not condemn the doctor when he only does that which many a wise and good doctor so placed would do.'<sup>35</sup>

Thus, according to Lord Denning there may be some circumstances where the doctor is permitted to tell a 'little white lie' to the patient if they feel it will be for their benefit, notwithstanding the fact they have been specifically quizzed about the risks.

Clearly this is problematic and as Williams points out:

'If doctors give information which is positively false because they believe the treatment to be beneficial, the very existence of the duty is threatened.'<sup>36</sup>

The position in English law now appears to have changed. In *Sidaway* Lord Bridge stated:

'When questioned specifically by a patient of apparently sound mind about risks involved in a particular treatment proposed, the doctor's duty must, in my opinion, be to answer both truthfully and as fully as the questioner requires.'<sup>37</sup>

This was subsequently clarified by Lord Woolf MR in *Pearce*. Presumably then, *Hatcher v Black* must now be treated with caution, and in all probability is no longer an accurate statement of the law, if indeed it ever was. Nevertheless, the controversy

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<sup>34</sup> *Hatcher v Black* [1954] *The Times*, 2<sup>nd</sup> July.

<sup>35</sup> *ibid.*

<sup>36</sup> Williams, K. "Pre-operative Consent and Medical Negligence" (1985) 14 *Anglo-American LR* 169 at 177.

<sup>37</sup> *op cit* n 13 at 898.

may lie in the precise extent to which the doctor is obliged to answer questions and this may be reflected in the realities of everyday practice. In *Sidaway* Lord Diplock commented that the highly trained and experienced judge may well be better placed to cross-examine their doctor and exercise their autonomous right of self-control as opposed to other less educated people.<sup>38</sup> Brazier observes:

'It would no doubt be made crystal clear to a Harley Street surgeon when a Law Lord required further and better particulars of proposed treatment. In a busy NHS clinic doubts and questions may be less articulated.'<sup>39</sup>

Thus, whilst it may well be understandable and acceptable that a well educated and intelligent patient may wish to specifically question their doctor about treatment, the same may not be true of patients who are less confident and perhaps not as well educated. Moreover, patients may be reluctant to engage with their doctor for a number of ulterior reasons. For example, they may feel intimidated, embarrassed or indeed may well not have the capacity to articulate specific questions when faced with the socially dominant medical practitioner. Nevertheless, this culture of silence amongst patients does not necessarily mean they do not want further information about their treatment, and it does not inevitably follow that they do not want to be involved in their health-care decisions.

In view of the above, the legal contention resides in the doctor's apparent duty to answer questions 'fully'. Kennedy and Grubb ask, what does this actually mean? Apparently the distinction may lie between where there is a specific question asked and when there is a more general inquiry made. In the New Zealand case of *Smith v Auckland Hospital Board*<sup>40</sup> it was suggested that if the patient only asks a general question then the doctor may be permitted to give a range of answers from the wholly truthful to the partially truthful to the somewhat deceptive. In contrast, the case of

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<sup>38</sup> *ibid* at 895.

<sup>39</sup> Brazier, *op cit* n 9 at 184.

*Hopp v Lepp*<sup>41</sup> states that if the question is a specific one, the doctor has no discretion and must answer the question wholly and truthfully. Therefore, it could be said that the duty to answer the question 'fully' as per Lord Bridge in *Sidaway*, might only be applicable in cases where there is a specific question, a requirement which may be affected by the relative educational background of the patient.

This has been reflected in the English case of *Blyth v Bloomsbury Health Authority*.<sup>42</sup> Here the Court of Appeal when faced with a chance to develop the law post *Sidaway* and enhance patient rights, instead chose to maintain the straightjacket distinction between a 'general enquiry' and a 'specific enquiry'. Here the claimant sought further and better particulars about the proposed operation after she expressed reservations about the treatment and asked for reassurance. It was held this only constituted a general inquiry. In light of this, it has been suggested by Tickner that although the Court of Appeal raised the question of what constitutes a specific line of enquiry, it failed to answer it.<sup>43</sup> Indeed, in view of the fact that Mrs. Blyth was a trained health professional, it makes one wonder what a patient would actually have to ask for the courts to hold it was a specific question. It may be the case that most patients' questions would 'rarely qualify.'<sup>44</sup>

Consequently, there is a situation where all parties, in particular patients, are confused about what constitutes a specific or general question. However, in reality the medical profession's view as to what counts as a specific inquiry undoubtedly provides the foundation for the law's perception of it. Thus, in attempting to clarify the issue, this study explores medical professionals' views about different types of patient inquiries and how they would classify them or respond to them. In turn these

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<sup>40</sup> [1965] NZLR 191 (NZCA).

<sup>41</sup> (1980) 112 DLR (3d) 67.

<sup>42</sup> [1993] 4 Med LR 151.

<sup>43</sup> Tickner, K. "Rogers v. Whitaker - Giving Patients a Meaningful Choice" (1995) 15 OJLS 109 at 117.

views will be compared to patients' beliefs as to what constitutes a specific or general question and their willingness or otherwise to engage with their doctor.

### **3.1.8 Therapeutic Privilege**

'...it would seem there is now a thin line between sensitivity to a patient's temperament and unacceptable paternalism.'<sup>45</sup>

A doctor's duty of disclosure is not an absolute one. In *Sidaway* Lord Scarman stated:

'Even if the risk be material, the doctor will not be liable if upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to the patient's health.'<sup>46</sup>

Here we are presented with what is commonly referred to as the therapeutic privilege. Whilst this may be referred to loosely as a 'defence', it is only a defence in the sense that it provides a justification for non-disclosure. It is not a defence that carries the same meaning as the general defences in negligence such as *volenti non fit iniuria*. Ordinarily, once the requirements for negligence are established, it is *then* for the defendant to raise any defences which may be available. The therapeutic privilege does not work this way; it is not a specific defence but rather a component of the doctor's overall duty of care. If the doctor feels, on a clinical assessment, that divulging certain information to the patient may be detrimental to their physical or mental health, they may withhold that information and in doing so will not breach their duty of care. As such, the practical worth of the therapeutic privilege only really kicks in where the prudent patient standard of disclosure is in operation; it provides justification for non-disclosure where ordinarily the reasonable patient would expect certain information. This, in all probability, is why Lord Scarman paid specific attention to it in *Sidaway* as noted above. If however the standard of disclosure is

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<sup>44</sup> *ibid.*

<sup>45</sup> Bidmeade I, "Disclosure of Information in Health Care" (1996) 4 *Australian Law Librarian* 180 at 181.

grounded in the *Bolam* test, reliance on the therapeutic privilege becomes almost unnecessary. Within this model there is already scope to withhold information and this can be done without dependence on the therapeutic privilege. Doctors may take into account the patient's best-interests and decide not to tell the patient certain information. If this decision is supported by reference to a responsible body of professional opinion the non-disclosure would be justified in the sense that there is no breach. Thus, in order to examine the true worth of the therapeutic privilege one must make an assessment of where English law is presently in relation to the standard of care. This is explored fully later in the thesis. (See 13.16.2 in the Solicitors' Study).

Williams thinks that accordingly all the doctor is obliged to do is perform his best assessment of what should be divulged bearing in mind the circumstances of the particular patient.<sup>47</sup> Thus, the operation of this has to be monitored closely since clearly the defence could be invoked to swallow up the principle if doctors are allowed too much leeway in what to tell their patients. Regardless of this, the legal significance of therapeutic privilege is the very fact that it exists only by way of a defence (only in the sense of a 'defence' for non-disclosure). Thus, Kennedy suggests the doctrine clarifies that the presumption is that disclosure is necessary, and this can only be rebutted on good evidence.<sup>48</sup> Similarly, the circumstances in which the patient will not wish to be informed are the exception and not the norm.

An example of the therapeutic privilege defence in action can be found in the Australian case of *Battersby v Tottman*.<sup>49</sup> Here a majority of the Full Court of the Supreme Court of South Australia<sup>50</sup> held that where a patient suffered from acute depression and suicidal tendencies, a doctor's decision to withhold information about

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<sup>46</sup> *op cit* n 13 at 889 - 890.

<sup>47</sup> Williams, *op cit* n 36 at 177.

<sup>48</sup> Kennedy, *op cit* n 1 at 187.

<sup>49</sup> (1985) 37 SASR 524.

the risk of serious and permanent eye damage associated with an anti-depressant drug was justified. In contrast, in *Gover v South Australia and Perriam*<sup>51</sup> the decision to withhold information about a thyroid-induced eye condition was not sufficient to trigger the defence of therapeutic privilege despite the apparent nervousness and volatile temperament of the patient. This was because Cox J was satisfied the patient had the capacity to judge the matter in a relevant and rational way. Thus it seems the only situations where this defence may apply are where the patient suffers from serious pathological anxiety disorders. However, Nagree has described this type of patient as 'an anomaly rather than the norm in everyday practice.'<sup>52</sup>

Moreover, the problem inherent in the use and application of this defence is found in the definition of what constitutes serious harm. Originally it was suggested the scope of the defence was limited only to psychological harm, but apparently harm can now include both psychological *and* physical damage.<sup>53</sup> The question is what counts as serious physical harm? For example, can harm to the patient encompass that patient refusing to undergo surgical or medical treatment because of the degree of fright or distress which information about the possible risks has prompted. If so, Skene suggests:

'...this provides a slightly different basis for the operation of the defence, for it may be easier for a doctor to prove that he or she was concerned about the patient's ability to use the information (so as to undertake treatment in his or

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<sup>50</sup> King CJ and Jacobs J, Zelling J dissenting.

<sup>51</sup> (1985) 39 SASR 543.

<sup>52</sup> Nagree, A. "Consent Forms and the Medical Profession" (1997) 4 JLM 336 at 345.

<sup>53</sup> In *Meyer Estate v Rogers* (1991) 78 DLR (4<sup>th</sup>) 307, Maloney J suggested that the defence of therapeutic privilege was originally intended to excuse doctors from upsetting patients whose psychological, not physical health may be detrimentally affected by receiving this information (at 20). It is unclear whether Lord Scarman in *Sidaway* perceived this defence as being exclusively restricted to psychological harm. At 887 he pays particular attention to 'serious threat of *psychological detriment* to the patient'. However, at 888 his assertion that the doctor would be excused from failing to disclose a risk if it would '*be detrimental to the health (including, of course, the mental health) of his patient*' seems to suggest he was considering harm other than the purely psychological.

hers best interests) than that the doctor believed that providing the information would seriously harm the patient's health.<sup>54</sup>

Once again, if the defence were allowed to operate on this footing the courts would have to proceed with caution and establish exactly *why* the doctor has withheld the necessary information. If it became evident that the information was withheld to prevent the patient being frightened about the proposed treatment, and the doctor failed to tell them about it as he was afraid it would deter them from undergoing any recommended operation, to justify this on the grounds of therapeutic privilege would effectively empty the duty of disclosure of much meaningful content.

Mulheron has opined that 'the probability of successful reliance upon the defence as a complete exculpation against any failure to warn of material risks or of some other failure is now almost completely nil.'<sup>55</sup> Despite this recent assertion, according to a US Presidential Commission in 1982 '...there is much to suggest that a therapeutic privilege has been vastly overused as an excuse for not informing patients of facts they are entitled to know.'<sup>56</sup> The basis of the problems associated with the therapeutic privilege defence stem from the failure of the courts to define what is actually meant by the term itself. Mulheron has further suggested:

'The failure of the courts...to better articulate the therapeutic privilege's content and scope leaves the law in an unsatisfactory state for medical practitioners who are concerned not to exacerbate their patients' anxieties or disclose risk information that would be likely to cause harm to their patients health.'<sup>57</sup>

Thus, the very fact that doctors themselves are confused, or even ignorant of the defence, may be having an unrecognised detrimental effect on medical practice.

Despite this it has been said that doctors, however well intentioned, are capable of

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<sup>54</sup> Skene, L. *Law and Medical Practice: Rights, Duties, Claims and Defences* (Sydney: Butterworths, 1998) at [6.97].

<sup>55</sup> Mulheron, R. "The Defence of Therapeutic Privilege in Australia" (2003) 11 JLM 201 at 202.

<sup>56</sup> Dworkin, "Autonomy and Informed Consent" in *Making Health Care Decisions*, President's Commission for the Study of Ethical Problems in Medicine [1982] vol.3 at 96.

<sup>57</sup> Mulheron, *op cit* n 55 at 211.

'disguising complex moral judgements as medical decisions.'<sup>58</sup> Thus, it is a purpose of this study to investigate medical practitioners' knowledge and awareness of the defence of therapeutic privilege. It also explores under which circumstances, if any, medical practitioners feel justified in withholding information from different patients and will address what *type* of information this may be. Finally it investigates how often, if ever, this defence is relied upon in practice.

### **3.1.9 The Spectre of Defensive Medicine and Informed Consent**

'...a doctor examining a patient, or a surgeon operating at a table, instead of getting on with his work, would be forever looking over his shoulder to see if someone was coming up with a dagger - for an action for negligence against a doctor is for him unto like a dagger.'<sup>59</sup>

Defensive medicine is often forwarded as an argument for protecting the doctor from the threat of litigation. A constant threat of legal action may impair their clinical judgment and place patients at disadvantages by doctors opting for the 'safer' techniques as opposed to more 'effective' ones. However, defensive medicine in terms of disclosure has not been given the same attention as its counterparts, diagnosis and treatment. For example, the perceived threat of litigation may lead to over cautious practices in terms of extra diagnostic testing, which of course takes time and costs money. Moreover, defensive practices in terms of treatment may hinder the development of modern medicine, as doctors are reluctant to take unnecessary risks and may prefer to opt for the most conservative option.<sup>60</sup>

On a cursory inspection one may be forgiven for assuming these factors do not carry over to disclosure issues in the same manner as it can hardly be described as defensive practice to engage the patient in a dialogue regarding the risks, benefits and

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<sup>58</sup> Buchanan, T. "Medical Paternalism" (1978) 7 *Philosophy and Public Affairs* 370 at 390.

<sup>59</sup> Per Lord Denning in *Hatcher v Black* [1954] *The Times*, 2<sup>nd</sup> July (QBD).

alternatives to proposed treatments.<sup>61</sup> With respect this may be inaccurate.<sup>62</sup> If the medical profession perceive the law as placing an obligation on them to bombard patients with risks, this can surely be described as defensive practice, particularly if the risks are slight. Demanding disclosure of these may unnecessarily deter the patient from undergoing relatively safe and necessary procedures, and perhaps more importantly, it may become clear the patient does not want to hear the risks. This being the case, if the doctor then feels compelled to inform them anyway, once again this could be classified as 'over-cautious' defensive medicine that is ultimately injurious to the patient.

However, there is much to suggest that defensive medicine is a myth, and as Kennedy notes, one person's defensive medicine could be another's good practice.<sup>63</sup> One of the aims of this work is to investigate doctors' perceptions of the law and to discover whether indeed they feel threatened by it, and if so, how they feel this affects their work. Also, patients were asked about their thoughts on the law, disclosure and whether providing them with too much information can sometimes be detrimental to good medical practice.

### **3.1.10 Patient Understanding as an Element of Consent**

Beauchamp and Childress remind us that although the term *informed consent* was born in a 'legal context, from a moral viewpoint, it has less to do with liability of professionals as agents of disclosure and more to do with the autonomous choices of

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<sup>60</sup> For discussion see Tribe, D. & Korgaonkar, G. "The Impact of Litigation on Patient Care: An Enquiry into Defensive Medical Practices" (1991) PN 2; Jones, M.A. & Morris, A.E. "Defensive Medicine: Myths and Facts" (1989) 5 *Journal of the Medical Defence Union* 40.

<sup>61</sup> Kennedy, *op cit* n 1 at 190.

<sup>62</sup> See Lamb, R.M. *et al.* "Hospital Disclosure Practices: Results of a National Survey" (2003) 22 *Health Affairs* 73 at 80.

<sup>63</sup> Kennedy, *op cit* n 1 at 190.

patients and subjects.<sup>64</sup> Thus, for any consent to be truly informed, not only must the patient be given the necessary information before they can make a decision, they must also understand that information. This is problematic when it comes to dealing with medicine, as obviously there is an imbalance in knowledge and understanding within the doctor/patient relationship. It is both impractical and unworkable to place a duty on the physician to ensure complete understanding, as short of educating the patient to their standards, this is never going to happen.

Empirical evidence has been produced which suggests patients commonly do not understand or misinterpret what they are told. Ley suggests two reasons for this. Firstly, clinicians often present information in a manner that is confusing and, secondly, patients often have their own theories about illnesses and diseases.<sup>65</sup> Here the law is faced with a dilemma. As Williams reminds us, any legal inquiry is made in functional terms i.e. what was said and done rather than focusing on the true meaning of self-determination which is the ability of the patient to make a considered choice.<sup>66</sup> Moreover, this inquiry is predominantly concerned with the disclosure of risks. Thus the significance of patient understanding is often overlooked in terms of legal analysis and has the potential to be underestimated. However, no doctor can ever ensure complete comprehension which is by its nature subjective and difficult to assess. How then does the law compensate for this and what is the standard to be expected of a doctor?

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<sup>64</sup> Beauchamp, T.L. & Childress, J.F. *Principles of Biomedical Ethics* Fifth Edition (Oxford: Oxford University Press, 2001) at 81.

<sup>65</sup> Ley, P. *Communicating With Patients: Improving Communication, Satisfaction and Compliance* (London: Chapman & Hall, 1995) at 14.

<sup>66</sup> Williams, K. "Comprehending Disclosure: Must Patient's Understand The Risks They Run?" (2000) 4 *Med Law Int* 97 at 99.

In *Smith v Tunbridge Wells Health Authority*<sup>67</sup>, Morland J framed the defendant's

duty to the patient in the following manner:

'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.<sup>68</sup> [Author's emphasis].

Whilst Grubb suggests this does not represent the law as it places too onerous a duty on the doctor and goes beyond the reasonableness standards of negligence,<sup>69</sup> it is submitted that this is the only decision from a judge at any level which seeks to address this major issue which is at the very heart of the informed consent debate.

Irrespective of this there have been encouraging signs that judges, are of late, beginning to perceive the importance of understanding in the consent process. For example in *Lybert v Warrington Health Authority*<sup>70</sup> it was held that a gynaecologist must take reasonable steps to ensure the patient has some comprehension of the information that has been imparted. In a similar case, *Smith v Salford Health Authority*<sup>71</sup>, it was held that a warning of a risk of paralysis was inadequate as it was given to a patient who was unable to take it in because she was suffering from the after-effects of a myelogram. In addition to this, and more recently, it is a pleasing facet of Lord Woolf MR's speech in *Pearce* that he pays attention to the comprehension element of informed consent.<sup>72</sup>

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<sup>67</sup> [1994] 5 Med LR 334.

<sup>68</sup> *ibid* at 339.

<sup>69</sup> See Grubb, A. "Medical Negligence: Information and Bolam" Case note *Smith v Tunbridge Wells HA*. (1995) 3 Med L Rev 198 at 201. He suggests that Morland J's dictum should be interpreted as being a requirement from a doctor to exercise *reasonable care* in making information intelligible and understandable.

<sup>70</sup> (1995) 25 BMLR 91.

<sup>71</sup> [1994] 5 Med LR 321.

<sup>72</sup> '...in determining what to tell a patient [a doctor] has to take into account all the relevant considerations, which will include the ability of the patient to comprehend what he has to say to him or

Williams suggests the only possible legal duty to place on doctors would be to take reasonable steps to enable the patient to understand.<sup>73</sup> However, what is needed is some consideration from the courts about what these reasonable steps should be. Undoubtedly, in order to develop these the courts will need guidance from the medical profession themselves as to what they consider to be reasonable steps in the circumstances. Therefore, this thesis explores the steps doctors can and do take to ensure some level of understanding and explores a number of tests for assessing levels of understanding. For example, it has been suggested that analogies<sup>74</sup> are often an effective method for conveying risks. Also, the use of written information may be advantageous for the patient coupled with dissemination of information via the electronic medium.<sup>75</sup>

### **3.1.11 Doctor/Patient Communication and Personality Factors Affecting Communication in the Consent Process**

Clearly it is impossible to train patients to fully understand medical procedures unless we put them through medical school. Of course we cannot do that and that is not the purpose of a consent process anyway. Patients can meaningfully agree to a procedure without knowing how it works. However, in order for them to do this, there needs to be effective communication on the part of both the doctor and patient, yet as much as a shared-decision making process is a desirable concept, both ethically and legally, it is fraught with difficulties. Ley asserts that the level of understanding is shrouded by lack of communication by both parties in the relationship.<sup>76</sup> For example, Korsch and Negrete found that complex medical terms such as 'labia' 'sphincter' and 'lumber

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her and the state of the patient at the particular time.' Per Lord Woolf MR in *Pearce*. *op cit* n 19 at 124.

<sup>73</sup> Williams, *op cit* n 66 at 101.

<sup>74</sup> Edwards, A. "Communicating Risks Through Analogies" (2003) 327 BMJ 749.

<sup>75</sup> Woloshin, S. "Making Sense of Risk Information on the Web" (2003) 327 BMJ 695.

<sup>76</sup> Ley, *op cit* n 65 at 23.

puncture' were being used in a paediatric unit. These terms were often misunderstood. For instance, many thought that lumbar puncture was a procedure to drain the lung.<sup>77</sup>

The particular manner in which the information is phrased may have a bearing on the outcome of any decisions. For example, in a recent article Edwards has suggested that implementing and designing patient-friendly charts and diagrams to illustrate the success rates of certain treatments is one method to encourage communication and participation on the part of the patient.<sup>78</sup> Similarly, it has been suggested elsewhere that not enough attention is paid to identifying patient objectives in the communication process. Thus, the onus should be on clinicians to explore patient's aims rather than merely discussing risks and benefits associated with procedures.<sup>79</sup> Patient's who want to share decisions often find it easier to do so if the process begins with an exploration of their objectives. In a sense, what may be needed to improve the communication and informed consent process is for medical practitioners to suspend their professional judgments and assumptions about the management of any illness, and to allow themselves to be led by what patients want. However, a knock-on effect of the above, is that in the context of risk communication, patients must also learn to deal with uncertainty. This is often difficult to accept, as they are only concerned with one identifiable outcome, that is getting better.

Accordingly, problems with communication do not lie solely with doctors. In the context of the doctor patient relationship it is often the patient who is reluctant to communicate. Firstly, many patients are reluctant to ask questions. Ley points out that this could be due to over-deferential attitudes towards doctors. Also, patients

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<sup>77</sup> Korsch, B.M. and Negrete, V. "Doctor-Patient Communication" (1972) *Scientific American* at 66-73.

<sup>78</sup> Edwards, A. "The Key to Sharing Decisions" (2003) *Doctor*, 13<sup>th</sup> November.

<sup>79</sup> Charles, C. *et al.* "What Do We Mean About Partnership in Making Decisions About Treatment?" (1999) 319 *BMJ* 766-9.

may be scared to ask about the nature of any illness for fear of bad news. This leads to an incorrect assumption on the part of the doctor that the patient does not want further information and means that patients are less informed about their condition than they would like. This problem is further compounded by the fact that patients have their own misconceptions about diseases and, in the absence of their hopes/fears being clarified, this may lead to a state of confusion.<sup>80</sup>

Ley, Skilbeck, and Tulips discovered that although 27% of patients wanted more information when they visited their doctor they never asked questions. Likewise, a number of patients interviewed after their latest consultations were asked if they had sought further information in different areas where they had wanted it. The percentage of patients that had wanted information in those areas but had not asked for it were diagnosis 42%, treatment 41% and for other advice 75%.<sup>81</sup>

This apparent reluctance to communicate could be for a number of reasons which are connected to the patient's individual personality. For example, at a very basic level, a patient may be 'grumpy' and may not want to engage in an extensive dialogue with the doctor. Similarly, they may be upset or annoyed with the doctor due to unexpected treatment results. There is evidence to suggest that some patients are more willing than others to ask questions and become involved in their treatment depending on their personality type. Rotter introduced the distinction between *internal* and *external* health locus of control with *internals* believing that events are a consequence of their own actions and *externals* believing that events are unrelated to their actions and thereby beyond their personal control.<sup>82</sup> Thus, according to the

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<sup>80</sup> Ley, *op cit* n 65 at 23.

<sup>81</sup> Ley, P. *et al.* (1975) Satisfaction, Understanding and Compliance in a General Practice Sample. Unpublished Manuscript. In Ley, *op cit* n 65.

<sup>82</sup> See for example, Hobbis, I.C.A. *et al.* "Abnormal Illness Behaviour and Locus of Control in Patients with Functional Bowel Disorders" (2003) 8 *British Journal of Health Psychology* 993-408; Gopinath,

health locus of control theory, patients with strong *internal* HLOC beliefs will be more likely to engage in health promotional behaviours such as seeking out more information from doctors, co-operating with them and seeking advice about how best to promote their health. Conversely, patients with strong *external* HLOC beliefs feel their health is beyond their control and is due to chance or fate. Hence, they will be less likely to engage with practitioners at all levels and will not want to become actively involved in their treatment or take part in health promotional activities, instead preferring to leave everything for the doctor to decide. Clearly this may have a significant effect on the consent process and the difficulties faced by medical practitioners surface in recognising which particular patient has which particular personality and identifying those which want to become involved in their treatment decisions and those which do not.

It is a purpose of this research to develop an understanding of some of the problems doctors face when communicating with patients. It attempts to discover what they find difficult in the communication process, how they try to remedy this and how they deal with patients who are reluctant to ask questions. It also asks doctors how they deal with pre-conceived ideas about illness. These issues are also addressed from the patient's point of view by interviewing them to find out why they are reluctant to communicate and what can be done to encourage communication. Moreover, the research focuses on exploring the health locus of control theory by investigating the difficulties encountered by doctors when dealing with the idiosyncrasies of individual patients with differing personality types.

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B. *et al.* "A Questionnaire Survey about Doctor-Patient Communication, Compliance and Locus of Control Among South Indian People with Epilepsy" (2000) 39 *Epilepsy Research* 73-82.

### **3.1.12 Professional Guidelines and Consent**

Professor Jones was quoted earlier in this literature review as suggesting that the legal rules governing informed consent may be an inappropriate tool to employ as a method of safeguarding patients' rights.<sup>83</sup> Mainly because the law is reactionary and only seeks to provide redress for the patient once the damage has already been done. Thus, its effectiveness as a tool for enhancing informed consent in a clinical setting is limited. This coupled with the fact that many doctors may be ignorant of the law and its requirements governing information disclosure may serve to abate any efforts to improve the consent process.<sup>84</sup> Thus, although the common law can provide some guidance to doctors, this guidance is relatively unhelpful and somewhat hazy when compared to the modern guidelines concerning the consent process as drafted by the medical profession.

The modern guidelines are clearly defined, detailed and specific. They have the potential to play a key role in elevating the patient's right to be informed as a paramount consideration in any consultation process, more so than the law itself could ever provide. This may be demonstrative of a paradigm shift within the medical profession itself where the underlying theme is that patients should be given enough information in order that they can make an informed decision about any proposed treatment.

For example in the most recent circular distributed by the Department of Health on behalf of the medical profession stresses the importance of self-determination as both a legal and ethical right.<sup>85</sup> It places emphasis on consent as a 'joint decision making process' based on the 'patient's values and preferences and the

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<sup>83</sup> See S. 2.1.12 in part one of the Literature Review of this thesis.

<sup>84</sup> Jones, *op cit* n 3 at 106.

<sup>85</sup> "Good Practice in Consent Implementation Guide: Consent to Examination or Treatment" (London: Department of Health Circular, 2001) at 9.

health professional's clinical knowledge.<sup>86</sup> When dealing with the provision of information the guidelines stipulate the 'presumption must be that the patient wishes to be well informed about the risks and benefits of operations.'<sup>87</sup> Although there will always be an element of clinical judgement involved in this, patients need to be provided with sufficient information pertaining to risks and benefits of treatments (including the risks and benefits of doing nothing).<sup>88</sup> Furthermore, when looking beyond the mere requirements of disclosure, the guidance from the profession suggests that although the role of obtaining of consent should lie with the person who is ultimately performing the procedure, consent is very much a team-based activity. Emphasis is placed on the role of specialist nurses and providing the patient with the opportunity to contact medical staff outside clinical consultations when they have had time to reflect and articulate further questions.<sup>89</sup> All in all, the needs of the patient are given central importance in the modern consent process. This is perhaps best summed up in a statement given by the GMC's recent guidelines that suggest:

'When providing information you must do your best to find out about patients' individual needs and priorities...You should not make assumptions about patients' views, but discuss the matters with them, and ask them about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.'<sup>90</sup>

As a result of this, there is evidence to suggest that many hospitals now have disclosure policies in operation<sup>91</sup> and that 'the leaders of the medical profession have begun to respond to the demands for greater openness and accountability, and are now

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<sup>86</sup> *ibid* at 10.

<sup>87</sup> *ibid* at 17.

<sup>88</sup> *ibid*.

<sup>89</sup> *ibid* at 18-20.

<sup>90</sup> "Seeking Patient's Consent: The Ethical Considerations" (London: GMC, 1998) at para 6.

<sup>91</sup> See Lamb *et al*, *op cit* n 62.

issuing much more detailed guidance to the profession about information disclosure.<sup>92</sup>

Clearly, these guidelines are advantageous to all parties. Medical practitioners now have clearer frameworks to work within when deciding what to tell the patient. Moreover the benefit for the patient is that they profit from being entitled to more information. However, the legal effect of these guidelines is also in need of explanation. As Jones has stated:

'...as professional attitudes to the question of information disclosure change (whether through gentle persuasion or the threat of litigation) patients will become 'entitled' to more information under the Bolam standard.'<sup>93</sup>

The legal significance of this statement becomes telling when considered through the prism of the professional standard of care and information disclosure. If the courts interpret these guidelines as being determinative of a responsible body of medical opinion it may prove far easier to establish a breach of duty if these guidelines are not followed. The flip side to the coin is that if followed, the guidelines may render any legal challenge a near impossibility.<sup>94</sup>

There are a number of points to consider here. Firstly, and as Maclean has pointed out, it is by no means certain the courts will insist that the guidelines dictate the legal standard as there is some disparity between the legal standard of reasonableness and the ethically commendable standards of the new guidelines.<sup>95</sup> Secondly, disclosure and consent obligations are subject to prevailing healthcare policy which will depend in part on resource implications and political objectives of the profession themselves. In short, the guidelines remain predominantly a professional issue and as Maclean has further opined 'so long as the standard remains

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<sup>92</sup> Jones, *op cit* n 3 at 130 - 131.

<sup>93</sup> *ibid* at 125.

<sup>94</sup> This of course does not alter the issue of causation which has the ability to defeat even the most stalwart of claims.

governed by professional practice, it is a castle built on shifting sands.<sup>96</sup> This indicates that the guidelines are flexible and have the capacity to develop over time to reflect developments on contemporary medical care.

Finally, and perhaps most importantly, if the guidelines are to have any substantial effect they must be followed by the profession in order to set the wheels in motion and enforce this newly commendable standard. The education of medical practitioners at all levels must encourage them to adhere to these guidelines wherever possible. However, there is little research which identifies doctors' awareness of, and indeed willingness to adopt these standards and how easy or otherwise they may be to implement in practice.

Thus, the project investigates, through various interview and observational techniques, whether in practice doctors are affected by the new guidelines. Have their disclosure practices changed due to the implementation of these protocols? Are they aware of them and how, if at all, does this effect what they say? Similarly, the project aims to discover how easy doctors feel the guidelines are to follow in the busy day-to-day activities of an NHS hospital and if they are aware of the consequences both legally and professionally if they do not adhere them.

The following chapter discusses the various methodologies employed in the empirical components of this study.

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<sup>95</sup> Maclean, *op cit* n 24 at 411.

<sup>96</sup> *ibid.*

## 4 METHODOLOGY

### 4.1 INFORMED CONSENT: A JUSTIFICATION FOR EMPIRICAL RESEARCH

The deliberation surrounding informed consent and its short-comings as a legal doctrine were elevated to the forefront of contemporary legal literature in the mid to late eighties. Academic legal scholars such as Kennedy<sup>1</sup>, Grubb<sup>2</sup>, Jones<sup>3</sup>, Brazier<sup>4</sup> and Teff<sup>5</sup> were instrumental in their critical analysis of the doctrine and the inadequacies of it as a vehicle for enhancing self-determination and patient-rights.<sup>6</sup> This culminated in the definitive thesis in this area, which was written by McLean in 1987<sup>7</sup> and subsequently published as a monograph in 1989.<sup>8</sup> This remains the authoritative doctoral thesis on informed consent, at least as far as the theoretical legal concepts and underlying themes are concerned.<sup>9</sup>

Undeniably the most common way for academic scholars to research topical legal areas is to provide a systematic analysis of the relevant case law. Cases act as primary sources which allow for a generation of critical analysis, subsequently this is supplemented by cross-referencing to secondary sources such as journal articles, textbooks, etc. Seminal cases such as *Bolam*<sup>10</sup>, *Sidaway*<sup>11</sup>, *Bolitho*<sup>12</sup>, *Blyth*<sup>13</sup>, *Rogers*<sup>14</sup>

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<sup>1</sup> Kennedy, I. "The Patient on the Clapham Omnibus" (1984) 47 MLR 454 in Kennedy, I. *Treat me Right - Essays in Medical Law and Ethics*. (Oxford: Clarendon Paperbacks, 1988) at 175.

<sup>2</sup> Kennedy, I. & Grubb, A. *Medical Law*. Third edition (London: Butterworths, 2000).

<sup>3</sup> Jones, M.A. "Informed Consent and Other Fairy Stories" (1999) 7 Med L Rev 103.

<sup>4</sup> Brazier, M. "Patient Autonomy and Consent to Treatment: The Role of the Law?" (1987) 7 LS 169.

<sup>5</sup> Teff, H. "Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance" (1985) 101 LQR 432 at 436.

<sup>6</sup> All these papers have been subject to review in the Literature Review of this thesis.

<sup>7</sup> McLean, S, A, M. "Information Disclosure, Consent to Medical Treatment and the Law" Thesis (Ph.D.) - University of Glasgow, 1987. Thesis no. 7828 available on Microfilm.

<sup>8</sup> McLean, S.A.M. *A Patient's Right to Know* (London: Dartmouth Publishing, 1989).

<sup>9</sup> Recent publications from Maclean, Dr. A.R. (lecturer in law at Glasgow University) and also the Glasgow University staff web-site suggest that his doctoral thesis concerns informed consent. However, as of yet, the author has been unable to track this document down. See Maclean, A.R. "The Doctrine of Informed Consent: Does it Exist and Has it Crossed the Atlantic" (2004) LS 386.

<sup>10</sup> *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

<sup>11</sup> *Sidaway v Board of Governors of the Bethlem Royal Hospital and others* [1985] AC 871.

<sup>12</sup> *Bolitho v City and Hackney Health Authority* [1998] AC 232.

and perhaps more recently *Pearce*<sup>15</sup> and *Chester*<sup>16</sup> have all provided the basis for excellent academic papers and have all contributed something towards the informed consent discussion.<sup>17</sup> Yet, although the assertions made by the various academic lawyers in this area are valuable in the sense that they are expressing original and insightful opinions concerning the consent process, in the absence of any empirical evidence, they remain untested hypotheses and the views are therefore mainly speculative in nature. Academic lawyers in this field have carried out Very little empirical work.<sup>18</sup>

This project arises out of a need for some in-depth qualitative data, supplemented by quantitative material, which aims to develop a clearer understanding of the dynamics of informed consent in practice to provide a basis for further critical and contextual legal analysis. The core objective of the research is to investigate the dynamics of the consent process in order to develop a clearer understanding of what happens in practice by reflecting on the views of those people who are actively involved in the process. This cannot be found by merely fuelling an already over-substantial review of the current case law. What is needed is a study of informed consent beyond the courts.<sup>19</sup> This will assist in recognising what is important to the different parties involved in the consent process. It will encompass their opinions, values and objectives in relation to the doctrine, identify the problems they are faced with in reality, which are directly linked to their experiences, and provide for an

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<sup>13</sup> *Blyth v. Bloomsbury Health Authority* [1993] 4 Med LR 151.

<sup>14</sup> *Rogers v Whitaker* (1992) 109 ALR 625.

<sup>15</sup> *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118.

<sup>16</sup> *Chester v Afshar* [2004] UKHL 41; [2005] 1 AC 134.

<sup>17</sup> All these cases have been reviewed in the Literature Review of this thesis.

<sup>18</sup> See recently Maclean, A. "Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence" (2005) 7 Med L Int 1.

<sup>19</sup> See Jones *op cit* n 3 at 123-133. There are two sections in this paper entitled 'informed consent beyond the courts' and 'the future' with connotations that suggest when dealing with informed consent it is now necessary to look at the bigger picture and go beyond the courts. It has already been ventured to

overall assessment of consent which reflects on current legal thinking. In this sense, the study will aim to develop a clearer understanding of previously unidentified issues and answer the questions which the courts have failed to address.

A mixture of both quantitative and qualitative methodologies were used to complement the critical overview of the relevant legal principles which were provided in the literature review of this thesis.<sup>20</sup>

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suggest that this paper provided the inspiration and basis for the investigation being undertaken in this project.

<sup>20</sup> A decision was made to combine quantitative and qualitative methods to enhance the validity of the research. It has been suggested that it is important not to over-emphasise the distinction between the two research methods. Bryman suggests 'the distinction between qualitative and quantitative research is a technical matter whereby the choice between them is to do with their suitability in answering particular research questions.' See Bryman, A. *Quantity and Quality in Social Research*. (London: Hyman, 1998). Indeed Henwood and Pidgeon suggest 'A more immediate concern is to avoid viewing qualitative and quantitative methods as deriving from incommensurable paradigms. In practical terms this would deny the possibility of strengthening research through the use of a principled mixture of methods.' See Henwood, K. & Pidgeon, N. "Qualitative Research and Psychological Theorising" (1992) 83 *British Journal of Health Psychology* 97 at 97-111. For further discussion see Brannen, J. *Mixing Methods: Qualitative and Quantitative Research* (Hants: Ashgate Publishing, 1992); Hammersley, M. *Social Research: Philosophy, Politics and Practice* (London: Sage, 1999) at 9-33.

## **4.2 AIMS OF THE STUDY**

1. To investigate how final year medical students are trained to deal with informed consent issues and to analyse how confident they feel in dealing with consent and how effective they feel their training has been.
2. To examine both doctors and practice nurse's perspectives on informed consent in order to generate a clearer understanding of the consent process in primary care.
3. To examine the operation of informed consent in secondary care and in clinical settings. This will be achieved by eliciting the views and opinions held by various levels of medical practitioners in secondary care, which in turn will be compared to the views held by patients. The aim of this is to negotiate a clearer understanding of what happens in practice and to identify the difficulties and concerns held by both parties. In turn this will be reflected upon and related to the law in order to identify any problematic areas that may have been overlooked.
4. To observe a number of consultations in secondary care to assess how consent is obtained in practice and to relate this to the legal requirements of consent.
5. To investigate how practising solicitors' view and deal with informed consent cases and to see if there is any difference in opinion between those that represent claimants and those who represent clients.

## **4.3 DISCUSSION OF METHODOLOGIES**

There are four component parts to this thesis. These can be broken down into:

- Assessing how medical students are educated in terms of consent.
- Studying informed consent in primary care.

- Studying informed consent in secondary care (encompassing medical practitioners' views, patients' views and observational studies).
- Investigating the views and opinions held by practising solicitors.

Accordingly, a number of appropriate methodologies were considered and the ones that were most suitable in addressing the initial aims of the study were implemented.

These will be discussed below.

## 4.4 QUESTIONNAIRES

### 4.4.1 Applicability

In relation to the component of the study dealing with medical students' perceptions of how they have been educated and how confident they feel in terms of informed consent, a questionnaire was considered as the most appropriate methodology to employ. The reasons for this are discussed in detail below.

### 4.4.2 Advantages

Questionnaires boast a number of advantages over more intricate and complex qualitative data collection techniques such as semi-structured interviews and observational techniques.

1. This aspect of the research required data to be collected from a large sample of students. The development of a questionnaire allowed this to happen in the sense that it could take a number of formats.<sup>21</sup>
2. A questionnaire is a quick, efficient and inexpensive way of gathering large amounts of data. This was essential for this component of the study.
3. Questionnaires can adopt a range of different ways to measure data. One of these ways is attitude scaling. Attitude scales are designed to 'divide people roughly into a number of broad groups with respect to a particular attitude, and to allow us to study the ways in which such an attitude relates to other issues in the survey.'<sup>22</sup>

One of the most effective ways of measuring participants attitudes is via the medium of a Likert scale.<sup>23</sup> Likert scales are advantageous in the sense that they claim enhanced reliability. One reason for this is because of the greater range of

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<sup>21</sup> For example, Black has suggested the range of questionnaire can range from employing free-response questions, checklists, or rating scales. See Black, T.R. *Doing Quantitative Research in the Social Sciences* (London: Sage, 1999) at 225.

<sup>22</sup> Oppenheim, A.N. *Questionnaire Design, Interviewing and Attitude Measurement* (London: Pinter, 1992) at 187.

answers permitted by the respondents. They tend to perform well when it comes to reliable ordering of people with regard to a particular attitude and the ease of construction lends itself towards projects of this kind. Moreover, this type of scale was thought to be appropriate when dealing with students' attitudes towards informed consent because, as Oppenheim suggests, they provide more precise information about the respondents' levels of agreement or disagreement, and participants usually prefer this to a simple agree/disagree response.<sup>24</sup> In addition, the Likert approach is flexible in the sense that the scale can be adapted to fit the particular type of research. For example it may or may not be appropriate to include a neutral point on a scale. In some situations respondents may be inclined to always chose the neutral mid-point, whilst in others it may not be unreasonable for participants to have a neutral view on some components of the construct.<sup>25</sup>

#### **4.4.3 Combining Quantitative and Qualitative**

1. Whilst the majority of questionnaires work from the quantitative philosophy, there remains scope for combining the use of predominantly quantitative data with some qualitative material.
2. It was thought that a questionnaire was particularly useful for this element of the project because of the wide range of issues that could be addressed in a concise and easily decipherable manner. For example, it was considered that it was appropriate to include some open-ended questions that permitted the respondents to elaborate on the issue in hand, and which would allow them to generate a wider range of response by not restricting their answers to a pre-defined set of responses. The implementation of a questionnaire facilitated this effectively.

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<sup>23</sup> Oppenheim, *op cit* n 22 at 195.

<sup>24</sup> *ibid.*

<sup>25</sup> Black, *op cit* n 21 at 229.

#### **4.4.4 Planning and Origins of Questions**

The design of attitude surveys is not a trivial task and entire books have been written on this topic.<sup>26</sup> It has already been identified that the format of questionnaires can vary widely and the design of the written instruments in this study required extensive planning.

The first task was to establish exactly what the questionnaire wanted to discover. Clearly there were some attitudes that would be potentially difficult to measure. This issue was compounded by the fact that any questionnaire needs to ensure that the actual questions asked are understood by the participants.<sup>27</sup> Difficulties were encountered as originally it was envisaged the survey would investigate students' knowledge of the law concerning informed consent. However, this overlooked the fact that understandably the students would have a very limited knowledge of the law. Thus, it was decided the questionnaire would be designed to approach the issue from a slightly different perspective.

This was concluded after a number of meetings with The Director of Teaching at the Medical School. He suggested the line of inquiry should focus more on how effective students' education has been in terms of informed consent and how much confidence they feel they had gained and whether (if at all) this will carry over into practice. Accordingly the origins of the questions were shaped and guided by the Director of Teaching and this was supplemented by focus groups with the researcher and the supervisory team. The initial topics and themes were agreed at this point. These encompassed questions suggested by the Director of Teaching, ideas by the researcher and supervisors, and questions which were devised as a result of

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<sup>26</sup> Black, *op cit* n 21 at 225.

<sup>27</sup> *ibid* at 226.

researching the literature on this topic.<sup>28</sup> These initial topics and themes were then developed into specific questions. The majority of these were more elaborate than mere binary questions and required more than just a 'yes' or 'no' answer. Indeed additional information was sought by asking the participants to rate the level of importance they attached to certain statements in the form of a Likert scale, the advantages of which are discussed in the section above.

The study also incorporated a qualitative element that took the form of an open response question. This asked the students to give their definition of informed consent and served as an evaluation of perceived knowledge measure against a 'gold-standard' definition of informed consent.

#### **4.4.5 Disadvantages**

1. The disadvantages of adopting questionnaires are that the type of data generated is limited in the sense that, whilst it may be the most appropriate for this section of the study, the philosophy underpinning questionnaires is still very much grounded in the positivist paradigm. Questionnaires often follow the experimental quantitative methods of the natural sciences. Within this model a great deal of emphasis is placed on characteristics such as identifying an 'objective truth', logic and validity. In essence questionnaires look to explain things objectively and quantifiably, but do no more than that.
2. Also attitude scales of this type are still somewhat limited. Oppenheim has suggested: 'Attitude scales are relatively overt measuring instruments designed to be used in surveys, and we must not expect too much of them. They are not designed to yield subtle insights in individual cases.'<sup>29</sup>

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<sup>28</sup> See section in Literature Review for discussion.

<sup>29</sup> Oppenheim, *op cit* n 22 at 187.

However, the aim of this component of the study was purely to assess students' knowledge of informed consent and to collect this data from a relatively large group; as such a questionnaire was ideal.

## 4.5 DISCUSSION AND APPLICABILITY OF QUALITATIVE METHODOLOGIES

### 4.5.1 *Applicability: The Main Methodology in the Study*

The qualitative work in this study represents the main methodology. It was felt that a more in-depth exploration of informed consent was appropriate when working with participants who had direct experience of dealing with consent issues in practice. Thus, a number of qualitative methodologies were considered for the various components of the study which dealt with informed consent issues in primary care, informed consent issues in secondary care and informed consent issues in legal practice. These methodologies are considered below.

### 4.5.2 *A Qualitative Approach: Understanding Informed Consent from the Different Parties and the Researcher's Perspectives*

'Qualitative research takes an interpretive, naturalistic approach to its subject matter; qualitative researchers study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings that people bring to them.'<sup>30</sup>

Although strictly speaking qualitative methodologies are not directly connected with the law or indeed legal research, Lord Denning neatly demonstrates how many of the key characteristics of the law run parallel to the qualitative philosophy. He stated:

'Words are the lawyer's tools of trade...The reason why words are so important is because words are the vehicle of thought. When you are working out a problem on your own - at your desk or walking home - you think in words, not in symbols or numbers. When you are advising...in writing or by word of mouth - you must use words. There is no other means available.'<sup>31</sup>

Denzin and Lincoln suggest qualitative inquiry 'is a situated activity that locates the observer in the world. It consists of a set of interpretive, material practices that make the world visible. These [turn the world] into a series of representations, including

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<sup>30</sup> Denzin, N.K. & Lincoln, Y.S. "Introduction: The Discipline and Practice of Qualitative Research" in Denzin, N.K. & Lincoln, Y.S. eds. *The Landscape of Qualitative Research: Theories and Issues*. Second Edition. (London: Sage, 2003) at 5.

<sup>31</sup> Denning, A.T. *Lord Denning: The Discipline of Law* (London: Butterworths, 1979) at 5.

field notes and conversations.<sup>32</sup> The golden thread from which all of this becomes possible is via the medium of words. Qualitative research concerns words and the context in which people use them. It is about accepting the notion that there is no one definite and set way of doing things, it is simply about justifying the approach you have taken using the appropriate arguments.<sup>33</sup>

The primary aim of an interpretive methodology is one of *understanding*, that is a break away from the natural science approach, which is one of *explanations* of social, behavioural or physical phenomena.

Of course justifying one's own position does not necessarily mean pointing to weaknesses in others. Defending a position as a researcher often boils down to individual preferences in adopting what is deemed to be the most 'appropriate' methodological stance for the topic under investigation. Whilst principles of subject/object dichotomy, neutrality and impartiality are suitable in many natural and human science research, in a project of this kind they miss the complexity of the dynamics of consent in the real world. This being the case, an interpretive and naturalistic approach was adopted, with an emphasis on understanding.

Indeed, Pope and Mays suggest qualitative methods are particularly useful in terms of health research because:

'...qualitative work can reach aspects of complex behaviours, attitudes, and interactions which quantitative methods cannot. As a result it has been extremely useful for examining clinical decision making by probing and exploring both the declared and the implicit or tacit routines and rules which doctors use.'<sup>34</sup>

Thus, these particular methods are best suited to the current research question as the aim is to develop a deeper understanding of informed consent by discussing what is

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<sup>32</sup> Denzin & Lincoln, *op cit* n 30 at 4.

<sup>33</sup> Somekh, B & Lewin, C. *Research Methods in the Social Sciences* (London: Sage, 2005) at 128.

important and meaningful to the parties actively involved in the process. This enables a deeper investigation into values, opinions and objectives that the differing parties attach to the concept of informed consent and to examine why they feel, and why they act as they do.

Likewise, when talking about improving consent systems arguably there can never be one identifiable solution to a problem that hinges on the balancing of competing professional interests against human rights. Thus, a more appropriate way of looking at things may be to suggest ways of creating a more effective consent system, one which takes into account the interests of all parties involved. In order that things can be improved and if solutions are ever to be reached, there needs to be a higher level of understanding developed about what happens in practice and the problems that the different parties are faced with. This research attempts, via the medium of semi-structured interviews and observations, to proffer a more complete understanding of consent issues by looking at how active participants behave and what they actually mean when they describe their experiences, attitudes, and behaviours.<sup>35</sup>

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<sup>34</sup> Pope, C. & Mays, N. "Qualitative Research: Reaching Parts other Methods Cannot Reach" (1995) 311 *BMJ* at 42-45; See also, Silverman, D. *Communication and Medical Practice*. (London: Sage, 1987); Strong, P. *The Ceremonial Order of the Clinic*. (London: Routledge, 1979).

<sup>35</sup> Pope & Mays, *ibid* at 44.

#### 4.5.3 Phenomenology: Clarifying the 'Lived-World' and the Experiences of Those Who Live It

Phenomenology is the study of phenomena, of things or events, in the everyday world. Phenomenologists study situations in the everyday world from the viewpoint of the experiencing person. This experiential view helps phenomenologists understand people and human life so that they can work effectively with them.<sup>36</sup>

The term phenomenology derived from the early German philosophy Edmund Husserl (1859-1938). His fundamental concern was an epistemological one, that is to provide a foundation for knowledge.<sup>37</sup> Husserl believed that experience of life events in the everyday world, with theoretical understandings suspended, was an invaluable source of knowledge.<sup>38</sup> Thus, the life-world, which is neither originally 'mental' nor 'physical', refers to experiential 'happenings' or 'occurrences' that we live before we know. Such happenings cannot merely be described behaviourally from an external perspective as they irreducibly include understandings, feelings and relationships.<sup>39</sup> It follows that the life-world is always more complex than anything we can say about it: the lived is greater than the known.

Phenomenology attempts to describe experience, without any considerations about the origin or cause of experience.<sup>40</sup> In other words, it is possible to understand the subjective meaning of action (grasping the actor's beliefs, desires and so on) yet do so in an objective manner. This methodology requires researchers to step outside their historical frame of reference<sup>41</sup> and, as Schutz<sup>42</sup> suggests, take on the role of the disinterested observer. The concept of taking a step back safeguards against mis-

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<sup>36</sup> Becker, C.S. *Living and Relating: An Introduction to Phenomenology* (London: Sage Publications, 1992) at 7.

<sup>37</sup> Todres, L. and Wheeler, S. "The Complementarity of Phenomenology, Hermeneutics and Existentialism as a Philosophical Perspective for Nursing Research" (2001) 38 *International Journal of Nursing Studies* 1 at 3.

<sup>38</sup> Becker, *op cit* n 43 at 10.

<sup>39</sup> Todres and Wheeler, *op cit* n 44.

<sup>40</sup> Kvale, S. *Interviews: An Introduction to Qualitative Research Interviewing* (London: Sage Publications, 1996) at 53.

<sup>41</sup> Schwandt, T.A. "Three Epistemological Stances for Qualitative Inquiry" in Denzin & Lincoln, *op cit* n 30 at 298.

interpretation. Consequently, the meaning the researcher reconstructs is considered the original meaning of the action.<sup>43</sup> A further key element to the phenomenological methodology is that the researcher suspends any pre-conceptions or judgments about the topic under investigation. This is known as phenomenological reduction and can be pictured as the bracketing of the researcher's own backgrounds and opinions in order to arrive at an unprejudiced description.<sup>44</sup> In this sense, phenomenological reduction does not involve the absolute absence of presuppositions, but rather a critical analysis of the researcher's own pre-understandings.<sup>45</sup>

It seeks to elicit rich and thick descriptions about everyday meanings and events, and aims to identify and understand what is important to the subjects living the events by bringing to the forefront some linguistic meaning to these lived complexities. The philosophical underpinnings of phenomenology are relevant in relation to certain elements of this study and in particular are of importance in describing the consent process in practice, and in identifying what is important to the parties actively involved in the process. This is because, as Kvale suggests, '[Phenomenology is]...understanding social phenomena from the actors' own perspectives, describing the world as experienced by the subjects, and with the crucial assumption that the important reality is what people perceive it to be.'<sup>46</sup>

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<sup>42</sup> Schutz, A. *Collected Papers* Vol. 1; M. Natanson. ed. (The Hague: Martinus Nijhoff, 1962).

<sup>43</sup> Schwandt, *op cit* n 41 at 298.

<sup>44</sup> Kvale, *op cit* n 40 at 54.

<sup>45</sup> *ibid.*

<sup>46</sup> Kvale, *op cit* n 40 at 52.

#### **4.5.4 The Phenomenology of Medical Practice in Respect of Consent**

'Phenomenologists investigate people's experiences of life events and the meanings these events have to them.'<sup>47</sup>

The phenomenological position is linked to the development of some areas of this project. One component of the study investigates the different parties experiences of the consent process. This will assist in developing a clearer description of informed consent in practice by eliciting what is meaningful to all the parties involved in the process, whether it be medical practitioners, patients, students or practising solicitors.

In employing qualitative interviews, the project seeks privileged access to the basic experiences of the lived world<sup>48</sup> of medical practitioners, patients and solicitors. Thus, it is expected that participants will, to a certain extent, rely on their own personal experiences. If this happens these examples clearly need to be interpreted in accordance with the respondents' perspective. This calls for a bracketing of any pre-conceptions with a view to analysing just the basic face-value description of events in respect of consent by the interviewee.

#### **4.5.5 Hermeneutical Considerations**

'While Phenomenology focuses on describing the human experiences of 'what' and "how", hermeneutics focuses on interpreting "why".'<sup>49</sup>

Hermeneutics is defined as the art and science of understanding and interpretation.<sup>50</sup>

It seeks to address the most important, and often the most unanswerable of all questions in any discipline. *Why* has this happened? Leonard suggests that: 'Interpretive inquiry never seeks to simply describe a phenomenon but is always

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<sup>47</sup> Becker, *op cit* n 36 at 8.

<sup>48</sup> Kvale, *op cit* n 40 at 54.

<sup>49</sup> Mak, Y. & Elwyn, G. "Use of Hermeneutic Research in Understanding the Meaning of Desire for Euthanasia" (2003) 17 *Palliative Medicine* 395 at 396.

<sup>50</sup> Broin, V. *The Act of Understanding and the Possibility of a Critical Hermeneutics* (Department of Philosophy: University of Colorado, 1998) at 267.

concerned with some breakdown of human affairs.<sup>51</sup> Therefore, it is pertinent to healthcare research as it seeks to understand *why* subjects act as they do. Leonard has opined: 'The goal of a hermeneutic, or interpretive, account is to understand everyday skills, practices, and experiences; to find commonalities in meanings, skills, practices, and embodied experiences.' Benner further elaborates on this by suggesting the researcher looks 'to find paradigm cases that embody the meanings of everyday practices...in such a way that they are not destroyed, distorted, decontextualized, trivialized, or sentimentalized.'<sup>52</sup> Accordingly, hermeneutics offers healthcare researchers the opportunity to understand the meaningfully rich and complex lived world of those human beings they are both researching and caring for. Similarly, it provides a theoretical basis for conducting research projects that does not reduce issues of human beings' concerns to mere characteristics, absolute properties or brute data.<sup>53</sup>

In addition to the previously discussed phenomenological approach, certain characteristics of the hermeneutic philosophy are incorporated into the qualitative studies. Firstly, hermeneutics allows for an exploration *why* doctors act in the way they do as opposed to exploring merely *what* happens on the wards and *how* this comes about in practice. For example, it explores *why* doctors withhold information under certain circumstances. Secondly, it delves into issues such as *why* patients do not ask questions, *why* are they reluctant to communicate and *why* certain issues are of greater importance to some parties and not to others. In adopting certain traits of the hermeneutical methodology and asking the '*why*' questions of consent instead of just

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<sup>51</sup> Leonard, V. W. "The Heideggerian Phenomenological Perspective of the Concept of Person" in Benner, P. *Interpretive Phenomenology: Embodiment, Caring, and Ethics in Health and Illness* (London: Sage Publications, 1994) at 56.

<sup>52</sup> Benner, P. "Quality of life: A Phenomenological Perspective on Explanation, Prediction and Understanding in Nursing Science" (1985) 8 *Advances in Nursing Science* 1 at 1-14.

the 'what' and 'how', the project provides a critical, contextual and legal analysis of the wider issues in the terms of consent. As Plager suggests, it will serve to: '...fill in the gaps in understanding that are often left by empirical science research approaches.'<sup>54</sup>

Indeed, Todres and Wheeler suggest that both phenomenology and hermeneutics can complement each other as a philosophical perspective for healthcare research by adopting certain characteristics from the two.<sup>55</sup> They suggest, 'hermeneutics without phenomenology can become excessively relativistic. Phenomenology without hermeneutics can become shallow.'<sup>56</sup>

It is now appropriate to advance the concept of classical phenomenology beyond its conventional format to consider the philosophical underpinnings of both interpretive phenomenology and philosophical hermeneutics in an attempt to justify the researcher's position.

#### **4.5.6 Interpretive Phenomenology / Philosophical Hermeneutics**

##### 4.5.6.1 The Philosophy of Heidegger

As a result of the various criticisms of pure objective phenomenology, Heidegger sought to develop his own version of an interpretive or hermeneutical phenomenology which rejected this subject / object dichotomy. Heidegger, in his work entitled '*Being and Time*' (originally published in 1927), shifted from an epistemological to an ontological project.<sup>57</sup> As Mak and Elwyn suggest, he rejects the notion of subject/object duality, and believes the person exists as 'being in the world', whereby

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<sup>53</sup> Taylor, C. "Interpretation and the Sciences of Man" in Rainbow, P. & Sullivan, W.M. eds. *Interpretive Social Sciences: A Second Look* (Berkeley: University of California Press, 1987) at 33-81.

<sup>54</sup> Plager, K. A. "Hermeneutic Phenomenology: A Methodology for Family Health and Health Promotion Study in Nursing" in Benner, P. *Interpretive Phenomenology: Embodiment, Caring, and Ethics in Health and Illness* (London: Sage Publications, 1994) at 66.

<sup>55</sup> Todres & Wheeler, *op cit* n 37.

<sup>56</sup> *ibid* at 6.

the persons' historical and traditional contexts are already integrated into their experience and become part of their existence, without separation of subject-object.<sup>58</sup> The key thing to remember here is that Heidegger rejects the notion that pre-conceptions can be bracketed. Fleming, Gaidys and Robb intimate that he was interested in the possibilities of being, in which existence knows itself only in relation with others and other objects.<sup>59</sup> In an attempt to raise 'understanding' to a fundamental category of existence,<sup>60</sup> Heidegger suggested that interpretation and understanding is not something that a human being has, but what she/he is.<sup>61</sup> Hence, we are always in a position of understanding and interpreting as a result of our everyday life experiences. We always *take* something *as* something because we have a background of shared human experiences.<sup>62</sup>

#### 4.5.6.2 Heidegger's Critique of 'Pure' Phenomenology

According to Heidegger (1889-1976) the routes of classical phenomenology, that is taking descriptions at face value, are burdened with the categories of natural science in seeking certainty and absolute clarity. In this sense he believed that the subjective pre-understandings can be of some value in the understanding and interpretation process and are useful attributes that should be used to guide and shape research. For this reason Mak and Elwyn suggest: 'Heideggerian phenomenology is hermeneutic and focuses on how to use this preconception to interpret meaning of a phenomena.'<sup>63</sup>

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<sup>57</sup> Heidegger, M. *Being and Time*. J. Macquarrie & E. Robinson. trans. (New York: Harper & Row, 1962).

<sup>58</sup> Mak and Elwyn, *op cit* n 49 at 396.

<sup>59</sup> Fleming, V., Gaidys, U. & Robb, Y. "Hermeneutic Research in Nursing: Developing a Gadamerian-Based Research Method" (2003) 10 *Nursing Inquiry* at 114.

<sup>60</sup> Prasad, A "The Contest Over Meaning: Hermeneutics as an Interpretive Methodology for Understanding Texts" (2002) 5 *Organisational Research Methods* at 16.

<sup>61</sup> Todres and Wheeler, *op cit* n 37 at 2.

<sup>62</sup> Plager, *op cit* n 54 at 72; Schwandt, T.A. *op cit* n 41 at 301.

<sup>63</sup> Mak and Elwyn, *op cit* n 49 at 396.

#### 4.5.6.3 A Critique of 'Pure' Phenomenology in Relation to the Present Study: Paving the way for Gadamer.

Lord Denning sets the scene in highlighting the potential problems in taking things at face value, and thus provides the justification for the interpretive/hermeneutical position as a natural concomitant to the law, accounting for its esoteric nature. Denning suggested 'obscurity in thought inexorably leads to obscurity in language.'<sup>64</sup> Words may mean one thing in one context and another thing in another context, or something in one situation and something else in another. 'Difference is not settled by authority, but by individual choice. Constantly you will find ordinary people giving different meanings to the same word.'<sup>65</sup> To expect clarity in the current research, which deals with complex competing issues of moral values and human rights, would be foolish. To take everything at face value in this project would be naïve in what it pre-supposes. Values and issues often depend on the meaning the researcher gives to them. Accordingly, within any research project the subjective views of the researcher must be accounted for. Indeed, as Maggs-Rapport identifies, the inherent difference between interpretive (hermeneutical) and descriptive phenomenology is that in the latter, the interpreter is justified in going beyond the immediate and offers an interpretation of the data to attempt to make sense of disparate or ambiguous meanings. This requires a departure from the maxim 'let the data speak for itself', and is in contrast to the pure phenomenological position. In this sense the research does not try to reduce the data, but to describe the meanings in their ambiguous, complex and multiple forms.<sup>66</sup>

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<sup>64</sup> Denning, *op cit* n 31 at 5.

<sup>65</sup> *ibid* at 6.

<sup>66</sup> Maggs-Rapport, F. "Best Research Practice: In Pursuit of Methodological Rigour" (2001) 35 *Journal of Advanced Nursing* 373 at 380.

#### 4.5.6.4 The Philosophy of Gadamer: Subjectivity in Qualitative Research, Reflections and The Fusion of Horizons

As a student of Heidegger, Gadamer expanded on his philosophy by asking the question: How is understanding possible?<sup>67</sup> In his seminal work entitled *Truth and Method*<sup>68</sup> he used this question to develop philosophical hermeneutics, which rejected the possibility of interpretation needing an awareness of rules, and emphasised the need to identify one's pre-conceptions before any understanding or research can begin. This is in contrast to earlier classic hermeneutical insights as forwarded by Dilthey (1833-1911), who sought to develop a system of rules to guide the correct practice of interpretation and understanding. As Fleming *et al* imply, for Gadamer, and indeed Heidegger, this was cumbersome in the sense that it had the same limitations of validity and truth as contained in the Cartesian paradigm.<sup>69</sup>

Gadamer uses Heidegger's re-conceptualisation of understanding to develop a systematic philosophy of hermeneutics which, as Plager suggests, works from the following assumptions.<sup>70</sup> Firstly, that human beings are social and dialogical beings. Secondly, that understanding is always before us in the shared background practices, it is in the human community of societies and cultures, in the language, in our skills and activities, and in our intersubjective and common meanings. Thirdly, we are always in a hermeneutical circle of understanding. Fourthly, interpretation presupposes a shared understanding and, finally, understanding involves the interpreter and the interpreted in a dialogical relationship. Evidently the key themes here, as Prasad suggests, are the rejection of the subject/object division and the

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<sup>67</sup> It should be noted here that earlier versions of hermeneutics and indeed phenomenology made a distinction between interpretation and understanding. As a result of Gadamer's development of philosophical hermeneutics, the boundaries are refined. In view of this, in the following sections the terms may be used interchangeably.

<sup>68</sup> Gadamer, H. G. *Truth and Method*. Barden, G. & Cumming, J. trans. (New York: Seabury, 1975).

<sup>69</sup> Fleming, Gaidys & Robb, *op cit* n 59 at 115.

<sup>70</sup> Plager, *op cit* n 54 at 71.

abandonment of the idea that understanding is concerned with grasping the authors intended meaning. Instead emphasis is placed on the productive role of tradition and prejudice in the act of understanding, the nature of understanding between the text and the interpreter, and understanding as non-author intentional.<sup>71</sup>

#### 4.5.6.5 Application to Present Study: Using Preconceptions

It has been suggested previously that the phenomenological observer and the linguistic analyst claim the role of the uninvolved observer, which calls for a bracketing of pre-understandings. The philosophy of Heidegger and Gadamer rejects this notion. They suggest that everyone comes to a research project with some level of understanding. These pre-conceptions are not something we should strive to get rid of, rather they should be used in order to shape, refine and negotiate understandings of the topic under investigation. Thus, although it is the key aim of many objectivist researchers is to remove prejudices, as Fleming *et al* suggest, Gadamer claims it is impossible to do so because of the researchers own historical, cultural and professional awareness.<sup>72</sup> He argues we are all part of history and it is not possible to step outside of history to look at the past objectively. Accordingly, the conscious act of understanding is never independent of the researchers own background and awareness and is therefore subject to certain prejudices that cannot be removed. Any attempt to remove these serve as a negative effect on research.

It is worthy of note that the notion of prejudice should not hold the negative connotations that are often associated with it. As Mak and Elywyn suggest 'rather than considering pre-understandings as potential bias, it is a pre-condition to the truth.'<sup>73</sup> Gadamer advances this by stating it is our prejudices that signal participation

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<sup>71</sup> Prasad, *op cit* n 60 at 16.

<sup>72</sup> Fleming, Giadys, & Robb, *op cit* n 59 at 115.

<sup>73</sup> Mak & Elwyn, *op cit* n 49 at 396.

in our own historico-cultural tradition, and that defines the limits and potentialities of our horizon of understandings.<sup>74</sup> Instead of being viewed as obstacles to understanding, prejudices are a necessary pre-requisite to understanding; they serve as an initial horizon of comprehension. Bringing the pre-understandings to the forefront of any research essentially serves two purposes. It identifies legitimate and productive prejudices that make understanding possible, and then filters out the unproductive prejudices that may hinder the research. These pre-understandings are always in operation behind researchers' backs and will often go undetected in their sub-conscious thinking, therefore the only way to combat them is to bring them into the research. Thus, the researcher becomes aware of his or her prejudices when they encounter something which challenges the truth of their ideas. As Gadamer states:

'It is impossible to make ourselves aware of...[one of our prejudices] while it is constantly operating unnoticed, but only when it is, so to speak, stimulated. The encounter with an [interview] text can provide this stimulus.'<sup>75</sup> Researchers need to be aware of their prejudices.<sup>76</sup> Awareness takes place when the meaning of an interview text challenges the researchers own pre-understandings; the researcher can then use this to filter out the prejudices that may assist in understanding, from those that may hinder the work. Thus, in the qualitative studies, the researcher's own academic values serve as an 'initial' horizon of understanding that can be reflected upon and refined when the views of the various parties are collated.

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<sup>74</sup> Gadamer, *op cit* n 68 at 269; Gadamer, H.G. *Truth and Method*. Second Revised Edition. (J. Weinsheimer & D.G. Marshall, trans.) (New York: Continuum, 1989) at 302.

<sup>75</sup> Gadamer, *op cit* n 74 at 266.

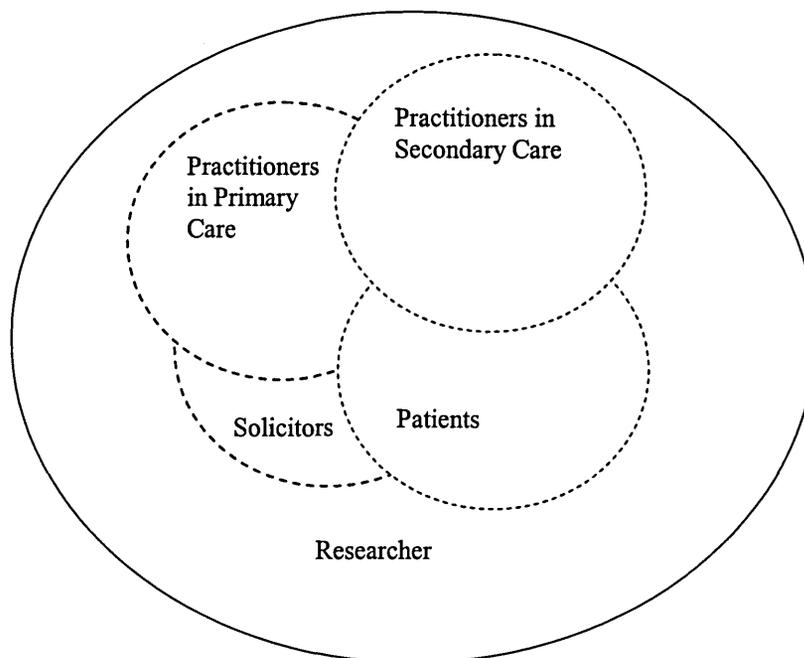
<sup>76</sup> Prasad, *op cit* n 60 at 19.

#### 4.5.6.6 Application to Present Study: The Circle of Understanding & the 'Fusion of Horizons'

There is a wealth of different values in existence in the real world about what is important in respect of informed consent and about what *does* and what *should* happen in practice. All these views are of equal importance and have, over time, been brought to the forefront of medico-legal literature. Yet no attempt has ever been made to explore these views in detail by synthesising and correlating them into a definitive research project. Understandably these views may conflict with each other, and in particular with that of the researcher himself. However, to try and remove the academic legal values and opinions from the study in an attempt to achieve objectivity would serve as more of a hindrance than an advantage. This is because when discussing the various issues with the different parties, legal values will undoubtedly be in operation subconsciously and may have an adverse effect on the research. Here issues may be dismissed inadvertently if they do not correlate with the researcher's legal opinions. Instead of merely dismissing these as being legally incorrect, the researcher reflects on these findings. Accordingly, whilst an initial suggestion may be made that something is not strictly correct as per the legal understanding; there is scope to look beyond that preliminary assessment. This allows for an exploration of perhaps why this is happening or why that particular party holds that view which is in conflict with the law. This will assist in answering the question, is the law correct in its attitude towards consent, and if not why not?

Mak and Elwyn demonstrate how the researchers pre-understandings which are made up of past experiences, perspective and anticipation, serve as an initial horizon of understanding.<sup>77</sup> During the data analysis, the researchers own perspective intersects with that of the participants transcribed interview and a renewed

understanding emerges from an blending of these two horizons. Gadamer describes this as the 'fusion of horizons'.<sup>78</sup> This involves continuing questioning, reflection and validation within the dialogue between the researcher and the text, endorsing the hermeneutic circle of understanding. As such, Leonard suggests the understanding process is necessarily circular moving back and forth between the parts and the whole and between the initial horizon of understanding and what is being revealed in the data of the inquiry.<sup>79</sup> Through systematic analysis of the whole, a new perspective of depth and understanding is gained. This is used to examine the parts of the whole, and then to re-examine the whole again in light of what has been discovered from the parts. We use this understanding to examine the parts of the whole, and then re-examine the whole in light of what we have gained from the parts. This process continues until the researcher is satisfied with the depth of the understanding. In this manner understanding is 'negotiated' between the researcher and participant as opposed to 'created.' The diagram below illustrates how the fusion of horizons and circle of understanding operates in respect of the qualitative studies.



<sup>77</sup> Mak and Elwyn, *op cit* n 49 at 396.

<sup>78</sup> Gadamer, *op cit* n 74.

<sup>79</sup> Leonard, *op cit* n 51 at 57.

#### 4.5.6.7 Dispelling the Criticism of Gadamer

Gadamer's philosophy has been criticised by some as being too subjectivist and relativistic.<sup>80</sup> Yet, subjectivity forms the basis of the majority of qualitative methodologies. Gadamer's defence of his philosophy against objectivist criticisms stems from his rejection of the subject-object dichotomy. He argues that failure to recognise personal biases can lead to misinterpretation and obscurity in understanding. This is a valid claim. Fleming *et al* explain: 'Gadamer's explanation of pre-understanding is directed against Husserl's opinion of reduction and is one of the main differences between philosophical hermeneutic and Husserl's phenomenology.'<sup>81</sup>

#### 4.5.6.8 Combining Methodologies

The project adopts a methodology drawing on 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.<sup>82</sup> In pointing to the life-world, phenomenology grounds our research inquires, turning us to concrete happenings of living situations, and the *what* of our reflections. For example, complex medico-legal research of this kind is best defined by reference to concrete experience which gives it substance. Without this, 'over-generality and theoretical abstraction' may compromise any exploration of informed consent.<sup>83</sup> Similarly, in acknowledging the positionality of knowledge, hermeneutics adds reflexivity to the research turning to the meaningful questions and

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<sup>80</sup> For example Prasad, *op cit* n 60 cites Betti, E. "Hermeneutics as the General Methodology of the *Geisteswissenschaften*" in Ormiston, G. & Schrift, A. eds. *The Hermeneutic Tradition* (New York, Suny Press, 1990) at 159-197. Betti Upholds the notion that the text must be regarded as an autonomous object independent of the subjectivity of the interpreter, and maintains the aim of interpretation must be to uncover the original intention of the texts author.

<sup>81</sup> Fleming, Gaidys, & Robb, *op cit* n 59 at 115.

<sup>82</sup> Todres and Wheeler, *op cit* n 37 at 6.

<sup>83</sup> Todres & Wheeler, *ibid*.

concerns that are relevant. The nature of this research draws on the academic background of the researcher. This may unconsciously colour interpretations relating to consent and therefore demands a reflection of the researcher's own personal, cultural and professional background, which in turn sensitise any issues that may have been neglected.

## 4.6 FROM METHODOLOGY TO METHODS

### 4.7 DATA COLLECTION

Atkinson suggests that 'in itself [phenomenology] does not constitute a method of data collection and analysis; it does not uniquely specify particular research techniques.'<sup>84</sup> However, there is something that both theories seem to agree on, all understanding takes place through the medium of language. This is particularly important to Gadamer,<sup>85</sup> who suggested that the lived world 'gets constituted in and through our language.'<sup>86</sup> Hermeneutical phenomenology methods of data collection can be multi-dimensional spanning across a range of techniques. Understanding is viewed as participative, conversational, and dialogical. The epistemological basis for this study is transactional and dialogical and supports Bernstein, Grondin and Taylor's view that understanding is always bound up in language and is achieved only through the logic of question and answer.<sup>87</sup> As a result, it was decided that the most effective way to generate appropriate data was to adopt semi-structured interview techniques, to be supplemented with an observational component which focuses on doctor/patient consultations.

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<sup>84</sup> Atkinson, P. "Some Perils of Paradigms"(1995) 5 *Qualitative Health Research* 117.

<sup>85</sup> Gadamer, H.G. *Philosophical Hermeneutics*. Linge, D.E. ed./trans. (Berkeley: University of California Press, 1976) at 62.

<sup>86</sup> Prasad, *op cit* n 60 at 20.

<sup>87</sup> Bernstein, R.J. *Beyond Objectivism and Relativism: Science, Hermeneutics, and Praxis* (Philadelphia: University of Pennsylvania Press, 1983); Grondin, J. *Introduction to Philosophical Hermeneutics*. Weinsheimer, J. trans. (New Haven: Yale University Press, 1994); Taylor, C. "The Dialogical Self" in Hiley, D.R., Boham, J.F. & Shusterman, R. eds. *The Interpretive Turn* (Ithaca: Cornell University Press, 1991) at 304-314.

## 4.8 SEMI-STRUCTURED INTERVIEWS

### 4.8.1 Advantages

'If you want to know how people understand their world and their life, why not talk with them? In an interview conversation, the researcher listens to what people themselves tell about their lived world, hears them express their views and opinions in their own word and learns about their views on their work situation.'<sup>88</sup>

The qualitative research interview attempts to understand the world from the subjects' point of view, to unfold the meaning of peoples' experiences and to uncover qualitative descriptions of their lived world with respect to interpretation of their meaning.<sup>89</sup> The research interview is a conversation about the human life world. Therefore hermeneutics is pertinent to interview research because, as Kvale suggests, it initiates the dialogue producing interview texts to be interpreted, and subsequently clarifies the process of interpretation of the interview texts, which may be conceived as a dialogue or conversation with the text.<sup>90</sup>

The advantages of employing interview methods are mainly directed at engaging in a dialogue and guided conversation with all the parties that are actively involved in the consent process.

The most appropriate way of doing this is to adopt a semi-structured paradigm. In this approach the interviews have a number of themes to be covered as well as suggested questions. The themes and topics are introduced allowing the respondent to elaborate further on any major issues. Specific questions only act as a guide that can be prompted from if the interview dries up. The advantage of this model of interview is that it is flexible. There is openness to changes in sequence and the forms of questions in order to follow up the answers given and the stories told.

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<sup>88</sup> Kvale, *op cit* n 40 at 1.

<sup>89</sup> Kvale, *op cit* n 40 at 124.

<sup>90</sup> Kvale, *op cit* n 40 at 47.

Kvale suggests: 'The research interview is an interpersonal situation, a conversation between two partners about a theme of mutual interest. It is a specific form of human interaction in which knowledge evolves through a dialogue.'<sup>91</sup> The interviewer has immediate access to the world and experiences of the participant. Meanings may be articulated by voice, expressions, gestures that arise out of natural conversations and, in a sense, the interviewer may also be used as a research instrument.<sup>92</sup> Another significant advantage of the semi-structured model is the way in which emphasis between description and interpretation is easily interchangeable. For example, in some situations the interviewer may only seek descriptions of a phenomenological nature. However, it is with relative ease that the focus can switch to clarifying and interpreting what the subject means by working together with them.<sup>93</sup>

#### **4.8.2 Origin and Planning of Questions**

A number of interview schedules were devised with very broad interview themes; certain key words were also used to 'jog' the researcher's memory.

The content of the schedules derived mainly from the problematic legal areas as identified and discussed in the literature review. However, other issues were brought in to compensate for an examination of issues beyond the mere legal context. These particular themes were often revised as the study progressed.

The themes and topics were also discussed in focus groups with the researcher and the supervisory team. It was decided the questions should address what happens in practice, what are the views and opinions of the various parties, what they perceived as being important in consent, and what are the difficulties inherent in the process that are in need of improvement. It was also suggested that the questions be

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<sup>91</sup> Kvale, *op cit* n 40 at 125.

<sup>92</sup> *ibid.*

<sup>93</sup> Kvale, *op cit* n 40 at 127.

sufficiently related to the ones asked in the questionnaire so the project developed from the 'base' upwards. Thus, the qualitative studies are a continuation of what the medical students perceived would happen upon entering practice, to what practitioners actually experience and what their views were after being actively involved in the consent process.<sup>94</sup>

### **4.8.3 Disadvantages**

#### **4.8.3.1 Problems with subjectivity**

One of the criticisms of interview research is that it is inherently subjective in nature and thus raises questions of validity and trustworthiness. Kvale has suggested that in any interview situation the interviewer and the interpreter will unavoidably co-determine the results.<sup>95</sup>

Thus, whilst most of the criticism levelled at interviews concerns the lack of objectivity as a result of human interaction, it is an accurate portrayal by Kvale that interview methods are neither objective nor subjective. Language, the medium through which knowledge is generated in an interview situation, is neither objective or universal, nor subjective or individual. Interviews are thus intersubjective.<sup>96</sup> He states:

'The interviewee's statements are not collected - they are co-authored by the interviewer...[The researcher's] questions lead up to what aspects of a topic the subject will address, and the interviewer's active listening and following up on the answers co-determines the course of the conversation.'<sup>97</sup>

To give an illustration of this in practice, the questions asked in interview settings are nearly always constructed in and around the pre-existing knowledge of the researcher; likewise how the data is interpreted and portrayed will be effected by

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<sup>94</sup> See *op cit* n 20 for discussion.

<sup>95</sup> Kvale, *op cit* n 40 at 49.

<sup>96</sup> *ibid* at 67.

<sup>97</sup> *ibid* at 183.

these subjective views. Moreover, the personal views of the participants shape the understanding of the researcher as the dialogue progresses and thus may alter or add to the initial interview themes.

This is the benefit of adopting a hermeneutic philosophy as the researcher attempts to make these presuppositions explicit. As Kvale suggests: 'What matters here is being as aware as possible about one's own presuppositions and modes of influence and to attempt to take them into account.'<sup>98</sup>

#### 4.8.3.2 Problems with leading questions

The use of leading questions is clearly a concern for many sceptics of interview research. Clearly the wording of a question may inadvertently shape the content of the answer. If leading questions are posed to vulnerable groups such as patients this may effect the validity of the research. This was accounted for when interviewing patients and, to some extent, medical practitioners. However, it was expected that these groups will not be so easily led due to the novice/expert power relationship in the interview setting. The upshot is, of course, they could lead the researcher in the opposite manner which will be the subject of discussion below.

Often the benefit of leading questions may become lost in an assessment of the objectivity inherent in the research. However, in interview work which is underpinned by interpretive philosophical tenants, the issue is not whether to lead or not to lead, but where the topics should lead, and whether they will lead in important directions, producing new and interesting knowledge.<sup>99</sup>

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<sup>98</sup> *ibid.*

<sup>99</sup> *ibid* at 159.

#### 4.8.3.3 Power Relationships within Interview Settings

The hermeneutic philosophy and the post-modernist position both agree on the importance that is attached to language, albeit in different modes of significance. Gadamer perceived language has having an ontological importance in that the world is constituted in and around language.<sup>100</sup> In contrast, post-modernist view language as transparent and as a grid through which all knowledge is constructed.<sup>101</sup> For post-modernists language constitutes reality and constructs this reality in its own way.

However, despite these differences both positions acknowledge the effectiveness of language as a medium for generating perceived 'knowledge' and 'understanding.' The interview transaction is necessarily bound up in language and as a result provides an ideal forum for developing this understanding based on a conversation between two parties.

However, drawing on the work of Habermas, there is the distinct possibility that language can be used to manipulate, dominate and ultimately mislead.<sup>102</sup> Habermas, whilst accepting the importance of language and understanding, rejects Gadamer's view of language as having an ontological significance in determining how the word is understood. Habermas suggested as a result of conditions of social labour and domination, linguistic structures becomes altered. The result of this is that language can be used not only to understand traditions, but also as a medium for domination, manipulation and for social power.<sup>103</sup> In other words language and

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<sup>100</sup> Gadamer, *op cit* n 85 at 62.

<sup>101</sup> See Brown, T. "From Hermeneutics to Poststructuralism to Psychoanalysis" in Somekh, B. & Lewin, C. *Research Methods in the Social Sciences* (London: Sage, 2005) at 294.

<sup>102</sup> Habermas, J. "A Review of Gadamer's *Truth and Method*" (F.R. Dallamayr & T. McCarthy, trans.) in Ormiston, G.L. & Schrifft, A.D. (eds.) *The Hermeneutic Tradition* (New York: Suny Press, 1990) at 213-244.

<sup>103</sup> *ibid* at 239.

tradition, in the way Gadamer perceives it, are ideals which can become 'systematically' distorted.<sup>104</sup>

The dynamics of this study involve a number of interviews that are carried out in the face of fluctuating power relationships. These include a number of bilateral power relationships. The most prominent being the role of the socially dominant medical practitioner pitted against the novice researcher. Here clinicians could potentially use language to distort the research and influence the researcher both in terms of their views on the subject, and the subsequent refinement of the researcher's opinions. There is also the possibility of using language to mislead by saying what they think the researcher wants to hear.

The bilateral aspect of the power relationships in the research also calls for an appreciation that the researcher, when dealing with a vulnerable group of participants, could also subconsciously use language to mislead and unduly influence the study due to the role reversal of the power relationship.

Thus, within the interviews themselves it was necessary to account for this. Firstly, a rapport was established to minimise the effect of the power relationship. This was the case regardless of which group to whom they belonged; 'powerful' or 'vulnerable.' This put both parties at ease prior to the commencement of the recorded interview session. Secondly, contradictions were identified within the interviews. An attempt was made to elaborate and 'sift' out these contradictions by asking further questions; this was accounted for during the analytical stages.

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<sup>104</sup> Prasad, *op cit* n 60 at 22.

## 4.9 OBSERVATIONAL STUDIES

### 4.9.1 Use and Applicability

In adopting a qualitative methodology, the research sought to embrace characteristics such as depth, complexity and roundness in data.<sup>105</sup> In projects of this kind it is not uncommon for researchers to conduct interviews with participants and then to supplement these with observations.<sup>106</sup> In this sense the study is triangulated.<sup>107</sup> It was considered an ideal opportunity to develop the section of the study which dealt with informed consent in secondary care, by adding to the interviews with observations of what happens in practice. This provides a direct insight into the dynamics of the consent process in practice. It also allows for a comparison of data between the observations and interviews to check for consistency and reliability. In addition, as noted above, this component of the study allows for a point of triangulation in the data. It is a theory into practice issue allowing the researcher to check if what clinicians actually do is an accurate reflection of what they say they do.

### 4.9.2 Advantages

Somekh has suggested: 'Observation is one of the most important methods of data collection. It entails being present in a situation and making a record of one's impressions of what takes place.'<sup>108</sup> Thus, through the habit of observation, researchers becomes sensitised to the fascinations of going about their daily lives.<sup>109</sup>

The epistemological position in terms of observational studies suggests that knowledge can be generated by observing or experiencing natural or real life settings.

Mason suggests that: 'Such a position is based on the premise that these kinds of

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<sup>105</sup> Mason, J. *Qualitative Researching* (London: Sage, 1996) at 62.

<sup>106</sup> *ibid* at 63.

<sup>107</sup> See n 20 for discussion. Triangulation means employing multiple methods to investigate the same research question.

<sup>108</sup> Somekh, B. "Key Concepts in Observation" in Somekh, *op cit* n 101 at 138.

settings, situations and interactions "reveal data", and also that it is possible for a researcher to be an interpreter or "knower" of such data as well as an experiencer or observer.<sup>110</sup> This method of data collection was introduced to reveal what happens in the consent process and to generate knowledge about the realities and difficulties faced by both parties in clinical settings.

Observational techniques are flexible and can take a number of formats such as structured observations, unstructured observations and shadow studies. As Somekh suggests, the choice depends on how the researcher conceptualises himself or herself in the world and his or her place within the research.<sup>111</sup> The ontological position of this study conceptualises the researcher as active and reflexive in the study. As a result, an unstructured format was adopted which was supplemented with a number of shadow studies. In this approach the researcher is 'guided by prior knowledge and experience and "sees" through the unique lens of his or her values'.<sup>112</sup>

In addition, a number of consultants were shadowed. This was done with a view to sharing their direct experiences of obtaining consent and dealing with patients.

### **4.9.3 Disadvantages**

#### **4.9.3.1 The 'Hawthorne Effect'**

One of the main criticisms levied at observational studies concerns the potential impact the researcher may have on the participants in the study. In a series of experiments conducted between 1927 and 1932, it was established that individual behaviour may be altered because participants know they are being studied. This has become known as the 'Hawthorne Effect' and is closely aligned to the problems

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<sup>109</sup> *ibid.*

<sup>110</sup> Mason, *op cit* n 105 at 61.

<sup>111</sup> Somekh, *op cit* n 101 at 138.

inherent in observational studies.<sup>113</sup> It has the effect of improving production, regardless of the experimental manipulation employed. In these various studies the participants altered their behaviour as a result of feeling closely attended to and the fact that they were pleased to receive attention from the researchers who expressed an interest in them.<sup>114</sup>

This may adversely effect the research findings in respect of observing doctor/patient consultations and the obtaining of consent in practice. The most common occurrence of this may involve consultants 'tailoring' their consent process in the knowledge that they are being observed by lawyers. Conversely, patients may be aware of the researcher and thus strive to become more involved in the consent dialogue. This may not truly reflect the realities of the consent transaction and provide a distorted view. Despite this, the theory can actually be turned on its head to produce the exact opposite effect. It is not beyond the realms of possibility that highly experienced consultants may be reluctant to alter their lifetime practices as a result of outside observation. Indeed, some may view the presence of researchers as a 'direct challenge' to authority and thus may be adamant not to change their practice in anyway as a result of the perceived intrusion.

The Hawthorne Effect does little more than define a common sense problem with all overt research studies, and for this reason much criticism has been levelled at not only the concept, but also the validity of the research itself.<sup>115</sup> For example one

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<sup>112</sup> *ibid.*

<sup>113</sup> Note that "Hawthorne" is not the name of the researcher, but of the factory where the effect was first described. The Hawthorne works of the Western Electric Company in Chicago. For discussion of the various experiments see Roethlisberger, F.J. & Dickson, W.J. *Management and the Worker* (Cambridge: Harvard University Press, 1939) cited by Draper, S.W. "The Hawthorne effect and other expectancy effects" at <http://www.psy.gla.ac.uk/~steve/hawth.html>.

<sup>114</sup> Mayo, E. *The Human Problems of an Industrial Civilisation* (New York: MacMillan, 1933) at ch.3.

<sup>115</sup> For example one eminent industrial psychologist, H. McIlvaine Parsons, sought to investigate the validity of the research into The Hawthorne Effect. He found that, amongst other things, there were a number of 'confounding variables' that previous researchers had ignored. These included such things as better working conditions for the participants under observation, the replacement of two out of five

may be justified in arguing that the Hawthorne effect, in some way shape or form, is applicable to all research where the participants are aware they are being studied. This will clearly represent the majority of research projects nowadays as a result of ethical considerations towards volunteers. It could be used as a mechanism for anyone who wants to question the validity of research in ignorance of the true significance of any results. In stretching the concept to its limits it could be relied upon to suggest that no research should ever be carried out as the results will always be untrustworthy. The following steps were taken to minimise the Hawthorne Effect:

1. The participants were spoken to about the nature of the research before any of the observations took place. It was explained that the role of the researcher was one of a disinterested observer and the aim of the study was not to assess personal performances of clinicians or patients.
2. Participants were informed that the nature of the research was to investigate consent in everyday settings and clinical environments. Thus, it was essential that participants acted as normal and, in the circumstances, did not feel the need to alter their approach to consent in anyway.
3. Rapport was built with both medical staff and patients, and in the course of informal conversations the researcher explored whether or not what was being observed represented a true reflection of clinical practice. Notes from these informal conversations were recorded in the research journal.
4. The findings from the interview studies were compared to the field notes from the observations during the analytical stages. This acts as a point of comparison and allows the researcher to assess and check if what medical practitioners said

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participants mid-experiment for actually being too slow, the knowledge that individual performance would have a much greater significance on the impact of weekly pay, and the availability of 'performance feedback' which was denied in the case of non-participant workers. For discussion see

married up to what they were actually doing. Any discrepancies were identified and accounted for in the analysis and write-up of the various studies.

#### 4.9.3.2 Subjectivity

In observational studies the primary research instrument is the self, consciously gathering sensory data through sight, hearing, taste, smell and touch. By various means of record-keeping, traces of those impressions are stored for careful scrutiny and analysis after the event.<sup>116</sup> The disadvantage to this is, of course, the findings are closely linked to the subjective position of the researcher. Clearly the researcher is the person charged with making sense of impressions and interpreting the meanings of observed behaviour and events. As Somekh has suggested:

'The record of the observations becomes, necessarily, a product of choices about what to observe and what to record, made either at the time of the observation in response to an impression or in advance of the observation in an attempt prospectively to impose some clarity on the data.'<sup>117</sup>

Thus, it is important to account for the researcher's own role in the analysis of the work.<sup>118</sup> In this sense, and in keeping with the general reflective and subjective nature of the hermeneutic philosophy underpinning the qualitative work in this study, subjectivity is transformed from a disadvantage to an advantage.

#### 4.9.3.3 Data Management and Handling

Somekh has suggested an obvious problem with observational studies is the enormous complexity of human behaviour and the fact that it is a near impossibility to make a complete record of all the researcher's impressions.<sup>119</sup> This is an accurate assertion. It was accounted for by keeping organised and structured field-notes and logging down

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Rice, B. "The Hawthorne defect: Persistence of a flawed theory" at <http://www.cs.unc.edu/~stotts/204/nohawth.html>.

<sup>116</sup> Somekh, *op cit* n 101 at 138.

<sup>117</sup> *ibid.*

<sup>118</sup> Mason, *op cit* n 105 at 62.

any significant issues within a research journal. In keeping the field notes accurately up to date, the analysis process is much easier and allows large amounts of data to be dealt with more effectively.

#### 4.10 REFLEXIVE RESEARCH JOURNAL

Fontana and Frey have suggested that many studies using unstructured interviews are not reflexive enough about the interpreting and understanding process.<sup>120</sup> Thus, in order to facilitate the reflective and interpretive process, in accordance with other interpretive researchers, a research journal was kept from the outset of the study.<sup>121</sup> This began by laying out the researcher's preliminary thoughts. These served as an initial horizon of understanding. For example, Turner stated 'prior to meeting any participants...[she] wrote a journal of her own ideas on the subject under investigation.'<sup>122</sup> She suggested this enabled her to develop a clear yet evolving understanding of the topic at that particular time that would enabled her to move towards a closer understanding of participants points of view in light of her own prejudices. Thus, before the empirical component of the study began, and before the interview schedules were devised, a research journal was created and the understandings of the researcher (from a purely legal academic background) were identified. Entries were made into the research journal after each interview and observational situation; these continued throughout the study when the researcher thought it necessary to reflect on certain issues. This was maintained until the completion of the project allowing the researcher to utilise and correlate the changing

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<sup>119</sup> *ibid.*

<sup>120</sup> Fontana, A. & Frey, J.H. "Interviewing: The Art of Science" in Denzin, N.K. & Lincoln, Y.S. *Collecting and Interpreting Qualitative Materials* (London: Sage, 1998) at 69.

<sup>121</sup> Lavery, S.M. "Hermeneutic Phenomenology and Phenomenology: A Comparison of Historical and Methodological Considerations" (2003) *International Journal of Qualitative Methods*, 2 (3). Article 3. Retrieved 25/8/2004 from [http://www.ualberta.ca/~iiqm/backissues/2\\_3final/pdf/lavery.pdf](http://www.ualberta.ca/~iiqm/backissues/2_3final/pdf/lavery.pdf).

views and interpretations of the different participants, whilst at the same time keeping track of any changes in the researcher's own thought patterns. The field notes from the research journal were used to supplement the computer assisted-analysis.<sup>123</sup>

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<sup>122</sup> de Sales Turner, R.N. "Horizons Revealed: From Methodology to Method" (2003) *International Journal of Qualitative Methods*, 2 (1). Article 1. Retrieved 25/8/2004 from [http://www.ualberta.ca/~iiqm/backissues/2\\_1final/pdf/turner.pdf](http://www.ualberta.ca/~iiqm/backissues/2_1final/pdf/turner.pdf).

<sup>123</sup> For examples of extracts from the reflective research diary, which include the initial thoughts of the researcher, please see appendix [4].

## **5 ETHICAL CONSIDERATIONS**

Before a project of this scale could be undertaken there were a number of ethical considerations to be examined. This chapter discusses those considerations, processes and mechanisms that were implemented to ensure that the project withstood ethical scrutiny.

### **5.1 Obtaining Ethical Approval from the Relevant Committees**

The NHS Research Governance Legislative stipulate that before any research can be undertaken, and before any participants can be approached, all studies must pass the scrutiny of the relevant NHS ethics committee and receive approval. Also the study had to be granted NHS research governance.

There was awareness from the outset that there were likely to be ethical issues within a study of this nature; utilising qualitative methods of data collection in what could be sensitive settings with vulnerable people. Consequently at each stage of planning the ethical implications were considered, issues were identified and solutions were sought.

The following issues were identified:

1. Informing participants.
2. Recruiting participants and avoiding coercion.
3. Ensuring informed consent.
4. Data collection issues such as maintaining the confidentiality and anonymity of participants, the right to withdraw, the storage of data and the transcribing of interview tapes.
5. Dealing with participant distress.

## **5.2 Informing Participants**

It was essential that all the volunteers were adequately informed about the nature and purpose of the research, and that they had the right not only to refuse to take part in the study, but also to withdraw at any point. Thus, a number of participant information sheets were devised. These were tailored to meet the needs of the different categories of individuals who were to be involved in the study.<sup>1</sup> The information sheets were submitted to the ethics committee for scrutiny before they were distributed to the participants.

## **5.3 Recruiting Participants & Avoiding Coercion**

Due to the wide ranging number of participants there were a variety of different methods of recruitment.

Firstly, in relation to the medical students' questionnaire an initial meeting was arranged with The Director of Teaching. Here the construction of the questionnaire was discussed and the protocol of the study was assessed and greeted with enthusiasm by The Director of Teaching. A number of participant information sheets were taken and these were discussed in lectures with the students, where they were asked if they would be willing to take part. They were informed that this was purely voluntary and they were free to refuse. All the students agreed to fill out a questionnaire.

Secondly, in terms of the component of the study that dealt with informed consent in primary care, an initial letter was sent to the manager of a local practice inviting them to take part in the research. A meeting was subsequently arranged to discuss the research protocol. Here the participant information sheets were given to the manager. The practice manager kindly circulated the information sheets and agreed to raise the

research at the next practice meeting. It was then left to any interested parties to contact the researcher. Four practitioners (kindly) did so.

In relation to the medical practitioners in secondary care, an initial letter was forwarded to all members of the hospital by the senior consultant in charge of the department where the research was to be based. The researcher was then invited to attend the weekly multi-disciplinary team meetings (MDT meetings) in order to recruit participants. This avoided coercion from the senior consultant. The participant information sheets were circulated and there was discussion with the clinicians. It was made clear to them that their co-operation was on a voluntary basis. However, generally the responses were excellent from the medical practitioners. They took a participant information sheet and were then invited to contact the researcher at their convenience. Thankfully, a great many of them did, so much so that by the end of the project there were so many volunteers that some had to be turned away for fear of expanding the project beyond its intended remit.

Finally, in respect of recruiting patients for the interviews, a number were written to by the hospital to invite them to take part. A sample responded accordingly. Also, the researcher attended patient support groups to discuss the research with patients beforehand and to leave participant information sheets with them. A number of the patients expressed interest and sought to contact the researcher on their own accord to arrange convenient times for interviews. In terms of the patient observations, the researcher shadowed a number of consultants on a daily basis over a period of four months. The scope of the study was explained to them by the consultant in charge, time was taken for them to read the participant information sheet, and they were then

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<sup>1</sup> See appendix [1] for an example of the participant information sheet.

told they were under no obligation to take part and could withdraw at any time. All but one of the patients agreed to allow the researcher to observe the consultations.

## **5.4 Ensuring Informed Consent**

Clearly there were a number of issues pertaining to how best to secure fully informed consent. The key element was to avoid coercion. This was particularly an issue in terms of patients, and especially in relation to the medical practitioners based within the surgical unit at the hospital. There was potential for them to feel pressured and unduly influenced to take part in the study at the demand of the senior consultant. A number of methods were employed to avoid this. All the participants were given an information sheet which was issued before the commencement of any interviews. At this point it was always stressed their participation was on a purely voluntary basis. The participants were then asked to contact the researcher if they wished to take part as opposed to the other way round. Prior to any interview the participants were asked to sign a consent form which asked them to confirm they had read the information sheet. At this point they were given the opportunity to ask further questions and it was re-iterated that their participation was on a voluntary basis and they were free to withdraw at any time. In turn the researcher signed the consent form and these were filed away in a secure place. The patient was also given a copy.

## **5.5 Confidentiality & Data Protection**

In order for the project to obtain ethical approval the researcher had to ensure there were some mechanisms in place to protect confidentiality and to abide by the requirements of the Data Protection Act.

In relation to the medical students' questionnaire, all the data was anonymous and the questionnaires were stored in a secure filing cabinet.

In relation to the qualitative data, all the interviews and observational notes, with the participants consent, were recorded and subsequently transcribed using computer-assisted software. During the transcription the identity of the interviewees remained completely anonymous and illnesses were only discussed in very general terms. The transcripts and tapes were locked away in a secure filing cabinet and access was restricted to the researcher alone. A computer-assisted software package was used to analyse the data. This enables the identity of participants to remain unknown. Access to this program was restricted by use of a password, which only the researcher held.

In accordance with The Data Protection Act 1998, the information was made available to the participants upon request.<sup>2</sup> However, no participants sought to enforce this right.

## **5.6 Dealing with Participant Distress**

As this project was investigating some potentially sensitive issues and dealing with vulnerable participants, it was necessary to ensure there were some mechanisms in place for dealing with distressed individuals. In both the participant information sheets and the consent forms it was stressed that the volunteers had the right to withdraw at any time if they became distressed. There was also further information provided about where they could seek additional help and advice from should they feel the need to do so. This included material about counselling and also where free legal advice could be sought. The researcher was careful not to advise either way on issues of liability.

## **5.7 Submission of 'Full Protocol' to NHS Ethics Committee and NHS Research Governance**

In order to obtain full ethical approval the official ethical application form was filled out electronically. In addition, a full protocol was devised and the participant information sheets and consent forms were collated. This documentation was sent off to both the ethics committee and research governance in order to gain approval for the commencement of the study.

## **5.8 Independent Scientific Review**

Once the study gained ethical approval, and in order for it to proceed, it was first necessary to obtain research governance. This is granted after all the relevant documentation has been passed by ethics and once the project has been subject to the scrutiny of independent scientific review. The research protocol was distributed to a number of anonymous and independent assessors in order to check for scientific validity.

## **5.9 Receiving Approval**

After taking the time to consider all the qualitative components of the research, the study was granted full approval to proceed from both the ethics committee and research governance. This was subject to only a few minor amendments that were dealt with accordingly.<sup>3</sup>

At first instance there was a slight problem with the medical students' questionnaire. The committee attempted to veto this. However, as all the necessary ethical requirements had been met, this component of the study was in effect an agreement

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<sup>2</sup> Incidentally, none of the participants sought to invoke this right.

<sup>3</sup> Please refer to appendix [1] for a copy of the full letter of approval.

between two universities. Subsequently, the manager of COREC overruled the decision of the committee as being ultra-vires. The study proceeded with the agreement of The Director of Teaching.<sup>4</sup>

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<sup>4</sup> Please refer to appendix [1] for a copy of the letter, which overruled the initial decision of the ethics committee.

## **PART I**

# **THE QUANTITATIVE STUDY**

## **6 STUDY 1 - MEDICAL STUDENTS' QUESTIONNAIRE**

### **6.1 INTRODUCTION**

This component of the study seeks to explore the concept of informed consent beyond the mere legal context. It does so by providing empirical evidence relating to how medical students perceive informed consent. Furthermore, it provides some information about how students are trained and educated in consent and the difficulties they feel they may encounter upon entering practice. To ascertain this, a questionnaire was circulated to all final year medical students based within one medical school in the UK.

### **6.2 JUSTIFICATION**

It is the purpose of this component of the study to look beyond the legal doctrine of informed consent. It provides empirical data relating to how medical students perceive the doctrine of informed consent. The value of this approach has previously been overlooked. Firstly, medical students, as individuals entering the profession, are people who have the ability to improve things in practice. Secondly, in exploring how they are educated in consent, some knowledge may be generated to explain why medical practitioners perceive consent in the way they do, which of course may provide a valuable point for comparison in terms of legal developments in the future.

## 6.3 THE RESEARCH QUESTION

There are two components to this part of the study. A quantitative and a qualitative element.

The quantitative element can be broken down into a number of research questions:

1. What do medical students perceive to be the function of the doctrine of informed consent?
2. What level of importance do they attach to the doctrine?
3. How effectively do they feel they have been prepared to deal with informed consent in practice?
4. How difficult do they feel it will be able to obtain informed consent in practice?

The qualitative component of the research evaluates how medical students define informed consent. This will be measured against a 'gold standard' definition of informed consent contained in the most recent guidelines circulated by the Department of Health.<sup>1</sup>

## 6.4 METHODS

### 6.4.1 *Background and Preparation*

In order to construct an effective questionnaire it was recognised at an early stage that a preliminary meeting would be required with a member of the academic teaching staff from the medical school where the survey was to take place. The Director of Teaching suggested that medical students would have little knowledge of consent issues in practice. Thus, it was decided to focus the questionnaire on how students have been educated in informed consent and how effective they feel their education has been. It also explored how confident they felt about putting their acquired

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<sup>1</sup> Department of Health Circular. *Good practice in consent implementation guide: consent to examination or treatment* (London: Department of Health Circular, 2001) at para. 9 & 28.

knowledge into practice and asked them to identify what problems they felt they may encounter upon entering practice. The survey was limited to those questions that would generate the appropriate data as the questionnaire needed to be concise and easily administered.

## **6.4.2 Development of Questionnaire<sup>2</sup>**

### **6.4.2.1 Quantitative Questions**

The origins of the quantitative questions employed in this part of the research are discussed in detail in the methodology chapter of this thesis.<sup>3</sup> Drawing on the direct input, experience and knowledge of the Director of Teaching<sup>4</sup>, the final questionnaire covered 12 issues, as follows:

1. What the students perceived as being the most important basis for the doctrine of informed consent. They were asked to choose from one of three options ethical obligation, legal obligation or professional obligation.
2. The level of importance the students attach to each basis of the doctrine of informed consent. They were then given three options ethical, legal and professional and then asked to rate the level of importance they would attach to each of them. They were permitted to give a series of answers ranging from very important, important, unimportant and very unimportant.
3. How important the students thought informed consent is to medical treatment. They were given a range of permitted answers from very important, important, unimportant and very unimportant.

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<sup>2</sup> See appendix [2] for a copy of the medical students' questionnaire.

<sup>3</sup> See Methodology chapter 'Planning and Origin of Questions.'

4. Which area of medical treatment they felt informed consent was most important in. The options to chose from were surgery, non-surgical intervention and drug therapies.
5. The level of importance the students attach to informed consent in the different treatment areas. The students were given the three treatment options as in question four and asked to indicate the level of importance they would attach to each area ranging from very important, important, unimportant and very unimportant.
6. How effectively they felt they had been prepared to deal with informed consent. They were given a range of permitted response including very effectively, effectively, ineffectively and very ineffectively.
7. How important they thought it was to be trained effectively in each of the different treatment areas as listed in question 4.
8. How confident they felt in dealing with informed consent in practice. They were given a choice of four options ranging from very confident, confident, unconfident and very unconfident.
9. How important they felt it was to be confident in informed consent in the three different treatment areas as listed in question 4.
10. How difficult they thought it would be to obtain informed consent in practice. The permitted responses were very easy, easy, difficult and very difficult.

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<sup>4</sup> The Director of Teaching kindly agreed to assess and comment on the suitability of the questionnaire before it was distributed to the medical students. Based on his recommendations, certain questions were altered.

11. How difficult they thought it would be to obtain informed consent in the three different treatment areas as listed in question 4.
12. To rate the difficulty they would associate with a number of complicating factors which may affect the obtaining of informed consent in practice. Here the item pool consisted of a number of issues such as patient understanding, patients' lack of communication, patients' misconceptions about illness, patients' unwillingness to ask questions, identifying patients' objectives and their ability to explain treatment in an appropriate manner. The item pool was constructed with input from both the supervisory team and the Director of Teaching. The students were then asked to rate the difficulty they would associate with each of these factors. They scale they were allowed to work within ranged from very easy, easy, difficult and very difficult.

#### 6.4.2.2 Quantitative Scale

The survey employed a variation of the Likert scale.<sup>5</sup> This works from the premise that a number of item pools are constructed, then subjects have to place themselves on an attitude continuum for each statement within that pool.<sup>6</sup> The Likert scale usually incorporates a scale of 1-5 ranging from very important to not important at all. Accordingly, there is usually a neutral option that the participants can choose from, for example 'unsure'. However, it was decided, after careful consideration and consultation with various parties, that this neutral option should not be included in the current questionnaire.<sup>7</sup> Because everything the students were being asked constituted

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<sup>5</sup> This is the standard scale used to measure attitudes by presenting the participant with a list of declarative statements and asking them to rate these in terms of importance or unimportance. See Black, T.R. *Doing Quantitative Research* (London: Sage, 1999) at 227; Oppenheim, A. *Questionnaire Design, Interviewing and Attitude Measurement* (London: Pinter, 1992) at 195. Discussed in Methodology chapter 'Advantages'.

<sup>6</sup> Oppenheim, *ibid* at 195.

<sup>7</sup> For discussion see Black, *op cit* n 5 at 228.

important questions on which they could be expected to have an opinion in one way or another at this stage in their medical careers, to include a neutral option may have served as a 'get out' clause by allowing them to select the easy option and this may have adversely affected the data set. Thus, in the current survey an adapted variant of the Likert scale was implemented where the attitude continuums ranged from very important, important, unimportant and not important at all.<sup>8</sup>

#### 6.4.2.3 Qualitative Component

The justification for including a qualitative component is discussed in greater detail in the methodology chapter of this study.<sup>9</sup> The final question in the survey offered the medical students an opportunity to give their personal definitions of informed consent. The philosophical aim underpinning this qualitative element approaches issues from a slightly different perspective than the main body of qualitative work in the remainder of this thesis, both in terms of the type of data the research is trying to generate and the methods of analysis. This study allowed the students to demonstrate what they have been taught and retained about consent. It acts as an evaluation of perceived knowledge, which is achieved by comparing their definitions of informed consent to a 'gold-standard provided by the Department of Health.'<sup>10</sup>

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<sup>8</sup> In some questions the wordings of the options changed yet the scale remained the same. For example, when dealing with difficulties the students perceive they will face in practice the choices ranged from very easy, easy, difficult and very difficult.

<sup>9</sup> See Methodology chapter. 'Advantages.'

<sup>10</sup> *op cit* n 1.

## **6.5 PILOT STUDY**

The questionnaire was devised in various focus groups with both supervisors and the Director of Teaching from the Medical School. Due to tight time constraints and ethical considerations, the questionnaire was not piloted amongst medical students before it was distributed. The time-scales of the undergraduate medical syllabus and the current project clashed. The students were to receive the survey in their final lecture before departing to become House Officers. Thus, to attempt to run a pilot study would have been unrealistic and would have had to be done at a far earlier stage in the project which, at that point, would not have been sanctioned by the ethics committee.

However, prior to the questionnaire being distributed, it was circulated amongst a sample of the post-graduate researchers at Sheffield Hallam University (N=12). They were non-lawyers and were asked to complete the questionnaire with a view to assessing the ease with which the questions could be understood and answered, and the appropriateness of the language used in the study for non-experts in the field. The feedback was mainly positive. There were no alterations made to the substantive questions or style and layout of the survey. However, some terms were suggested as being ambiguous and were replaced accordingly.

## **6.6 ETHICAL CONSIDERATIONS**

This component of the study was subject to the scrutiny of the Sheffield Hallam University School of Social Science and Law Research Ethics Committee. The study was granted approval with the agreement of both parties to the research.

## **6.7 PARTICIPANTS**

The questionnaire was distributed to all final year medical students. (N=162).

## **6.8 PROCEDURE**

The questionnaire was distributed to all final year medical students in their last lecture before they departed to become House Officers. This was particularly useful as it was a time and a place when all the students were together thus ensuring a 100% response rate. Sufficient time for the completion of the questionnaire was allowed in the lecture.

## **6.9 DATA ANALYSIS**

### ***6.9.1 Quantitative Analysis***

The data generated from the quantitative part in this study was inputted into SPSS software package. The data was subsequently analysed using this program to generate basic percentage frequencies for each question.

### ***6.9.2 Qualitative Analysis***

The final question within the survey allowed the students to give their definitions of informed consent. These statements were collected and compared to the standard definition given by the Department of Health in their most recent guidelines on obtaining consent. This definition was preferred to the guidance issued by the GMC. This was due to the fact that whilst the General Medical Council's guidelines potentially have greater impact on doctors insofar as the GMC has disciplinary powers, it was decided, for the purposes of this research question, that the Department of Health guidelines provide a more comprehensive definition which was easier to break down into a number of individual components.

The working definition is set out below:

'Consent is a patient's agreement for a health professional to provide care. For consent to be valid, the patient must be competent to take that particular decision, have received sufficient information, and must not be acting under duress. Sufficient information should include information about the risks and benefits of the proposed treatment, and information about alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.'<sup>11</sup>

The above statement was broken down into eight constituents which can be listed as follows:

1. Patient's agreement
2. Competence to make a particular decision
3. Received sufficient information
4. Must not be acting under duress
5. Information about risks
6. Information about benefits
7. Information about alternatives
8. Information in a form they can understand

All of the students' definitions were read through in their entirety and the scores were recorded based on how many of the above components each of the students' definitions mentioned. Also, the number of occasions each particular constituent was mentioned was collected.

## **6.10 STUDY LIMITATIONS**

This study was based in only one medical school within the UK. Thus it is impossible to generalise in relation to the findings. The study itself was extremely concentrated in the sense that it targeted one group of students at a particular point in their medical careers. Despite this, the research was conducted at what is generally recognised to

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<sup>11</sup> *op cit* n 1.

be a leading medical school in the country, whose undergraduate curriculum undoubtedly accords with national standards. Thus, it can be said to be a fair reflection of what takes place across the country in respect of undergraduate teaching and consent. Teaching methods may vary, but the substantive content of what is taught will not. In addition, what the study lacks in representativeness, it makes up for in terms of depth, boasting an excellent response rate with some very detailed answers in relation to the qualitative sections.

## 6.11 RESULTS AND DISCUSSION OF QUANTITATIVE DATA

### 6.11.1 Explaining 'Statistical Significance'

To test whether the differences in responses to each question are significant, a chi-square goodness of fit test (often referred to a chi-square test of independence) was computed where the data merited it. This provides a means of expressing the degree of likelihood that an observed or reported pattern of frequencies could have been produced by chance. However, in some instances the differences were so apparent that statistical testing would have been redundant.

### 6.11.2 Basis and Importance of Informed Consent

#### 6.11.2.1 Results

Q.1. What do you think is the most important basis for informed consent?

1. Table One: The most important basis of the doctrine of informed consent.

<b>Basis</b>	<b>Frequency</b>	<b>Percentage</b>
Ethical Obligation	101	62.3%
Legal Obligation	36	22.2%
Professional Obligation	25	15.4%

These results indicate that the majority of students perceive the most important basis for the doctrine of informed consent as being an ethical obligation.

Q.2. Please rate the level of importance you would attach to the basis of the doctrine of informed consent from the three choices below.

2. Table Two: The level of importance attached to each basis of informed consent.

<b>Basis</b>	<b>Very Important</b>		<b>Important</b>		<b>Unimportant</b>		<b>Very unimportant</b>	
	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>
Ethical Obligation	132	81.5%	29	17.9%	1	.6%	N/A	N/A
Legal Obligation	101	62.3%	61	37.7%	N/A	N/A	N/A	N/A
Professional Obligation	109	67.3%	52	32.1%	1	.6%	N/A	N/A

\* N/A means no students selected the category. This applies to all questions.

The differences in the level of importance attached to each basis of informed consent, shown in the above table were statistically significant.  $X^2 (2, N=162) = 9.94, p=.007$ .<sup>12</sup> Significantly more participants noted ethical obligation as being the rationale for informed consent than legal or professional obligations.

### 6.11.2.2 Discussion of Findings

This data provides insight into how medical students' perceive the nature of informed consent. The results seem to be consistent with Jones's assertion that:

'Doctors are familiar with the principle of informed consent as an ethical requirement of their practice, though they are less familiar with the legal ramifications. The underlying ethical principle of informed consent is that one should respect the patient's autonomy.'<sup>13</sup>

This seems to be in contrast with suggestions that medical practitioners perceive informed consent as nothing more than a medico-legal requirement that requires them to obtain a signature on a form in order for them to escape liability. The majority of medical students (62.3 per cent) perceive the most important basis for obtaining a patient's consent as being an ethical obligation. This demonstrates that they are able to look beyond mere conformity with the black-letter legal doctrine that asks them to consider primarily disclosure of risks. This signifies that the majority, at least, recognise that informed consent is about something more than just the law. Consent is clearly more concerned with the patients themselves. This could indicate a movement towards a more patient-centred consent system,<sup>14</sup> synonymous with the concept of shared-decision making.<sup>15</sup>

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<sup>12</sup> See above section 6.3.1 for an explanation of the statistical significance. The symbol 'p' denotes statistical significance or probability value derived from the Chi test as described above. The smaller the number, the greater the likelihood that an observed or reported pattern of frequencies could not have been produced by chance. A difference is regarded as significant if it is equal to or less an 0.05 (less than or equal to a one in 20 chance).

<sup>13</sup> Jones, M. "Informed Consent and Other Fairy Stories" (1999) *Med L Rev* 103 at 123.

<sup>14</sup> For a discussion of the benefits of a patient-centred consent system see Teff, H. "Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance" (1985) 101 *LQR* 432.

<sup>15</sup> For the desirability of such a concept see Gillett, G.R. "Informed Consent and Moral Integrity" (1989) 15 *Journal of Med Ethics* 117; Sugarman, J. "Informed Consent, Shared Decision-Making, and Complementary and Alternative Medicine" (2003) 31 *Journal of Law, Medicine & Ethics* 247;

### 6.11.3 Importance of Informed Consent

#### 6.11.3.1 Results

Q.3. How important do you feel informed consent is in relation to medical treatment?

3. Table Three: The importance of informed consent to medical treatment.

<u>Importance</u>	<u>Frequency</u>	<u>Percentage</u>
Very Important	119	73.5%
Important	42	25.9%
Unimportant	1	.6%
Very Unimportant	N/A	N/A

These results indicate the majority of the students perceived informed consent to medical treatment as being very important.

#### 6.11.3.2 Discussion of Findings

All but one of the medical students (99.4 per cent) recognised the overall importance of informed consent. Jones has commented: '...the leaders of the medical profession have begun to respond to the demands for greater openness and accountability, and are now issuing much more detailed guidance to the profession about information disclosure.'<sup>16</sup> Evidently it is not just the leaders of the medical profession who are responding to greater demands for openness and accountability. It may also be the people who are charged with educating medical students. This is exemplified by the fact that the majority of respondents realised the importance of informed consent and already demonstrated in previous questions that it is for reasons other than purely legal ones.

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Montgomery, J. "Power/Knowledge/Consent: Medical Decision Making" (1988) 51 MLR 245; Bridson, J. *et al.* "Making Consent Patient Centred" (2003) 327 BMJ 1159 at 1159; Beauchamp, T.L. & Childress, J.F. *Principles of Biomedical Ethics* Fifth Edition (Oxford: Oxford University Press, 2001) at 78.

<sup>16</sup> Jones, *op cit* n 13 at 130.

### 6.11.4 Informed Consent and Different Treatments

#### 6.11.4.1 Results

**Q.4.** Where do you feel informed consent is most important?

4. Table Four: Treatment areas where informed consent is most important.

<u>Treatment</u>	<u>Frequency</u>	<u>Percentage</u>
Surgery	149	92%
Non - Surgical Intervention	6	3.7%
Drug Therapies	7	4.3%

These results indicate that the majority of students perceived informed consent as being most important in surgery.

**Q.5.** Please could you rate the level of importance you would attach to informed consent in the three treatment options below.

5. Table Five: The level of importance attached to informed consent in different treatment areas.

<u>Treatment</u>	<u>Very Important</u>		<u>Important</u>		<u>Unimportant</u>		<u>Very Unimportant</u>	
	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>
Surgery	158	97.5%	4	2.5%	N/A	N/A	N/A	N/A
Non - Surgical Intervention	82	50.6%	77	47.5%	3	1.9%	N/A	N/A
Drug Therapies	65	40.1%	90	55.6%	7	4.3%	N/A	N/A

The differences in the level of importance attached to informed consent in different treatment areas were statistically significant,  $X^2 (2, N=162) = 75.61, p <.001$ . Surgery was perceived to be the most important area.

#### 6.11.4.2 Discussion of Findings

The results further indicate that the students perceive informed consent as being most important in terms of (invasive) surgery (92 per cent). This may reflect the fact that these operations carry with them greater medical risks and that litigation has mainly focused on disclosure of these.<sup>17</sup> The students may have been educated to perceive informed consent as being most important under this heading as it is here where

things are most likely to go wrong and where legal consequences are most likely to ensue. If this is the case, it is demonstrative that the legal side, although clearly not *the* most important aspect of informed consent, is still very much at the forefront of medical students' minds.

In comparison with invasive surgery, the students did not attach as much importance to informed consent in non-surgical intervention and drug therapies. This is perhaps surprising, particularly in relation to drug therapies where only 40.1 per cent considered informed consent as very important. Patients are likely to be more ignorant in relation to the risks inherent in drug therapies and thus keeping them informed ought to be more important. Nevertheless, the data indicates that they still recognise the significance of obtaining consent under these headings in accordance with their legal obligations.

### **6.11.5 Effectiveness of Training**

#### **6.11.5.1 Results**

**Q.6.** How effectively do you feel you have been prepared to deal with informed consent issues in practice?

6. Table Six: The effectiveness of training and preparation to deal with informed consent in practice.

<b><u>Effectiveness of Training</u></b>	<b><u>Frequency</u></b>	<b><u>Percentage</u></b>
Very Effective	3	1.9%
Effective	76	46.9%
Ineffective	77	47.5%
Very Ineffective	6	3.7%

These results demonstrate that the students were almost equally split in terms of whether their training to deal with informed consent in practice had been effective.

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<sup>17</sup> Beauchamp and Childress, *op cit* n 15 at 81; Godolphin, W. "The Role of Risk Communication in Shared Decision Making" (2003) 327 BMJ 692.

**Q.7.** How important do you feel it is to be trained effectively in informed consent in the three treatment options below?

7. Table Seven: The importance of being trained effectively in informed consent in different treatment areas.

<u>Treatment</u>	<u>Very Important</u>		<u>Important</u>		<u>Unimportant</u>		<u>Very Unimportant</u>	
	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>
Surgery	134	82.7%	27	16.7%	1	.6%	N/A	N/A
Non - Surgical Intervention	109	67.3%	51	31.5%	2	1.2%	N/A	N/A
Drug Therapies	105	64.8%	55	34.0%	2	1.2%	N/A	N/A

The differences in views about the importance of being trained effectively in informed consent in different areas were significant,  $X^2 (2, N=162) = 8.91, p \leq .01$ . Surgery was deemed to be the area where it was most important to be trained effectively in informed consent.

#### 6.11.5.2 Discussion of Findings

There is evidence suggests that over half (51.2 per cent) of newly qualified doctors in this sample feel ill-equipped to obtain informed consent.<sup>18</sup> This may be due to a number of reasons. Firstly, they may just be nervous. Secondly, they may be poor communicators or perhaps do not fully understand informed consent. Finally, they may not have sufficient understanding of medical procedures.<sup>19</sup> At least two of these factors are inextricably linked to the way in which medical students are educated in terms of informed consent. The majority of the students in the survey indicated that they felt their training in terms of informed consent has been ineffective. There may well be a number of difficulties associated with providing effective education in terms of consent. For example, it was noted in the preliminary interview with the Director

<sup>18</sup> This is confirmed in a number of empirical studies. See, Roberts, L.W. *et al.* "Evaluating Medical Students' Skills in Obtaining Informed Consent for HIV Testing" (2003) 18 *Journal of Genitourinary International Medicine* 112; Angelos, P. *et al.* "Residents Seeking Informed Consent: Are They Adequately Knowledgeable?" (2001) 59 *Current Surgery* 115; Richardson, N. *et al.* "Should House Officers Obtain Consent for Operation and Anaesthesia?" (1996) 28 *Health Trends* 56; Paterson, I.C. "Consent to Treatment: Somebody Moved the Goalposts" (1994) 6 *Clin Oncology* 179 at 181.

<sup>19</sup> *ibid.*

of Teaching that there is no separate unit within the undergraduate course that is dedicated to consent training *per se*.<sup>20</sup> The focus in undergraduate training is on patient communication.<sup>21</sup> Immediately the assertive non-medically trained lay person will point out that the crux of the informed consent debate is centred on effective communication. Nevertheless, herein lies the problem. It is accepted that effective communication from both parties (physician and patient) plays a key role in the obtaining of informed consent. However, it is the overall *aim* and *type* of communication that is the source of contention. It was intimated by the Director of Teaching that the central issue in terms of doctors' communication training is undertaken with a view to allowing them to reach an effective diagnosis in as short a time as possible. It seems a doctors' primary goal, above all else, is concerned with diagnosis. This has priority over surgery, drug trials and disclosure. Thus, for the most part students are educated to communicate in a way which gets them to where they want to be in terms of making a diagnosis.<sup>22</sup> Accordingly, emphasis on themes which are central to the informed consent process such as the disclosure of risks, alternatives and communication to allow the patient to understand what is being proposed, have the potential to be inadvertently de-prioritised.

A further problem is that it may well be extremely difficult to fit consent training into a syllabus that is mainly concerned with scientific fact.<sup>23</sup> There is little

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<sup>20</sup> See Richardson, *op cit* n 18. Here it was found that 82 per cent of House Officers denied having any formal legal training on the aspects of obtaining informed consent.

<sup>21</sup> Sedgwick, P. & Hall, A. "Teaching Medical Students and Doctors How to Communicate Risk" (2003) 327 BMJ 694; Godolphin, *op cit* n 17. Although communication issues are afforded a great deal of attention in the undergraduate training, Sedgwick and Hall suggest 'the need for doctors to have proficient communication skills is well recognised, but teaching students how to communicate risk to patients seems to have received little attention in the undergraduate medical curriculum.'

<sup>22</sup> Godolphin *op cit* n 17 at 692 suggests 'Formative medical training, when students are "professionalised", tends to be in acute care. They are taught to be responsible in settings where choices are few and patients' autonomy is limited. They are rewarded for being confident and getting to the "correct" answer...They are taught about interviewing and history taking but not much about giving patients information or risk communication.'

<sup>23</sup> Sedgwick and Hall, *op cit* n 21.

evidence to how much time is devoted to different areas of medical practice. Whilst it is beyond the remit of the present investigation, it would perhaps be interesting to compare and contrast the amount of time spent on fact acquisition, skills training and communication processes. It is possible that both practically and logistically there may not enough time to dedicate to intricate consent training, and to suggest this should be given prominence over other elements of the syllabus is perhaps unrealistic. This may however depend on how the purposes of medicine are conceptualised. There may be a call for more practical consent training within medical courses as opposed to undergraduate law courses where greater emphasis is on 'black-letter' fact.

### **6.11.6 Confidence of Obtaining Informed Consent in Practice**

#### **6.11.6.1 Results**

**Q.8.** How confident do you feel about dealing with informed consent issues in practice?

8. Table Eight: Levels of confidence in dealing with informed consent issues in practice.

<b><u>Levels of Confidence</u></b>	<b><u>Frequency</u></b>	<b><u>Percentage</u></b>
Very Confident	3	1.9%
Confident	57	35.2%
Unconfident	94	58%
Very Unconfident	8	4.9%

These results suggest the majority of students feel unconfident in dealing with consent issues in practice.

**Q.9.** How important do you feel it is to be confident in dealing with informed consent issues in the three treatment options below?

9. Table Nine: The importance of being confident to deal with informed consent issues in practice across a range of different treatment areas.

<u>Treatment</u>	<u>Very Important</u>		<u>Important</u>		<u>Unimportant</u>		<u>Very Unimportant</u>	
	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>	<u>Freq</u>	<u>%</u>
Surgery	120	74.1%	41	25.3%	1	.6%	N/A	N/A
Non - Surgical Intervention	100	61.7%	62	38.3%	N/A	N/A	N/A	N/A
Drug Therapies	97	59.9%	63	38.9%	2	1.2%	N/A	N/A

These results show the majority of students perceive it as being very important to be confident across all three treatment headings when it comes to dealing with informed consent in practice.

#### 6.11.6.2 Discussion of Findings

The results show that the majority (62.9 per cent) of medical students do not feel confident in obtaining informed consent in practice. This may be linked to the fact that most of the students, as indicated earlier, thought their consent training was ineffective (51.2 per cent). The disparity between this and the fact that the majority of students identified it was very important to be confident in obtaining informed consent across a range of different medical treatments is arguably a cause for concern. In considering the position of the student, they have been trained in the theoretical aspects of medicine for the best part of five years. They have reached a point in their careers where they will have to implement their acquired skills upon entering practice. In short, for the first time they will be giving up the relative calm and tranquillity of academia where time can be taken to ponder things, help is at hand, and mistakes are more easily rectified (and, even if they are not, they are generally not life threatening). This is in exchange for the 'hustle and bustle' of a busy NHS hospital where there is little if any margin for error, decisions may be rushed, they are responsible for their

own actions which could be the difference between life and death. This clearly is a daunting prospect for anybody. Accordingly, these results could simply reflect the final year students' anxieties about going into practice. They may well have been different if the survey had been conducted at an earlier or later stage in their medical education.

How does this relate specifically to confidence in consent training? An argument can be made that the students are justified in feeling a little less confident in consent issues. Although they may have been educated about the importance of obtaining informed consent (which the results of this survey clearly identify), the Director of Teaching suggested they do not have any practical consenting opportunities before they leave medical school. Indeed their first experience of obtaining a patient's consent may be presented before them in their roles as House Officers. Thus, even though technically it should not happen, if a consultant or registrar delegates consent to newly appointed House Officers, one can forgive the students for lacking confidence. As Paterson suggests 'the task of obtaining signed consent should not be delegated to a junior doctor whose own knowledge of the procedure is limited.'<sup>24</sup> There are two potential reasons for this. Firstly, and at a basic level, they may not know enough about the procedure they are consenting for. Secondly, they have no direct experience of communicating the necessary information about the procedure to the patient.<sup>25</sup> This needs to be performed within the context of the consultation process itself and in a manner which is consistent with the purpose of obtaining a valid and informed consent.

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<sup>24</sup> Paterson, *op cit* n 18 at 181.

<sup>25</sup> Jones, *op cit* n 13 at 125. Jones cites Houghton, D.J. *et al.* "Informed Consent: Patients' and Junior Doctors' Perceptions of the Consent Procedure" (1997) 22 *Clin Otolaryngol* at 505. Here the findings demonstrate that 37 per cent of junior doctors are obtaining consent for procedures of which themselves they have limited understanding. Also, see figures given by Richardson, *op cit* n 18.

The benefits of on-the-job consent training can be set out as follows. Students have the advantage of observing and learning from the experience and knowledge of senior colleagues who are likely to be more adept in the consultation and communication process, are experts within their specialisms and who may be well versed in both the underlying legal and ethical objectives of informed consent. Furthermore, it is often said that there is no better way to acquire skills than being thrown in at the 'deep- end' and learning from the realities of what takes place in the real world. However, if the practicalities of consent training on the wards are overlooked for reasons of time constraints or laissez-faire attitudes of senior colleagues, medical students will be restricted from developing their confidence in the consent process which may have a detrimental effect on doctor/patient relations.<sup>26</sup>

### **6.11.7 Perceived Difficulty of Obtaining Informed Consent in Practice**

#### **6.11.7.1 Results**

**Q.10.** How difficult do you feel it will be to obtain informed consent in practice?

10. Table Ten: The perceived difficulty of obtaining informed consent in practice.

<u>Level of Difficulty</u>	<u>Frequency</u>	<u>Percentage</u>
Very Easy	2	1.2%
Easy	100	61.7%
Difficult	57	35.2%
Very Difficult	3	1.9%

These results indicate the majority of students envisage they will find it easy to obtain informed consent upon entering practice.

<sup>26</sup> For an interesting discussion of these issues see Tallis, R. "Power and Trust: The God-Like Consultant" in *Hippocratic Oaths: Medicine and its Discontents* (London: Atlantic, 2004) at 74. Tallis paints the picture a stereo-typical consultant as someone who historically exploited junior doctors who do the majority of the work for which he is paid. However, whilst he acknowledges that some may well behave like this, this portrayal is between thirty and fifty years out of date. He suggests British medicine is far less hierarchical than elsewhere and students are afforded the opportunity to express opinions in consultations. He suggests students are sometimes wrong-footed by sincere requests to get involved. Thus, there needs to be recognition on their part that consultants are increasingly valuing their input. Godolphin, *op cit* n 17 at 692 suggests 'most communication skills are habitual and learnt from role models.' However he poses the question 'are the most influential role models and opinion leaders also competent at shared-decision making?'

**Q.11.** How difficult do you feel it will be in practice to obtain informed consent in the three different treatment options below?

11. Table Eleven: The perceived difficulty of obtaining informed consent across a range of different treatment areas.

<b>Treatment</b>	<b>Very Easy</b>		<b>Easy</b>		<b>Difficult</b>		<b>Very Difficult</b>	
	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>
Surgery	11	6.8%	99	61.1%	47	29.0%	5	3.1%
Non - Surgical Intervention	10	6.2%	92	56.8%	57	35.2%	3	1.9%
Drug Therapies	18	11.1%	67	41.4%	70	43.2%	7	4.3%

The differences in the perceived level of difficulty attached to informed consent in different treatment areas were statistically significant.  $X^2 (2, N=162) = 15.69, p<.01$ . Surgery was perceived to be the easiest treatment to deal with whereas drug therapies were perceived to be the most difficult.

#### 6.11.7.2 Discussion of Findings

Most of the students (62.9 per cent) demonstrated that they thought obtaining informed consent upon entering practice would be easy. These results do not mirror the findings that the majority of students feeling unconfident in obtaining informed consent. There is clearly a discrepancy. It is a strange proposition that the majority of the students think obtaining informed consent will be easy, whilst in the same breath the majority of them feel unconfident in the process. Ordinarily speaking the easier something is the more confidence you would expect to have in undertaking the task.

Seemingly these results cannot be related to a naïve confidence on the part of the students as previous results indicate the majority do not feel confident in obtaining patients' consent. Thus, what does the data tell us? It could just be that the students' perceive obtaining informed consent as easy. However this is hard to believe. Are there any 'easy' components to a medical practitioner's job? A pattern emerges here, which translates almost into a theory to practice issue. The students seem to think that in theory obtaining informed consent is easy, but knowing what to do in practice is more difficult. This being the case the results become clearer. Compared to complex

surgical procedures and diagnosis, obtaining consent may well be 'easier', but obtaining a true informed consent is far from 'easy'. This is something the students need to be made aware of very quickly upon entering practice, if not beforehand. Once again, there is of course the possibility that students may become anxious when anticipating practice. This may affect the responses and explain inconsistency.

### 6.11.8 Dealing with Factors Affecting the Obtaining of Informed Consent

#### 6.11.8.1 Results

**Q. 12.** Please indicate which of the issues below you feel will be most difficult for you when dealing with informed consent issues in practice.

12. Table Twelve: The perceived difficulty of dealing with various factors which may affect the obtaining of informed consent in practice.

<b>Factors</b>	<b>Very Easy</b>		<b>Easy</b>		<b>Difficult</b>		<b>Very Difficult</b>	
	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>	<b>Freq</b>	<b>%</b>
Patient Understanding	3	1.9%	69	42.5%	81	50.0%	9	5.6%
Patients' Lack of Communication	1	.6%	39	24.1%	107	66.0%	15	9.3%
Patients' Misconceptions about illness	38	23.5%	105	64.8%	19	11.7%	N/A	N/A
Patients' Unwillingness to Ask Questions	4	2.5%	44	27.2%	91	56.1%	23	14.2%
Identifying Patients' Objectives	1	.6%	76	46.9%	78	48.1%	7	4.4%
Ability to Explain Treatment	11	6.8%	119	73.5%	26	16.0%	6	3.7%

Due to the small numbers in the very easy category which would invalidate the chi-square test, very easy and easy were collapsed so too difficult and very difficult (this however is not represented in the table above). Thus the tested factors are easy vs. difficult. The differences are very significant.  $X^2 (2, N=162) = 163.27, p<.001$ . Students perceived it to be difficult to deal with understanding, communication, patients' reluctance to ask questions and identifying patients' objectives, whilst they perceived it as easy to deal with patients' misconceptions about illness and their ability to explain treatment. They were equally split about identifying patients' objectives.

### 6.11.8.2 Discussion of Findings

These results provided further insight into the students' perspectives on the difficulty of obtaining informed consent in practice and what they envisaged as being the most problematic areas.

#### **Understanding**

The majority of the students (55.6 per cent) recognised that dealing with patient understanding is a difficult factor in the consent process. It is encouraging that medical students recognise this, as in the opinion of the present researcher, patient understanding is one of the most difficult barriers to overcome when attempting to obtain informed consent. Some of the difficulties with patient understanding reside in the fact that it is a subjective concept and that complete understanding will never be achieved. This has to be balanced against the need to pitch any medical consultation at an appropriate level so the patient has 'sufficient' understanding. At least in recognising there is a problem clinicians can now focus on how to combat it. Thus, medical practitioners need to now concentrate on how they can improve patient understanding.<sup>27</sup> These issues will be explored in greater detail in the qualitative studies investigating consent in practice.

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<sup>27</sup> Gillet, *op cit* n 15 at 118 suggests the doctor 'should try his best to allow the patient to understand or see the problem they are facing.' Clearly there are ways to enhance understanding and key things to avoid such as using incomprehensible medical jargon. It has been suggested the use of analogies and the dissemination of information via the world-wide web are ways of improving understandings. See Edwards, A. "Communicating Risk Through Analogies" (2003) 327 BMJ 749; Woloshin, S. *et al.* "Making Sense of Risk Information on the Web" (2003) 327 BMJ 695.

## Patients' Lack of Communication & Patients' Unwillingness to Ask Questions

The next two questions were implicitly related to each other and therefore can be dealt with together.

When asked about the perceived problems with patient communication the majority of students (75.3 per cent) recognised the difficulties this may cause in the consent process. Linking into this question was the issue of patients' unwillingness to ask questions. The results seem to correspond with the above figures regarding communication in that it would be a difficult factor (70.3 per cent) to deal with in the obtaining of informed consent in practice.

Evidently the students visualise that many patients do not like to question their doctor and they may well have been warned about this in their training.<sup>28</sup> Arguably, patients have to be put at ease in any consultation process before they will consider engaging in a dialogue with their physician. A great number of patients remain silent throughout consultations. It does not follow from this apparent silence that they did not want extra information about their treatment.<sup>29</sup> As a result, doctors need to be good communicators in order to encourage joint participation in consultations. Indeed it was suggested by the Director of Teaching that in order to be accepted on the course in the first place, the key characteristic that admissions tutors look for is good communication skills. The very fact that emphasis is placed on communication training may be the underlying reason why students can relate to the difficulties connected with this.

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<sup>28</sup> In the initial interview with the Director of Medical Teaching it was suggested students were persistently reminded of this point in order to stress the importance of effective communication to them.

<sup>29</sup> Mayou, R. *et al.* "Attitudes and Advice after Myocardial Infarction" (1976) 1 *BMJ* 1577. Here it was discovered 70 per cent of their coronary inpatients did not intend to ask questions about their condition even if many of them wanted more information. See also Korsch, B.M. *et al.* "Gaps in Doctor-Patient Communication" (1968) 42 *Paediatrics* 855. Here it was found that 24 per cent of the parents of paediatric patients in their study did not ask the doctor questions even though they wanted more information.

## Patients' Misconceptions about Illness

The results show that a large majority (88.3 per cent) of the medical students perceived patients' misconceptions about illness as being an easy factor to deal with in the consent process. Hence, the students may have failed to recognise that patients often have fears and anxieties about treatment and illness before they enter the consultation process. This may affect their judgement and may influence their reasoning.<sup>30</sup> Indeed, many patients have often diagnosed themselves before any consultation. It has long been acknowledged that the problem of self-diagnosis exists and is also somewhat exacerbated by patient ignorance<sup>31</sup>, but it appears the medical students here may be unaware of this. It is essential to provide a careful explanation in spelling out all the treatment options and the different effects these may have on patient lifestyles. This is where discussions of alternatives plays an important part in the obtaining of informed consent, and more importantly, taking the time to ensure patient understanding by explaining treatment effectively in order to obtain a valid consent. However, it is possible most students are confident in their own abilities to identify and dispel misunderstandings.

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<sup>30</sup> It has been suggested, and it is contended rather condescendingly so, that the more educated and articulate the patient, the more likely they are to engage with their doctor. See Lord Diplock in *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 at 895. Whilst this undoubtedly may put them in a stronger position it does little to dispel the problem of self-diagnosis. Arguably the more educated one is, the more confident one may feel in self-diagnosis which in turn may lead to greater mis-conceptions about illness.

<sup>31</sup> Ley, P. & Spelman, M.S. *Communicating with the Patient* (London: Staples, 1967). Here it was discovered that 28 per cent of patients did not associate coronary thrombosis with the heart, and 44 per cent did not realise the prognosis in lung cancer was as gloomy as it was. Indeed 20 per cent thought it was easily cured. See also Leventhal, H. *et al.* "The Common Sense Representation of Illness and Danger" in Rachman, S. ed. *Contributions to Medical Psychology* Volume Two (Oxford: Pergamon, 1980). Here nearly a third of all patients thought that hypertension was an illness likely to be cured with short-term treatment.

### **Identifying Patients' Objectives**

The medical students were equally split on this question. Just over half (52.5 per cent) thought identifying patients' objectives is a difficult factor to deal with when obtaining consent. This may reflect the view that there is lack of prominence given to this aspect in teaching. However, it could also be that the medical students under investigation recognise that patients themselves are often unclear as to their own objectives. It is difficult to ascertain patients' objectives. These may often differ depending on the social and individual preferences of the patient. Nevertheless, time ought to be taken to engage with patients and ask them what they want. This will inevitably lead towards advanced levels of informed consent. There is now much more emphasis on encouraging patients to share decisions, and there is evidence to suggest patients find it easier to do so with a preliminary investigation of their objectives.<sup>32</sup>

### **Explaining Treatment to Patients**

The results here demonstrate that the majority (80.3 per cent) of students perceived it to be easy to explain treatment to patients when attempting to obtain informed consent. This perhaps echoes the fact that they are more familiar and at ease with this component of their job. This could be due to greater emphasis being placed on this aspect in the course of their medical education.

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<sup>32</sup> See Bridson *et al. op cit* n 15 at 1160. 'Patients who want to share decisions find it easier to do so if the process begins with an exploration of their objectives.'

## 6.12 THE QUALITATIVE COMPONENT

### 6.12.1 Comparison of Definitions Against a 'Gold-Standard'

The final question within the survey allowed the students to give their definitions of informed consent. These statements were collected and compared to the standard definition given by the Department of Health in their most recent guidelines on obtaining consent. This definition was preferred to the guidance issued by the GMC. This was due to the fact that whilst the General Medical Council's guidelines potentially have greater impact on doctors insofar as the GMC has disciplinary powers, it was decided, for the purposes of this research question, that the Department of Health guidelines provide a more comprehensive definition which was easier to break down into a number of individual components. The working definition is set out below:

'Consent is a patient's agreement for a health professional to provide care. For consent to be valid, the patient must be competent to take that particular decision, have received sufficient information, and must not be acting under duress. Sufficient information should include information about the risks and benefits of the proposed treatment, and information about alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.'<sup>33</sup>

The above statement was broken down into eight constituents which can be listed as follows:

1. Patient's agreement
2. Competence to make a particular decision
3. Received sufficient information
4. Must not be acting under duress
5. Information about risks
6. Information about benefits

- 7. Information about alternatives
- 8. Information in a form they can understand

All of the students' definitions were read through in their entirety and the scores were recorded based on how many of the above components each of the students' definitions mentioned. Also, the number of occasions each particular constituent was mentioned was collected.

### 6.12.1.1 Results

1. Table One: Total number of constituents mentioned in each definition.

<u>Number of Constituents Mentioned in Each Definition</u>	<u>Frequency</u>
0 Constituents	15
1 Constituent	21
2 Constituents	40
3 Constituents	51
4 Constituents	29
5 Constituents	5
6 Constituents	1
7 Constituents	0
8 Constituents	0

These results demonstrate that most of the students' qualitative definitions included at least two or three major constituents that are provided for in the Department of Health's guidelines. No students managed to identify seven or all eight constituents. Only one student managed to achieve six. In the main, most definitions centred on recognising three component parts.

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<sup>33</sup> *op cit* n 1.

2. Table Two: Number of times individual constituents were mentioned within each definition provided. For example, risks were mentioned in 113 of the definitions and understanding was mentioned in 82 of the definitions. 15 of 162 the definitions contained none of the individual constituents.

<b>Individual Constituent</b>	<b>Frequency</b>
Risks	113
Understanding	82
Patient's Agreement	73
Benefits	60
Alternatives	22
Competence	18
Not Acting Under Duress	17
Sufficient Information	16
No Constituents Mentioned	15

These figures demonstrate that all the individual elements were referred to at some point. In terms of the frequency with which individual constituents were mentioned, risks, understanding and patients' agreement scored the highest. Benefits also attracted considerable attention. In relation to the other elements, the disparity between them was minimal and they were all mentioned roughly on the same number of occasions. Therefore, the conclusion has to be that the majority of student definitions covered three constituents, and in the main these individual constituents were made up of risks, understanding and agreement. However, as can be seen from above, benefits were not far behind.

#### 6.12.1.2 Discussion of Findings

What does this tell us about the students' knowledge of informed consent when measuring it against a 'gold-standard' definition? Arguably there is cause for concern in that the majority identified only three key components out of a possible eight.

Firstly, it may well be the case that the Department of Health's definition is not that widely known or referred to. Of course the very nature of the term 'guidelines' in itself suggests that they are exactly that; guidelines as opposed to mandatory requirements. It is the purpose of the remainder of the qualitative studies within this thesis to investigate how much these guidelines are relied upon and adhered to in practice. However, if they are not utilised by medical professionals, the chances are they have yet to attain the status they may well deserve within the educational curriculum. Also the guidelines are rather elaborate and very specific. Whilst this is

only speculation, it is possible the professionals in charge of educating the students may well be forgiven for not teaching informed consent issues to the black-letter text book definitions. Indeed, the more experienced the tutor the less reliant they may become on text book meanings and are more likely to use their own skill and knowledge to sum up the essentials that the students will need in practice. Hence, although the Department of Health's interpretation can be classed as a 'gold-standard', it provides little guidance as a 'working definition' that can be concisely carried over into practice.

Moreover, there are a number of difficulties associated with the Department of Health's guidelines concerning the potential overlap with some of the components. For example, the phrase 'sufficient information' is prone to mislead. If the students had mentioned the separate components such as risks, benefits and alternatives they may well perceive this as constituting 'sufficient information' and thus may not have felt the need to name it separately. Perhaps more importantly, some of the factors within the 'gold-standard' statement, from a legal point of view at least, are associated with consent generally and in a wider context, and are not specifically linked to informed consent in itself. For example, issues such as capacity and not acting under duress are legal issues in their own right and are elements that lawyers may choose not to mention when discussing information disclosure.

What the results do show is that the majority of students have grasped what the present researcher would describe as 'the gist' of informed consent. Despite the limited time in which to construct a thorough definition, there was common identification of the patient's agreement, the requirement to disclose risks and the assessment of patients' understanding. Also, a fair amount of attention is given to disclosure of benefits as well as risks. Most of the definitions concentrated on

explaining the risk/benefit ratio of any treatment in order that the patient can understand what they are consenting to.

### 6.12.1.3 Legal Reflections & Conclusions

The results in the quantitative component of this study indicate that medical students perceive the most important basis for informed consent as an ethical obligation as opposed to a legal one. Within the qualitative section the greatest emphasis is on risk disclosure. The results may well evidence the commitment towards the ethical side of informed consent in the importance attached to disclosing risks as a key component of keeping the patient fully informed. Few would argue that whilst risk disclosure is not the only fundamental component of informed consent, it is definitely an integral part of it. Thus, it is to be expected that a certain amount of prominence be placed on this heading. Particularly in the sense that it is potentially where patients may suffer harm, and consequently they are entitled to be made aware of the risks they are running beforehand in order to comprehend the magnitude of any procedure.

Emphasis is also placed on understanding and the disclosure of benefits. Although understanding is a very important element in the obtaining of informed consent, it has not been given the attention it deserves in the law. So much of the law has focused on what a health professional is obliged to disclose in terms of risks; very little attention has been paid to defining the relevant steps a doctor must take to ensure some level of understanding. One of these factors is, of course, to discuss things in terms of a risk/benefit ratio so the patient can conceptualise and place into context the nature of the procedure they are agreeing to. It is submitted it is every bit as important to require the disclosure of benefits as a precursor to any risks. Consideration of risk/benefit ratios are at the heart of negligence calculations and are of central concern in questions of breach of duty generally. Since doctors presumably

want patients to take their advice it would be surprising if they did not emphasise why the procedure they recommend is a good idea. It is this commitment towards understanding and disclosure of benefits that takes us further than the legal definition of informed consent and may well be the inherent difference between the way in which medical students and lawyers perceive the concept itself.

The next component of the study focuses on the qualitative investigations of informed consent in practice.

## **PART II**

# **THE QUALITATIVE STUDIES**

## **7 THE QUALITATIVE STUDIES: PREPARATION, PROCEDURE AND PROTOCOL**

### **7.1 INTRODUCTION**

The qualitative components of the research serve as a continuation of the previous quantitative study. The research now develops from an investigation of consent in theory to an investigation of consent in practice. The qualitative aspects of the work focus on exploring the dynamics of the consent process in both primary and secondary clinical settings, amongst clinicians and patients. This is with a view to developing an understanding of how the various parties feel about informed consent and how they deal with the difficult issues they face in practice. In addition, the views of a number of practicing solicitors were explored in an attempt to gain insight into how the legal side of consent operates and how they feel about this.

### **7.2 JUSTIFICATION**

Presumably all clinicians engage in some kind of consent procedures before they examine or administer any treatment to patients. The questions that remain poorly understood are what are the dynamics of these procedures and how do they relate to legal theory and practice? To what extent do different grades of clinicians perceive consent as being important and how do they relate to each other? Similarly, what do patients think about consent and how do these views compare to those held by the clinicians? Finally, how do practicing solicitors view the operation of the law in practice and how does this relate to views about protecting the patient's right to self-determination?

Accordingly, as there is little in the way of empirical research concerning the above issues, these components of the study investigate these concerns using

qualitative research methods to uncover and supplement the somewhat vague and sketchy understanding of informed consent issues in practice.

### **7.3 RESEARCH AREAS**

The remaining qualitative components of the study can be broken down into five separate research areas.

1. To investigate and develop a clearer understanding of consent procedures and issues in primary care settings.
2. To investigate and develop a clearer understanding of consent procedures and issues amongst clinicians in secondary care settings.
3. To investigate and develop a clearer understanding of consent procedures and issues amongst patients in secondary care settings.
4. To observe and reflect upon consent procedures in secondary care.
5. To investigate and develop a clearer understanding of how the law operates in relation to consent and information disclosure in practice.

### **7.4 METHODS**

The following methods were applied to each of the above studies:

1. Primary Care Study: Semi-structured interviews.
2. Clinicians in Secondary Care Study: Semi-structured interviews.
3. Patients in Secondary Care Study: Semi-structured interviews.
4. Observations of Consent in Secondary Care Study: Overt observational techniques.
5. Solicitors' Study: Semi-structured interviews.

## 7.5 BACKGROUND AND PREPARATION

### 7.5.1 *Development of Interview Schedules*<sup>1</sup>

The origins of the interview topics and themes for all the qualitative studies are discussed in detail in the methodology chapter of this thesis. However, the topics were generated from the questions identified in the literature review of this thesis. As a result of reviewing the necessary material in this field a number of themes were articulated which were loosely connected to the contentious legal issues in this area. These topics were not an exhaustive list though and were left sufficiently flexible to allow participants to elaborate on any issues to whatever extent they wished. They were not confined to just pure legal issues, but allowed for some overlap of medical or wider social issues in terms of informed consent. They were also very broad topics with a few key words listed underneath to jog the memory of the researcher should the dialogue 'dry' up. This procedure remained the same throughout the development of the interview schedules for all the qualitative studies. However, certain themes had greater importance in primary than secondary care and vice versa. Also, although the themes remained roughly the same throughout the different clinicians' interviews, the wording of the questions were altered slightly to account for the patients' component of the study. Despite this, once again the patient's interview schedule covered the same general areas of inquiry as the clinicians. It should also be noted that the questions were sufficiently linked to the ones generated in the questionnaire study allowing the research to develop from in a coherent manner. The topics and themes for clinicians and patients can be summarised as:

1. Medical practitioners' definitions and views of informed consent.
2. Medical practitioners' understanding of the law.

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<sup>1</sup> For a worked example of the interview schedules that were implemented in practice see appendix [3].

3. Consent procedures in practice.
4. Diversity of consent procedures in practice.
5. Patient understanding.
6. Patient communication.
7. Differing patient personalities.
8. Therapeutic privilege.

As the focus of the solicitors' study was to investigate the operation of the law in practice, the procedure and style for developing the schedules remained the same as above, whilst the emphasis was modified slightly to cover the following topics:

1. Solicitors' views on informed consent.
2. Frequency of claims.
3. Difficulties associated with claims.
4. Evidential issues.
5. Consent and professional guidelines.
6. Development of the law.
7. Reform.

### **7.5.2 Pilot Studies**

The various interview schedules were piloted amongst a number of post-graduate researchers (N=12). In addition, one general practitioner, not involved in the study, kindly agreed to assess the general suitability of the schedules. He also agreed to a mock interview to check the clarity and ease with which the themes were understood and to assess the chronology and development of the interview topics. As the interviews progressed, in some situations, new topics and themes were added to account for the broadening of the researcher's knowledge generated from previous interviews.

### **7.5.3 Primary Care Study**

#### **7.5.3.1 Preparation, Procedure & Participants**

After the construction of participant information sheets, consent forms and full protocols, an initial meeting was set up with the practice manager at a primary care surgery. After the meeting she agreed to introduce the project at the next staff meeting. The manager contacted the researcher saying that a number of members of staff had expressed interest. She intimated that contact details had been left with the relevant members of staff and that she had left it up to them to make contact with the researcher at a time that was convenient. The participants accordingly made contact via e-mail and a number of interviews were arranged at convenient times for both parties. The interviews took place at the practice in the relevant participant's consulting room. At this point, the participants had already been given information sheets. However, before the commencement of the interview, participants were given the opportunity to question the researcher and informed consent was obtained. The interviews were conducted up to a point of saturation<sup>2</sup> and thus the number of participants in the primary care study included:

General Practitioners (N=3)

Practice Nurses (N=2)

The interviews were tape recorded and transcribed and then uploaded into the software program NVIVA Nudist for analysis.

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<sup>2</sup> This is the point where it becomes evident the participant's are covering the same issues and nothing new is being added to the research.

## **7.5.4 Secondary Care Studies**

### **7.5.4.1 Clinicians: Preparation, Procedure & Participants**

After making contact with the consultant who was head of the department where the majority of the secondary care research was to take place, a meeting was arranged. At this meeting the participant information sheets were circulated amongst medical staff. The researcher was also invited to attend the weekly multi-disciplinary team meeting to approach participants informally about taking part in the research. This way the research was not confined totally to experts from one specialism, there was opportunity to sound out staff from a range of disciplines. A number of clinicians expressed interest in the study at this point and arrangements were made for interviews. Also, a number of medical practitioners contacted the researcher via e-mail or mobile as a result of the participant information sheets being circulated around the department by the consultant in charge. Interviews were conducted at a time and place that was suitable and convenient for the medical practitioners and this was mainly in their private offices within the hospital. Before the commencement of the interview, participants were given the opportunity to question the researcher and informed consent was obtained. The interviews were conducted up to a point of saturation<sup>3</sup> and thus the number of clinicians involved in the study included:

Consultants (N=8)

Registrars (N=3)

Senior House Officers and House Officers (N=3)

Nurses (N=6)

The interviews were tape recorded and transcribed and then uploaded into the software program NVIVA Nudist for analysis.

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<sup>3</sup> See, *op cit* n 2.

#### **7.5.4.2 Patients: Preparation, Procedure & Participants**

The consultant who was head of the department approached a number of his patients by means of a letter. A number of patients subsequently contacted the researcher and agreed to take part in the study. At this point they were given participant information sheets and consent forms and a convenient date was subsequently arranged. Furthermore, the researcher was invited to attend the local patient help-group to introduce the research project and disseminate participant information sheets and contact details. A number of further volunteers were recruited at this point and interviews were arranged at convenient times for the patients. All the interviews took place in a confidential office at the hospital organised by one of the consultant nurses. Before the commencement of the interview, patients were given the opportunity to question the researcher and informed consent was obtained. The interviews were conducted up to a point of saturation and thus the number of patients in this study was:

Patients (N=8)

The interviews were tape recorded and transcribed and then uploaded into the software program NVIVA Nudist for analysis.

#### **7.5.4.3 Observations: Preparation, Procedure & Participants**

The researcher was invited to attend a number of outpatients' consultations. Also, the researcher spent a number of days shadowing individual consultants and observing their work. One day was actually spent in theatre. The researcher was invited to observe at the discretion of the individual consultant in charge and the patients were asked whether it was acceptable that their consultation was observed. Permission was sought and consent was obtained prior to the researcher being present at the consultation. During the observations a reflexive research journal was kept and this

was updated at the end of each observational session. These field notes were subsequently uploaded into NVIVA for computer generated analysis as described in the next chapter. The researcher attended the hospital for one day a week over a three-month period to conduct the various observations.

### **7.5.5 Solicitors' Study**

#### **7.5.5.1 Preparation, Procedure & Participants**

A number of local solicitors were written to. Two firms replied expressing an interest. One of these firms was predominantly claimant-based, whereas the other was defendant orientated. Thus, there was a balance of views. The solicitors who agreed to take part were sent a copy of the participant information sheet and consent forms prior to the interview. A convenient and suitable date was subsequently arranged by correspondence and the interviews took place at the respective participants' offices. Before the commencement of the interview the participants were given the opportunity to question the researcher and informed consent was obtained. The interviews continued until the participants exhausted their opinions on the subject. The number of participants in the solicitors' study was:

Solicitors (N=2)

The interviews were tape recorded and transcribed and then uploaded into the software program NVIVA Nudist for analysis.

## **7.6 ETHICS**

All the qualitative studies were subject to the scrutiny of the South Yorkshire NHS Ethics Committee. In accordance with the ethical considerations and guidelines as discussed earlier in the thesis, all the qualitative components of the thesis gained full approval.

## 7.7 ANALYSIS

The interviews were tape recorded and transcribed. After transcription they were uploaded into the qualitative analysis software package NVIVA Nudist. The analysis involved coding the transcripts into different categories by looking to identify certain interpretive themes, exemplars and particular paradigm cases.<sup>4</sup> As analysis was carried out, additional lines of inquiry often emerged and were added. A detailed account of the qualitative analysis is provided in the following chapter.

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<sup>4</sup> Benner, P. "Quality of Life: A phenomenological perspective on explanation, prediction and understanding in nursing science" [1985] 8 *Advances in Nursing Science* 1-14; Leonard, V. "A Heideggarian Phenomenological Perspective on the Concept of a Person" in Benner, P. *Interpretive Phenomenology* (London: Sage, 1994) at 59.

## 8 EXPLAINING QUALITATIVE ANALYSIS

### 8.1 KEY IDEAS

#### 8.1.1 *Qualitative Analysis: Key Issues*

A critical question in the analysis and write-up stage of any qualitative study is 'how should interpretive methodologies be judged by readers who share the perspective that *how* knowledge is acquired, organised and interpreted is relative to *what* the claims are?'<sup>1</sup> It is important to note from the outset that there is no right or wrong way to analyse qualitative data. Kvale stated:

'[One]...may, however, expect to find the magical tool for finally uncovering the treasures of meaning hidden in the many pages of opaque interview transcripts...[one] will be disappointed...The central task of interview analysis rests with the researcher, with the thematic questions he or she has asked from the start of the investigation and followed up through designing, interviewing and transcribing.'<sup>2</sup>

Thus, often notions of absolute truth, scientific rigour and objective validity are replaced. Kvale reinforces his above point in suggesting 'today, the legitimisation question of whether the study is scientific tends to be replaced by the pragmatic question of whether it provides useful knowledge.'<sup>3</sup> Thus, in examining and evaluating a qualitative inquiry the reader must accept the abandonment of a cut-and-dried scientific criteria to assess validity. Leonard suggests 'the fundamental point to be grasped in evaluating interpretive accounts is that there is no such thing as an interpretation-free objectively true account of "things in themselves", and that there is

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<sup>1</sup> Altheide, D.L. & Johnson, J.M. "Criteria for Assessing Interpretive Validity in Qualitative Research" in Denzin, N.K. & Lincoln, Y.S. (eds) *Collecting and Interpreting Qualitative Materials* (London: Sage, 1998) at 284.

<sup>2</sup> Kvale, S. *Interviews: An Introduction to Qualitative Research Interviewing* (London: Sage, 1996) at 187.

<sup>3</sup> Kvale, *ibid* at 42.

no technical procedure for "validating" that an account corresponds to this timeless, objective "truth".<sup>4</sup>

### **8.1.2 Analytical Guidelines: The Theoretical Perspective**

Benner suggests that in interpretive research, unlike in grounded theory, the goal is not to extract theoretical terms or concepts at a higher level of abstraction. The goal is to discover meaning and to achieve understanding.<sup>5</sup> As such, Benner suggests an interrelated analytical process:<sup>6</sup>

1. **Thematic Analysis:** All of the interview transcripts and field notes are read through several times. Here lines of inquiry are identified from the theoretical background of the study and from the themes constantly emerging in the data. The interpretive effort thus culminates in the identification of general categories that form the basis of the study's findings.
2. **Identification of Exemplars:** An exemplar is a "strong instance of a particularly meaningful transaction, intention or capacity."<sup>7</sup> This allows for identification of individuals' concerns, actions and practices that can capture meanings that are applicable across varying situations.
3. **Identification of Paradigm Cases:** This involves identifying strong instances of particular patterns of meanings. Paradigm cases embody rich descriptive information necessary for understanding participant's actions and understanding in a situational context:
4. **Saturation:** The transcripts are analysed up to a point of saturation. This is where it becomes evident the same themes are recurring within the interviews.

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<sup>4</sup> Leonard, V. "A Heideggerian Concept of Person" in Benner, P. *Interpretive Phenomenology: Embodiment, Caring, and Ethics in Health and Illness* (London: Sage, 1994) at 60.

<sup>5</sup> Benner, P. "Quality of Life: A Phenomenological Perspective on Explanation, Prediction and Understanding in Nursing Science" (1985) 8 *Advances in Nursing Science* 1 at 10.

<sup>6</sup> *ibid.*

5. Reflections: The findings are constantly reflected upon from the perspective of the researcher in order to negotiate a clearer understanding of the topic under investigation.

## **8.2 FROM THEORY INTO PRACTICE**

### **8.2.1 *Justifying Computer Assisted Analysis***

In order to implement the above theoretical guidelines into a practical and coherent method of data analysis it was decided that the use of tailor made qualitative analysis software was essential. This was as a result of the extensive amounts of data generated by the qualitative studies. The software package NVIVA was used as it is an effective way of collecting and correlating the data from large studies in a way that is manageable. Moreover, in accordance with the theoretical guidelines, it was decided the way in which NVIVA operates was most advantageous for a study of this kind. It allows for the identification of recurring themes; the identification of specific themes concerning groups of participants or individual interviewees; and allows for the combining of data to identify particular patterns and meanings.

### **8.2.2 *NVIVA: How it Works***

1. NVIVA operates by allowing the user to upload the various interview transcripts and observational fields notes into its database memory. The raw data can then be broken down into 'smaller projects' for each group of participants.
2. Once this has been done, the software allows the researcher to code the individual interview transcripts within each of the small projects. As each transcript is coded new 'coding categories' are created. These coding categories form the initial lines

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<sup>7</sup> *ibid.*

of inquiry and are the same across all the individual transcripts within a particular study.

3. Once all the transcripts have been coded within a small project, and the researcher is satisfied with the categories created, the data can then be collated. The program permits the researcher to view all the coding categories (tree nodes) within the small study and then identifies the number of coded entries within a particular category. This allows for verification of the recurring themes generated out of each small study and each specific group of participant's by highlighting the categories containing the most coded entries. This process remains the same for each small project containing the different groups of participants.
4. As such, once *all* the coding is complete across *all* the small projects, the researcher can compare and contrast all the themes created in reference to each particular group of participants by analysing the similarities and differences.
5. In addition to this, in order to identify specific points of interest within an individual participant's transcript, data-bytes can be used which allow the researcher to distinguish and reflect on particular issues.
6. The current project separated the raw qualitative data into the following smaller projects for the purposes of data analysis:
  - General Practitioners
  - Practice Nurses
  - Consultants & Registrars
  - Senior House Officers and House Officers
  - Consultant Nurses & Nurses
  - Patients
  - Observational Field Notes

### **8.2.3 Explaining the 'Coding' Categories<sup>8</sup>**

There are two ways in which coding can work in NVIVA. The researcher can go in with a pre-defined set of coding categories and try and 'fit' the different sections of each interview transcript into the most appropriate, or alternatively, the researcher can start from scratch and build up the categories as the coding progresses. Thus, specific themes are developed in the process of the analysis. The present research adopted the latter method.

#### **8.2.3.1 General & Recurring Themes From All Participants With Each Study**

After the initial coding was complete on each small project, there were initially a large number of coding categories, some only containing one or two entries. Thus, the aim is to condense these categories into what are the pertinent themes. In order to do this, the researcher sought to identify the general themes that seemed prevalent across all the participants from within that particular study. For example, in the medical practitioners in secondary care study the findings were presented as themes that were common amongst consultants, registrars, nurses etc. These coding categories included common issues that were identified by all the clinicians such as general problems with risk disclosure; problems with the consent form; the need to tailor information to individuals and methods of enhancing understanding. Often these general themes were broken down into sub-themes as they were analysed in more detail.<sup>9</sup> For example, it became evident that general theme of problems with risk disclosure had two key components that were broken down into problems with confusion over what to disclose and problems with statistics. This was the case with a number of the other general themes.

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<sup>8</sup> For a complete worked example of the analysis of an interview transcript see appendix [4].

<sup>9</sup> This was done with a view to maintaining a circular movement in the research process moving between the 'parts' and the 'whole' in order to negotiate a clearer understanding.

### 8.2.3.2 Specific Themes From Each Individual Group of Participants Within Each Study

Also, in order to act as a point of comparison, it was essential to identify any themes that were relevant to a specific group of participants. For example, in the medical practitioners in secondary care study it became evident a particular concern for consultants was the requirement to quote personal statistics. In addition, a specific theme in relation to nurses was how they perceive their role in bridging the gap in communication. Thus, it became possible to identify the similarities and differences in the themes as and between the different groups of medical practitioners. There were also some differences present in the primary care study between general practitioners and practice nurses and some variation in themes between the defendant and claimant solicitor.

### 8.2.3.3 Comparing Themes Across Different Studies and Different Participant Groups

Finally, all the themes from within each study were compared and contrasted with each other. Thus, for example, the themes portrayed by medical practitioners in secondary care were compared to those in primary care. One of the main differences being the emphasis on risk disclosure seemed greater in secondary care. Likewise, patient themes were compared to clinicians in secondary care and it became evident that the underlying importance attached to consent is different for patients than it is for the medical practitioners. Finally, the observational themes were compared with what both the patients and clinicians said to act as a point of triangulation.

## 8.3 ADDITIONAL REFLECTIVE TECHNIQUES

### 8.3.1 *The Research Journal: Tracking the 'Legal Reflections'*<sup>10</sup>

Fontana and Frey have suggested that many studies using unstructured interviews are not reflexive enough about the interpreting and understanding process. They suggest:

'Common platitudes proclaim that data speak for themselves, that the researcher is neutral, unbiased, and "invisible". Data reported tends to flow nicely, there are no contradictory data and no mention of what were excluded and/or why. Improprieties never happen and the main concern seems to be proper, if unreflexive, filing, analysing, and reporting of events.'<sup>11</sup>

They then say 'anyone who has engaged in fieldwork knows better.'<sup>12</sup> With this in mind, an on-going research journal was developed to assist in the reflective process. Entries were made in this journal after each interview and observation and after each stage of the analytical process in order to identify the on-going legal connotations of the research findings. This was used in addition to the paper-based analytical document (discussed below) to allow for the tracking, identification and discussion of significant legal reflections within this research.

### 8.3.2 *Assisting NVIVA: The Paper-Based Analysis Document*<sup>13</sup>

In addition to the research journal, a paper-based document was developed by the research to assist in the analysis the data. This enabled the researcher to chart the development of the work by identifying the major themes and legal reflections after each individual interview was analysed. This was used in conjunction with the

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<sup>10</sup> For extracts from the research diary, see appendix [4].

<sup>11</sup> Fontana, A. & Frey, J.H. "Interviewing: The Art of Science" in Denzin and Lincoln, *op cit* n 1 at 56. The concluding chapter of this thesis is written as a reflexivity chapter.

<sup>12</sup> *ibid.*

<sup>13</sup> For an example of the paper-based analysis document see appendix [4].

research journal and shaped the understanding of the researcher within each stage of the data analysis. This culminated in the reflexivity chapter at the end of the thesis.

## **9 STUDY 2: INFORMED CONSENT IN PRIMARY CARE**

### **INTERVIEWS WITH HEALTH CARE PROFESSIONALS IN PRIMARY CARE**

#### **9.1 INTRODUCTION**

This section of the study explores informed consent in primary care. It employs qualitative interview methods to investigate what actually happens in respect of consent in practice and elicits the views and opinions of health care professionals who are actively involved in the process. It looks at the dynamics of the consent transaction and identifies how consent is obtained, whilst at the same time ascertaining what is important to the health care professionals in their everyday practice when they are dealing with patients. Three GP's and two practice nurses were interviewed. The interviews were transcribed and uploaded into NVIVA for computer-assisted analysis. A thematic analysis was conducted on all the interview transcripts and the findings are discussed in the context of the identified themes.

The study begins by providing a brief justification for the work and then progresses to discuss the procedure, participants and methods of analysis. It then moves on to provide the substantial discussion of findings and, finally, in keeping with the philosophy which underpins the qualitative methodology, there is a reflexive section which reflects on the findings in a legal context.

#### **9.2 JUSTIFICATION**

Health care professionals engage in some kind of consent procedures before they examine or administer treatment to patients. What is poorly understood is the dynamics of these procedures in primary care and how they relate to legal theory. As there is little in the way of empirical research concerning the above, this study

investigates these issues using qualitative research methods to develop an understanding of informed consent in primary care.

### **9.3 RESEARCH QUESTION**

To investigate and develop a clearer understanding of consent procedures and issues in primary care settings. See chapter 7.3 for a full list of research questions.

### **9.4 SUMMARY OF PARTICIPANTS**

The number of participants in this study was:

General Practitioners (N=3)

Practice Nurses (N=2)

All the participants were practising health care professionals employed by a large general practice.

### **9.5 METHODS**

This component of the study employed semi-structured qualitative interviews. Please see chapter 4.8 for further discussion.

### **9.6 ANALYSIS**

The interviews were transcribed and uploaded into the software package NVIVA. The transcripts were then analysed using the computer-assisted software to identify recurring themes. See chapter 8 for further discussion. As this is a qualitative study, within the discussion there are no references to numbers of participants or percentages. However, for a summary of figures relating to the number of themes and the importance attached to each, please see the tables at the end of this study. (See section below for further details).

## **9.7 ORDER OF THEMES**

As the studies started out with no pre-defined themes, the themes are presented in the order in which they developed from the base upwards within each particular study. Within the findings below, the importance attached to each theme is noted in brackets underneath the relevant heading. The level of importance was assessed by the number of times each theme occurred within the transcripts. However, for a complete summary, and to identify the importance attached to each particular theme, refer to the table providing the summary of themes in section 9.12 of this study.

## **9.8 STUDY LIMITATIONS**

This study was based in only one general practice within the UK. Thus it is impossible to generalise in relation to the findings. The research itself was extremely concentrated in the sense that it targeted only one surgery, yet this was the aim of the question. Despite this, the work was conducted at an extremely modern surgery whose practices undoubtedly accord with national standards. Thus, in all probability, it can be said to be a fair reflection of what takes place across the country in respect of consent practices in primary care. In addition, what the study lacks in representativeness, it makes up for in terms of depth, boasting some very detailed qualitative findings.

## **FINDINGS**

### **9.9 THEMES FROM HEALTH CARE PROFESSIONALS IN PRIMARY CARE**

#### ***9.9.1 Researcher's Note***

Due to the nature of the semi-structured interview format not all the answers provided by the participants were directly related to the initial question posed by the researcher. Often a topic was introduced and then the participant would elaborate on this in great detail. Thus, a number of themes overlapped and this was drawn out in the analysis. Accordingly, within the discussion section, the extracts provided as evidence sometimes do not marry up with the precise nature of the question asked and, in some instances, the initial question posed by the researcher is not displayed. Also, in the findings which concern the common themes across all health care professionals, extracts provided are a mixture from both the general practitioners and practice nurses.

#### ***9.9.2 Theme 1: Emphasis on Understanding***

\* (There were 30 occurrences of this theme in the general practitioners' interviews and 12 occurrences within the nurses' interviews. A total of 42 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

The most evident pattern within the research findings is that the main concern for both general practitioners and practice nurses is to obtain consent not with a view to safeguarding themselves from the threat of legal action; rather the predominant issue is one of patient understanding. There are indications that consent is seen as a reciprocal process in which the patient should be involved in order to enhance the understanding of their condition and the subsequent treatment. This is demonstrative of a commitment towards shared-decision making.

**Researcher:** So...how would you define informed consent?

**General Practitioner No 3:** Informed consent would then be for me a feeling that they or their representative could read, had understood what the approximate diagnosis and prognosis of whatever we were talking of was. Within the concepts and the willingness of them to learn about it. And that they were happy with my diagnosis... and that they were also happy with my competence. And the ability to make a choice or they could go somewhere else and get a second opinion if they wanted which would be quite fine... and we would then proceed with their informed consent to make arrangements for that to happen.

In addition the participants seem to acknowledge that understanding is particularly subjective and is not dependant upon age. Whilst there may be some older patients who find difficulty in understanding what is said, others are extremely intelligent and articulate. Equally, there may be some younger patients who are poorly educated and who are less capable than older patients. It appears the health care professionals in this study feel the key to understanding is connected to the relative educational background of the patient and this can only be judged with reference to the individual.

**General Practitioner No 2:** ...Yes on a broad spread. But you will have the older person who has access to the Internet who has relatives who are involved in all kinds of professions and they will be as questioning as the 20-year-olds. So it is a bit of an education spread really amongst the older people so the more educated, better off older people will be more questioning than the less well off older people, but at the other end of the spectrum they will ask more questions the younger they get.

### **9.9.3 *Theme 2: Informal Consent Procedures***

\* (There were 24 occurrences of this theme in the general practitioners' interviews and 11 occurrences within the nurses' interviews. A total of 35 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

The findings indicate that generally the types of consent obtained in primary care in this study are largely consent by implication or consent expressed orally. For example, the most common type of procedure where consent is required is an injection. For the most part it seems patients roll their sleeves up and lift their arm to indicate their willingness to accept the treatment. This in itself constitutes a valid

consent. However this is likely to be accompanied by some sort of oral exchange between practitioner and patient. Apparently this process remains the same for physical examinations such as smear tests, intimate examinations or anything else that requires physical touching.

**Researcher:** What sort of minor operations do you do here?

**General Practitioner No 3:** Lumps and bumps mainly eg cysts, in-growing toe nails etc. I mean it might be that I would then go and get some cauterisation material and I would freeze off a wart on their back and I may have got a signature from them to do it or I may give them a prescription for an antibiotic. Or I might say well I am going to refer you to a counsellor. I very rarely get written consent for any of those things but I would like to think that I have a constant open dialogue.

It seems evident that the health professionals in this study feel that verbal consent is more appropriate. The findings demonstrate that the general practitioners and practice nurses are resistant to introduce formalities in consultations they believe are best carried out in a relaxed and informal atmosphere. The participants said that demanding written consent has the potential to make things 'a bit legalised'. Whilst it remains important not to generalise too much from such a limited study, the findings suggest the respondents believe this may create tension and worry for the patient which the triviality of treatment simply does not justify. On the other hand, there remains an acknowledgement that the benefit of a more formalised process stresses its importance.

**Researcher:** Do you think it is better to have it written down?

**General Practitioner No 2:** 'Well I think it can get a bit legalised really and a bit technical. So the downside of it is that. And that can play up the importance of it which can be a positive thing...but with something like immunisations, people have got enough doubts about immunisations and to put in another kind of process that makes it more official, more formal, doesn't feel absolutely right.

It appears these medical practitioners in primary care are not concerned with requiring written consent as a means of providing protection in the event of complaints. It seems they are unperturbed by the threat of legal action, rightly identifying the

chances of being sued as a general practitioner or practice nurse as very slim. What matters is not how the consent is expressed; the pivotal issue, from the participants' point of view, is that the patient actually has given consent after getting the relevant information and understanding it to a certain level.

**Researcher:** Would you prefer it, in order to protect you, from your point of view, because it is more documented, in writing?

**General Practitioner No 2:** I think the chances of us getting into trouble are quite small and we are also doing what is accepted practice. I mean having read through the PCT's Manual it was accepted that is the case. Really what I have to do as far as the law is concerned is do what most reasonable doctors would do and the PCT say it is a reasonable practice.

The practice under investigation carries out minor operations. It is apparent these are potentially invasive procedures that involve a degree of physical contact with the potential for some resultant harm should something go wrong. Thus, in accordance with standard consent procedures for invasive treatments in secondary care one might expect use of written consent. This proved not to be the case. Consent for these procedures is again oral or implied. There is varied opinion as to the appropriateness of this. Some of the participants indicated they feel it is appropriate to continue to adopt these methods of consent whereas others seem to be drawn one way with logic and reason and another by heart and tradition. Thus, although the basic principles of consent remain the same no matter what, there is some inclination towards harmonising consent procedures across primary care with further signals that it may be desirable to introduce written consent, particularly for patients from outside of the practice. It seems clear the real concern is the need for some guidance in relation to consent for minor procedures. This guidance does not need to be in the form of specific instructions requiring written consent, as there is an indication for distaste if things were to become too regimented. Nevertheless, it seems the feeling amongst the participants is that some sort of guidance, perhaps in the form of a PCT circular,

would be welcomed to allay their fears by confirming that verbal consent to these minor procedures is acceptable practice.

**Researcher:** Do you think it is possible to harmonise consent procedures throughout all primary care trusts?

**General Practitioner No 2:** I think the basic principles are the same and it would be good practice, in this situation to obtain a written consent. I mean we do minor operations for people outside of the practice and maybe we should get written consent from those people who we don't know and who we haven't referred. I don't know whether they do, they may do. So I think you should have some guidance but I would hate it to be "this is how it has to happen everywhere."

#### **9.9.4 Theme 3: Feelings about the Law**

\* (There were 41 occurrences of this theme in the general practitioners' interviews and 12 occurrences within the nurses' interviews. A total of 53 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

The findings demonstrate mixed feelings about the law. It appears that it does not feature greatly in the day-to-day thoughts of the general practitioners and practice nurses in this study. Their main concern seems to be the needs of the patient. However, the findings do suggest that more emphasis is placed on the legal side and that medical practitioners are certainly more conscious of the law than they used to be. Irrespective of this, it is evident that this new found awareness for the law has little effect on the day-to-day practices in primary care, particularly in respect of consent. This almost dispels any conjecture relating to defensive medicine, as it appears the law does not alter the practices of these medical practitioners in primary care. These general practitioners believe they are unlikely ever to be sued.

**Researcher:** Do you think there is a clear emphasis on the legal side of it nowadays in medical practice?

**General Practitioner No 2:** I think that people are more fearful of it the medical/legal stuff and if you do ever get involved in the medical/legal stuff it is horrendous. It is terribly pernicky. Personally I always just like to try and keep a balance on that one. I mean there is a lot more written about it and our insurance has gone up, but as an individual GP the chance of getting like sued for anything are actually quite small. Even informal complaints against GPs are not many.

The key for the health care professionals seems to be performing their role with as much skill and diligence as possible. Accordingly, it is evident that the interests of the patient are the paramount considerations at the forefront of the medical practitioners' minds.

**General Practitioner No 2:** ...Well I think that is certainly something that people worry about and I think to a degree it happens. I think the kind of question you would have at the back of your head "could I get sued for this" is actually the same question is "is the patient likely to come to any harm am I doing something wrong." So I think it is really healthy that we ask that question and that we have that fear and we get paid a lot of money so you know there are some consequences.

Two further points are worthy of mention here. Firstly, some of the participants acknowledge this may change in relation to secondary care where medical practitioners perform more invasive surgery.

**General Practitioner No 1:** Probably should but it doesn't actually come into my day-to-day thinking...no it is not at the front of my mind. On the other hand if you start doing operations you would probably be concerned a little bit more.

Secondly, the practice nurses note that there is some concern in relation to their specific role. Due to the changing nature of their job they are unsure as to the legal position regarding the standard they will be judged in accordance with. These issues are highlighted in the latter part of this study and are discussed specifically in respect of the practice nurse's themes.

#### **9.9.5 Theme 4: Disclosure Trends in Primary Care**

\* (There were 26 occurrences of this theme in the general practitioners' interviews and 15 occurrences within the nurses' interviews. A total of 41 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

It would appear from the findings that there is much less prominence attached to risk disclosure in primary care than in hospital settings. This may reflect the fact that any procedures administered tend to be minor and are only minimally invasive. However,

there is still an indication that providing the patient with adequate information is a desirable concept and one that is adhered to in the health care professionals' practice.

The key here is that the information remains adequate, but not excessive.

**Researcher:** As a medical practitioner what is your definition of informed consent?

**General Practitioner No 2:** That is really a patient agreeing to a procedure or a treatment in command of a reasonable amount of information. You can't necessarily tell somebody absolutely everything that might happen, but I think that people should know the things that are common consequences of a treatment both the harms and benefits and some of the rarer things. But like I say you can't go into everything and it is also about what the patient wants to know.

Drug therapies aside, which are dealt with below, surgical procedures in primary care are mainly trivial and risks so infrequent that they fall into the bracket of justifiable non-disclosure. Here a general discussion about common risks such as pain, bleeding and bruising may suffice, but anything more may be so insignificant that the doctors and nurses seem to disregard them, or they may well forget or even be unaware of them. Also, there may well be time constraints affecting the amount of information that can practically be disclosed. Medical practitioners in primary care work under a busy schedule and must be economical with their time. The perception seems to be that it is counter-productive to engage in elaborate discussions about issues which may well be surplus to requirements.

**Researcher:** What sort of risks do you disclose in practice?

**General Practitioner No 1:** At the moment we talk about procedures. With regard to the cryotherapy, sort of freezing things off, I explain to them that it may be painful, it might not work and they may get blistering.

**Researcher:** Do you think they ever get put off by you explaining the risks to them, are you conscious of that?

**Participant:** I have not really had any patient refuse outright. A few are concerned about the pain factor. The risks in minor surgery i.e. cutting things out, are so rare that we tend not to discuss the side effects.

**Researcher:** Do you think you should?

**Participant:** The side effects usually are the wound not healing properly or getting infected and as this so rarely happens it is probably not that significant.

In relation to medical practitioners' willingness to discuss different treatment options it seems clear that they do this. However, this in itself brings difficulties. The participants intimate discussions about alternatives are extremely useful for the diligent patient who wishes to go away and learn about their condition and make a decision in command of the full facts. The general feeling amongst the health care professionals seems to be that it is useful to disclose the different treatment options. However, this may cause problems in that it may not be what some patients want. The findings in the later patients' study suggest some patients may want decisions taken for them and are often willing to consent in ignorance. In these situations counselling about alternatives may serve to confuse almost to the extent where, as one participant suggests, they talk themselves into a corner saying 'should I or shouldn't I?' Thus, whilst it is encouraging that the professionals in primary care are willing to openly engage in treatment options, the real problem lies in actually getting the patient to co-operate and take an active interest. The view seems to be that putting 'the ball back in the patient's court' can cause a certain amount of tension.

**Researcher:** Would you disclose things like perhaps alternatives to the suggested treatment?

**Practice Nurse No 1:** Yes certainly I know, I am trying to think of examples which is difficult. But yes I would always work around the different options that are available. And that is where patients find it hard because if you are deciding, for example, if I was talking to somebody about a sore throat and there is not a lot of evidence to support that antibiotics work for sore throats I would give the patient the choice. You know...you can have antibiotics for this sore throat but there is the chance that they might not work and you are taking antibiotics that are unnecessary so you are actually putting the ball back in their court. And they are having to make decisions and sometimes people aren't that comfortable with that.

### **9.9.6 Theme 5: Paradigms of Care**

\* (There were 25 occurrences of this theme in the general practitioners' interviews and 15 occurrences within the nurses' interviews. A total of 40 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

There are a number of attitudes and opinions relating to the different models of care. Historically, the medical profession has been associated with a paternalistic standard of care. Yet, of late, within contemporary medical literature there has been a subtle move away from this towards a paradigm that respects patient autonomy. Nevertheless, the findings indicate that despite the fact that professionals recognise the importance of autonomy, it becomes clear they are often faced with a dilemma where they have no other choice but to resort to paternalism. Thus, it appears that even though the medical practitioners under investigation may have the best of intentions when it comes to getting patients involved, there are certain types of individuals who continue to pose problems for them. For example, the perception seems to be that older patients or very ill patients often ask for decisions to be taken for them and the health care professionals are not comfortable with this.

**Researcher:** ...do you find that happens a lot with patients?

**Practice Nurse No 2:** Maybe not quite so much here. It probably it does happen more with elderly patients because they come from more that type of culture. The doctor sort of knows best culture. And that often extends to the nurse knows best and I think particularly when people are quite ill they are not always in a position to make that sort of a decision. Sometimes they want that decision taking off them... sometimes I think they want you to make that decision for them and that can sometimes feel a bit uncomfortable because you don't want to push them.

In some situations both the doctors and nurses are aware they may influence patients' decision-making. However, in the face of comments such as 'whatever you think best', short of denying treatment altogether, health care professionals may have no other choice than to act in the best interests of their patient. The concept of 'best-interests' is something that many contemporary medical lawyers approach with

caution. It is often thought to be interchangeable with the concept of paternalism and thus in the present climate medical practitioners should be wary of relying on it as a ground for making decisions for patients. The health care professionals seem to frown upon acting paternalistically, whilst at the same time feel in some situations it is appropriate to act benevolently. Here we begin to gain real insight into the problems faced by medical professionals and how this relates to the dynamics of the consent process. Within some professional consultations experts may inadvertently lead the client towards the preferred professional course of action which they perceive will lead to the most desirable outcome. The participants in this study acknowledge that this problem is compounded by the environment in which they are brought up. According to the participants, historically, the concept that 'doctor knows best' has underpinned the way in which health care professionals have been educated, which, entwined with Hippocratic tradition to always act for the benefit of the patient, has made it difficult to depart from the cultural values associated with making the decision for the patient. This can happen even when they have the best of intentions to involve the patient in treatment decisions. What is illustrated by the findings in this study is that medical practitioners perceive a difference between paternalism and beneficence.

**Researcher:** So where do you feel that trust breaks down?

**General Practitioner No 2:** A basic lack of communication skills. Add to that an attitude of arrogance and good old-fashioned paternalism. Perhaps if it is benevolent it can be OK but it is when there is a loss of respect and the doctor is not treating the patient with respect and the doctor is behaving paternalistically is when things can start to go really wrong.

**Researcher:** Do you think that happens a lot? Do you think there is a historical tradition within the medical profession?

**General Practitioner No 2:** Yes and in health and even though things are shifting but we are still brought up in that tradition that the doctor knows best and it is hard to break those type of cultural norms.

One of the further sub-themes which becomes apparent is the way in which there is potential for professional discretion to overlap with paternalism and beneficence. There is scope for this, yet it appears the medical professionals under investigation here view the two as separate. As identified above, there are some situations where the autonomy enhancing model of care does not work. In these circumstances it is worth considering Henderson's assertion as early as 1935 that 'physician deference to the patients' autonomy rights is dangerous because it compromises clinical judgment and presents a hazard to the patient's health.'<sup>1</sup> For example, if the patient is adamant that they do not wish to exercise their right to certain information it seems strange to maintain medical professionals are still under an obligation to provide it. Indeed, this may directly conflict with the Hippocratic traditions of beneficence and non-malificence.

**Practice Nurse No 2:** ...Yes some situations are that they just shut off they don't actually want it. I can just think of one chap who I talked about cholesterol with him and I had just discovered about all the finer points of cholesterol and went into all this detail with him and he just did not want to know this. Absolutely did not want to know this. He just wanted to know "do I take the tablets or do I not?" That was all he wanted to know he wanted me to tell him that.

**Researcher:** Is that very difficult?

**Practice Nurse No 2:** Yes it can be because it is very difficult because you find yourself making a sort of a...sometimes...an almost a qualitative judgement as to that persons level of understanding and sometimes that can feel a bit uncomfortable.

Here the findings suggest that a certain amount of professional discretion is required in deciding what to tell the patient. More often than not this will usually be done with the patient's best-interests in mind in the sense that medical practitioners are sometimes required to make a judgment about how much to tell the patient without causing them unnecessary mental or physical anguish. As a result of this, the feeling amongst the participants seems to be that often doctors and nurses are in an awkward

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<sup>1</sup> Henderson, L.J. "Physician and Patient as a Social System" (1935) 212 *New England Journal of*

position of having to make a qualitative judgment as to what to tell the patient. There appears to be a general feeling of discomfort when this problem arises. This feeling of unease is caused because patients may ask them to withhold information or even make decisions for them which is in direct conflict with patient autonomy. On the other hand, forcing information on patients would almost defeat the very purpose it is striving to achieve. It seems the medical practitioners within this study view the exercise of professional discretion in deciding what to tell patients as different from paternalism.<sup>2</sup> As long as the original intention is one of information-sharing it seems making a judgement as to what to divulge based on an assessment of the individual patient may, in some circumstances, be acceptable. Typically this will include situations where the patient is elderly or is extremely sick; where they are of a particularly nervous disposition; or where they will become so anxious upon hearing certain information that disclosure of it will be detrimental. All of the above factors have the effect of hindering the patient's capacity to understand and use the information. These examples, coupled with where the patient explicitly requests not to be told something or to have the decision made for them, represent the times where the medical practitioners here feel justified in using some discretion in disclosure. Despite this, what is recognised is that each case should be judged on its own merits.

**Practice Nurse No 1:** ...I think it is quite exciting when patients come in and they are fully aware of what the treatment options are and they want to debate that with you. So no it is better that they have got a clear understanding. But then sometimes people talk themselves into a corner "shall I shan't I, what decision shall I make?" and you have to be careful that you are not trying to guide them into the place that you want them to be in.

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*Medicine* 819 at 823.

<sup>2</sup> It is important not to regard professional discretion with the same distaste as hard paternalism. Whilst it could technically be classed as a form of paternalism, Feinberg suggests there are two levels of paternalism that arguably should be treated differently. In invoking professional discretion when deciding what to disclose it may be medical practitioners are only engaging in what is known as 'soft paternalism'. This would encompass situations such as obtaining consent that is not adequately informed in light of particular circumstances. See Feinberg, J. "Legal Paternalism" (1971) 1 *Canadian Journal of Philosophy* 105.

### **9.9.7 Theme 6: Reluctance to Withhold Information**

\* (There were 5 occurrences of this theme in the general practitioners' interviews and 9 occurrences within the nurses' interviews. A total of 14 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

The findings provide a valuable insight into the reluctance of medical practitioners to act paternalistically by withholding information. Nearly all the participants exhibited distaste for withholding information from patients. A common theme amongst the health care professionals seems to be it is only on the rarest of occasions that it ever happens and this is usually only when the patient requests it. The participants indicate that if this request is made it should be respected as it would be detrimental to the patient to not conform to their wishes. Also, there is a suggestion made that even if the information is imparted, if the patient does not want to hear it they will not do so. This has the effect of rendering information disclosure a meaningless exercise. Irrespective, some interviewees said it is desirable to keep checking with the patient that they wish to continue in ignorance, because there are some instances where the patient may wish to change their mind and it is best to clarify this.

**Researcher:** Would you ever withhold information from a patient?

**General Practitioner No 2:** There are extreme situations where a patient has told you in advance "I do not want to know." And if a patient says to you "I just don't want to know the results of this test" or "I just want you to do what you think is right and I don't want you to discuss it with me." And over the course of the years I have had that once or twice.

**Researcher:** Is that very difficult?

**General Practitioner No 2:** It is very difficult but you have to go along with it. But you have to keep checking out "do you want to know anything else do you want me to tell you what is happening" because if they are not ready to hear the information they won't hear it. Or it could be devastating for them and they will not be able to handle it.

It was interesting to note that none of the participants in general practice specifically referred to withholding risks from patients. This may reflect the fact, as indicated by the extracts above, that risks are perceived to be so trivial in primary care that the health care professionals do not think it is necessary to

disclose them. The focus here centres on a reluctance to withhold general information about treatment and also treatment alternatives.

### **9.9.8 Theme 7: Language Problems**

\* (There were 2 occurrences of this theme in the general practitioners' interviews and 6 occurrences within the nurses' interviews. A total of 8 occurrences combined across both sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 9.12 of this study).

Within the sphere of general practice it seems there is a contentious area concerning language problems. Whilst this could perhaps be incorporated into a more general discussion about understanding and its role in the consent process, it presented itself as an issue worthy of discussion. The practice under investigation has a catchment area with a range of patients from different ethnic minority backgrounds whose first language is not English. Thus, the practice provides a number of written information sheets in minority languages. However, this does not provide a complete solution to all the problems. Firstly, one of the issues resides in the patient's capacity to understand the information. Arguably true consent can never be given in ignorance, and any information that is provided fades into insignificance if the patient does not have the linguistic capacity to digest it.

**Researcher:** So in some situations it seems the wrong thing to do to supply them with too much information?

**Practice Nurse No 2:** ...I suppose the other situation that we get here are lot are people who do not speak English as their first language and to be sure that you have got genuine informed consent there is extremely difficult. Sometimes they might come without an interpreter and then it can be very hard. And one situation that we might get is coming for childhood vaccinations and sometimes do you think "do they really understand this" but then again they are often very happy to let you do it. So it is a bit difficult that you are intent on trying to make them understand and they just say "stick this needle in my child I am sure it is best for them." But there might be the odd occasion when you feel that the interpreter is putting their slant on it, although having said that a lot of them are very very good and I would put that as a general thing. But maybe more in the using of a member of the family as an interpreter which we try to discourage but obviously doesn't always happen.

Secondly, often information is given via an interpreter. Here, it is evident that the participants are not entirely comfortable with obtaining consent in this situation because the discretion used in information disclosure switches from the medically qualified professional to the interpreter. What to say and how to say it is now a matter for a lay person and this poses difficulties, particularly as it is always possible that they could put their own slant on things. Indeed, a number of the medical practitioners intimated this is a problem that needs to be guarded against, even more so when the interpreter is a member of the family. This is an especially difficult situation. The cultural backgrounds of some of these patients may well lead them to perceive the medically trained expert as having an all-pervasive knowledge, which encourages acquiescence to medical advice. Moreover, often these values may place female patients in a particularly weak position in the face of male interpreters who may seek to exert strong influences over their decision-making. The desirability of implementing a certain number of safeguards is recognised by both doctors and nurses. These include employing a recognised body of interpreters with some specific training and discouraging the use of members of the family.

**Researcher:** Is there a problem in this practice in obtaining informed consent from people with ethnic backgrounds where there is a language barrier?

**General Practitioner No 1:** Oh yes. I think it is harder but we do have a paid interpreter present that is mainly for the asylum seekers. Many have a family member as the interpreter, but because of this it is not always easy to ascertain what has been understood and whether or not consent should be given through a third person.

## 9.10 SPECIFIC THEMES: *GENERAL PRACTITIONERS*

### 9.10.1 Theme 1: Problems with Risk Disclosure & Drug Therapies

\* (There were 15 occurrences of this theme in the general practitioners' interviews. For further details refer to the table providing the summary of GPs' specific themes in section 9.13 of this study).

One of the specific themes identified by the general practitioners concerns the problems inherent in drug therapies. These are by far the most common forms of treatment administered in primary care which entail risks, some trivial and some more serious. Manufacturers of drugs often provide an exhaustive list of all possible risks and side effects. The reality is that these risks may be insignificant and transpire extremely infrequently, if indeed at all. Medicine is dynamic and continues to evolve. The feeling portrayed in this study is that this poses a problem for doctors as new products are entering the market frequently and risks are developing all the time.

**Researcher:** So what sorts of risks would you disclose then to your patients?'

**General Practitioner No 3:** 'Not a lot. I don't have the time and this is something that I feel really embarrassed talking to you about informed consent. But I couldn't because I can't remember half the risks every time I prescribe a drug. I can't remember half the side effects. I only know about 1/10<sup>th</sup> of the side effects of any possible drug and I don't know whether people know that or understand it.

**Researcher:** I see...

**General Practitioner No 3:** I know what tends to happen and what doesn't happen within my own experience and if it hasn't happened I don't tend to register it because I can't remember. I have not read up on all the drugs half the drugs weren't around when I studied as a medical student and I have never even studied them. So if you look at the most common thing that I do prescribing drugs I think I am very bad at telling people what the risks are.

It is apparent that there are so many risks associated with drug therapies it is unrealistic to expect doctors to know or remember them all. The findings highlight that many of the drugs currently in circulation were not in existence at the time of doctors' education. It is evident that a lot of what is told to the patient regarding risks comes with practical experience. If the risk has transpired in the course of the doctor prescribing that particular drug, then understandably it will be etched in their memory

and is more likely to be disclosed. If certain risks have never occurred, which in respect of drug therapies may be many, the indication is the doctors may not register it. In addition, and specifically in relation to primary care, it is apparent the dynamics of the consultation process do not allow for an elaborate and detailed discussion of all the side effects associated with drugs. First and foremost there are simply too many, and secondly, there simply is not enough time.

### ***9.10.2 Theme 2: Identifying and Redressing the Imbalance of Power***

\* (There were 16 occurrences of this theme in the general practitioners' interviews. For further details refer to the table providing the summary of GPs' specific themes in section 9.13 of this study).

A further theme identified specifically by general practitioners was the imbalance of power within the doctor/patient relationship. The participants acknowledge this is a problem and indicate a number of ways in which they attempt to redress this. The findings suggest that patients, especially the older generation, are often afraid to question their doctor as they are conscious of technical jargon and the fact that the doctor's knowledge is superior. However, this problem is somewhat inescapable as imbalances of power exist within any professional consultation. Irrespective of the fact that there is no complete answer to this problem there are certain things that can be done to alleviate the difficulties encountered in professional relationships. For example, the participants demonstrate a number of ways in which to combat this problem. These are to listen to the patient, attempt to put them at ease and, where possible, explain things in simple terms. There are further indications that it is important to ensure the patient is concentrating and not losing track of what is being said. The knock-on effects of these measures are of course that they improve patient understanding in addition to encouraging communication.

**Researcher:** Why do think communication breaks down in the first place?

**General Practitioner No 1:** It is difficult. I am not sure that we always know. I do sometimes feel that they are intimidated and can sometimes feel inhibited in asking questions.

**Researcher:** Do you think sometimes that they feel "oh I don't want to bother the doctor?"

**Participant:** Yes and certainly you need to make sure that you do listen to the patient and that you try and make sure that the patient does not lose concentration whilst you are explaining the symptoms. Patients will sometimes switch off after you have mentioned one or two minor symptoms and then miss out on the most important thing.

In actual fact effective communication seems to figure highly on the general practitioner's minds. However, this ought to be approached with caution. On one interpretation of the interviews, it seems doctors' primary concern is to encourage communication about symptoms. Indeed, a suggestion is made that doctors are trained to encourage communication with patients in order to reach an accurate diagnosis. For example, it seems patients are often only willing to divulge minor symptoms and tend to miss out or forget the key ones; it is only after the doctor has encouraged them to be honest and discuss things openly that these important and underlying issues are identified. Encouraging openness and communication in respect of this is very much a means to an end and is different from the communication that is needed to enhance the consent process. In order to improve the consent process, communication has to be encouraged about the treatment and its subsequent effects in a much more general sense so the patient can be kept informed and in command of the necessary information about risks, benefits and alternatives.

### **9.10.3 Theme 3: Communication Breakdown**

\* (There were 28 occurrences of this theme in the general practitioners' interviews. For further details refer to the table providing the summary of GPs' specific themes in section 9.13 of this study).

One of the patterns which emerges from the findings highlights the fact that general practitioners seem to think it is highly unlikely that they will ever be subject to legal proceedings. In particular the participants seem to think that the chances of any complaints arising out of inadequate consent procedures in primary care are so slim as to be almost insignificant. In any event, some of the participants emphasise the law will condone informal consent procedures as long as this practice is standard across the board in general practice, and as long as it is a practice which is accepted by the majority of their peers. In addition, the findings provide an insight into where general practitioners feel complaints arise.

**General Practitioner No 2:** ...It isn't just in health it is across the board. If something happens then you want to blame somebody. I know that doesn't always happen, people may say it. I still think underpinning most of cases that go to court, or a lot of the cases that go to court, is actually a breakdown in the doctor/patient relationship. It is somebody feeling or it is being perceived that they are being rude, or dishonest or lacking in respect.

This is concerned with the doctor/patient relationship breakdown. Patients will only ever complain if feel they have lost trust in the doctor and this is where the close knit relationship tends to deteriorate. There are a number of reasons offered as to how and why the feeling of trust is lost. These include such things as lack of effective communication, failure to talk openly with the patient and, most importantly, where patients feel the doctor has not been honest with them. The general undertone seems to be that complaints are most likely to be pursued under these circumstances and it appears general practitioners are conscious of this fact.

#### **9.10.4 Theme 4: Changing the Cultural Norms**

\* (There were occurrences of this theme in the general practitioners' interviews. For further details refer to the table providing the summary of GPs' specific themes in section 9.13 of this study).

A further theme that developed was how the general practitioners felt about the power relationships, where they perceive the problem stems from and how it can be addressed. In a sense this can be categorised as a theme that is distinct from the consent process itself and is a wider concern related to society as a whole. The general practitioners in this study are all too aware that the imbalance of power is problematic and the feeling is that it is caused by the social norms that characterise the patient as being at a disadvantage. They may often feel trapped in a position of hopelessness in the face of medical consultations, which in turn has encouraged a culture whereby it is acceptable to receive advice from doctors unquestioningly. The findings indicate that these views may derive from a variety sources which influence and imprint into patients a feeling of intimidation which prevents them from questioning doctors' authority.

**General Practitioner No 3:** ...there is a complicated context there that historically people don't expect to do very much work themselves. The patients expect me to do it and I am constantly trying to change that in my practice locally and even nationally. And saying "hang on you people should be doing a lot more work on this yourself before you come and see me" because there is a lot of stuff I don't know. If there are several different options and I only know one the only thing I can give you informed consent for is for the one option I know. And I don't think that is good quality of care... there actually comes a time when you do make some decisions, you learn to control yourself, do stuff for yourself so I think the culture is changing but I don't think it is changing anywhere fast enough. And I don't think it ever will do. I think people just want to have simple decisions and simple lives and that is the way it should be I suppose.

This creates a paradox as doctors themselves, more often than not, would prefer patient input. It is evident from the interview extracts that one of the answers to this problem may be found in the youth of today. It has already been demonstrated that it is very difficult to encourage the older generation to break from the cultural values as

described above, yet it is possible to influence younger generations. Change is evolving very slowly, but it does seem clear that the perception amongst the participants is that young people are becoming more outspoken. Whilst there may be a tendency to frown on this in some circumstances, the findings suggest that this should not be the case.

**General Practitioner No 3:** ...So I find that the way young people are very in your face and saying stuff that you have never thought out at all. I find it quite painful it embarrasses me but what I think is so positive about it is they have got the ability to say what they think to be what they want to be.

In addition, there are a number of issues highlighted concerning the problems with shared-decision making as a concept. So much emphasis has been placed on the role of the doctor or the nurse in this model; very little emphasis has been placed on the patient.

**Researcher:** So you think there should be more emphasis on the patient to get informed?

**General Practitioner:** A huge emphasis on the patients. People in inner city Manchester die 6-7 years earlier than people in Cheshire or richer parts of the country and why is that? It is because they don't like choices. They don't take the time to do what they ought to do, they are not empowered to do it so they die 6-7 years earlier and it is not an opinion it is a fact. So they are not being shot, they are not being eaten by sabre-toothed tigers, they are not dying of malaria and typhus they have let their choices be taken away from them. I know it seems a horrible thing to say but it is a massive problem. If you talk to them they all want to live as long as possible, do they actually try? No they don't.

It seems evident that the doctors are frustrated by the reluctance of patients to take decisions and manage their own healthcare. So much has been written about the desirability of encouraging shared-decision making yet, by definition, this is a two-way process. If patients do not want to engage in this the model becomes inoperable. It seems clear that the doctors in this study do actively want to involve their patients in the healthcare process. However, they become irritated when patients demonstrate

apathy towards this and then subsequently complain when, under these circumstances, doctors have very few options other than to make decisions for patients.

## **9.11 SPECIFIC THEMES: *PRACTICE NURSES***

### **9.11.1 Theme 1: Willingness to Engage with Nurses**

\* (There were 5 occurrences of this theme in the practice nurses' interviews. For further details refer to the table providing the summary of practice nurses' specific themes in section 9.13 of this study).

In relation to the practice nurses in this study, it is apparent that whilst they still identify and relate to the imbalance of power, their emphasis is on improving communication as a means of keeping the patient as informed as possible. It seems that this is how they feel the consent process can be improved. The nurses seem to stress that the imbalance of power in medical consultations directly affects the levels of communication and whilst they indicate this imbalance exists between the doctor and patient, they suggest that patients are much more likely to open up and engage in discussions with them. Nurses' perceptions are that patients are more willing to communicate with them as they feel less intimidated and more at ease.

**Researcher:** So do you find that the problem is that patients don't tend to communicate, or ask questions?

**Practice Nurse No 1:** I think they are more willing to ask questions of a nurse because nurses are perceived to be more approachable than doctors. Still even though there is an element that patients are less scared of doctors and medics. But I think sometimes they are afraid to ask a doctor "what do you mean by that doctor" but they are probably more willing to ask a nurse.

This view is supported by the findings in sections 11.7.6 and 11.7.7 of the patients' study later in the thesis. It seems that nurses are perceived as being more personable and approachable. This is a strong argument for suggesting that nurses play one of the most important roles in the consent process as a whole as they are the people who can encourage patients to engage in a more open and questioning dialogue with

medical practitioners. This enhanced communication will undisputedly improve how informed the patient becomes in the consent process.

### **9.11.2 Theme 2: The Changing Role of the Nurse**

\* (There were 4 occurrences of this theme in the practice nurses' interviews. For further details refer to the table providing the summary of practice nurses' specific themes in section 9.13 of this study).

Within the nurse's transcripts there are a number of issues relating to the changing role of the nurse. These seem to be of some concern for the participants. Firstly, there is the issue of nurse prescribing which is dealt with below. Secondly, it appears that if patients have to see a health care practitioner for an emergency appointment, it is a nurse they will see as opposed to a doctor. This may well be an innovative and entirely appropriate move in respect of primary care and bears some similarities to the system of triage nurses in hospitals. However, it appears the nurses are a little perturbed at some of the potential legal issues that could arise out of this arrangement. The findings indicate that nurses perceive themselves in a more precarious position than doctors when it comes to these emergency consultations. They believe they are being asked to operate to a standard of care which is potentially higher than that which they are qualified for.

**Practice Nurse No 1:** ...So you have to take risks and I think that for nurses who are undertaking extended roles that can be quite difficult, because we don't know where we would stand in the law. And our risk, which is probably the same as a doctor, would have taken. They have always done that and we never have and I think there is some anxiety over that.

Moreover, there is a suggestion that patients may be more likely to complain as, in their eyes, they may be receiving a second rate service. Whilst this is probably not the case, it certainly seems to be a pressing issue which the practice nurses highlight in this study.

**Researcher:** Did you say that in this practice it is the nurse that sees patients on emergency appointments?

**Practice Nurse No 1:** We have a system of same day appointments, well you can't really call them emergency appointments because emergencies go to Accident and Emergency don't they? But same day appointments, things that can't wait 3 or 4 days the first point of contact is a nurse and we either treat or triage in some way... I think it might put some off. Yes sure I think some people do see it as second rate service and that you are a cheap option you know and as one of my colleagues, not here, put it "are you a good nurse or a crap doctor?"

### **9.11.3 Theme 3: Nurse Prescribing**

\* (There were 2 occurrences of this theme in the practice nurses' interviews. For further details refer to the table providing the summary of practice nurses' specific themes in section 9.13 of this study).

As is suggested above, in modern medical practice the role of the nurse is an expanding one. Accordingly, one of the specific themes concerned the issue of nurse prescribing. Increasingly nurses are being asked to carry out roles traditionally dealt with by doctors. As a result, there is now an opportunity for nurses to undertake training to allow them to prescribe drugs for patients. The participants stress that nurse prescribing is an encouraging move in primary care as it reduces the workload of doctors and allows nurses to develop their medical skills. Clearly this has its advantages for the NHS budget, as long as the infrastructure is in place for suitable training and development.

**Researcher:** What are your concerns over the developing role of the nurse?

**Practice Nurse No 1:** Things like nurse-prescribing issues really. And that will be issues around do the patients know who you are, do they know that you are a nurse and not a doctor, making sure that when you prescribe something for a patient that the patient is aware that you are a nurse because this has implications. And equally you don't want patients to think that they are getting a second rate service because you are only a nurse but equally it is not right to be hoodwinking them into thinking that you are a doctor either.

Based on the findings here, it is clear that the participants are keen to flag up the importance of effective training and they demonstrate that a great deal of emphasis is placed on the legal implications of nurse prescribing. Despite the fact that this is generally perceived to be an encouraging move in contemporary medicine, there are a

number of legal issues in respect of consent which are analysed in the legal reflections component of this study.

#### **9.11.4 Theme 4: MMR Vaccination**

\* (There were 4 occurrences of this theme in the practice nurses' interviews. For further details refer to the table providing the summary of practice nurses' specific themes in section 9.13 of this study).

A number of the practice nurses focused on issues relating to the MMR vaccination. This drug has been linked with the development of autism in children. Within the context of obtaining consent from parents to allow their children to be immunised, it seems the participants are indirectly prepared to acknowledge a slight risk may exist and are conscious of not leading the patient in any way. Thus, despite the fact there is evidence that disproves any connection between the drug and autism<sup>3</sup>, for the nurses it is such a contentious issue that they prepared to go into an extensive discussion about the drug. It seems the nurses are very conscious about their own opinions of the drug. Clearly, most medical practitioners will have some sort of a view about the vaccination and whilst this is bound to come across within the consultation, the participants suggest it should not be used to influence the decision of the patient.

**Researcher:** So what sort of information would you ordinarily give to a patient in terms of risk and side effects perhaps?

**Practice Nurse No 2:** I think we would try and give them, I mean like in immunisations obviously people do sometimes want to discuss those in quite some depth especially things like the MMR. One thing I do find quite often with MMR is that people will say "what would you do?" Which brings you back to Tony Blair. I have had my children immunised but I am never quite sure if I ought to tell them that because is that fair? is that a reasonable judgement? I don't know. But that seems to carry quite a lot of weight with people. I am never quite sure on that one. I always want to make clear that this has got to be your choice and your decision, what you do and try and present to them as best I can the information such as it exists. But obviously I have an opinion on it and my opinion is bound to come across, isn't it?

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<sup>3</sup> Farrington, C.P. *et al.* "MMR and Autism: Further Evidence Against a Causal Association" (2001) 19 *Vaccine* 3632; Miller, E. "Measles-Mumps-Rubella Vaccine and the Development of Autism" (2003) 14 *Seminars in Paediatric Infectious diseases* 199.

However, as exemplified above, the trouble is that this is more or less unavoidable. For example, the findings illustrate that often parents seek reassurance by asking the nurses what they would do. In this situation it seems the participants feel they are left with little choice but to give their opinion although it does seem the interviewees feel uncomfortable with this.

## **9.12 COMPARING AND CONTRASTING THEMES IN PRIMARY CARE**

The majority of the participants' themes within this component of the study tended to overlap. Indeed, many of the views held by general practitioners were also shared by practice nurses. For example, there is agreement that informal consent procedures are more appropriate in primary care and that the benefits of keeping these procedures relaxed outweigh those of introducing 'red-tape' and legal formalities. In addition, there is a general feeling that the most important aspect of consent in primary care is that of understanding. There seems to be a pattern which suggests patient understanding varies and is dependent upon a number of different factors. It seems common ground that the risks in primary care are so infrequent and minor that they are almost insignificant. Also, there is a reluctance to deliberately withhold information from patients and confirmation of the difficulties associated the language barriers.

Despite agreement over the majority of issues, there are some differences. These seem related to specific issues inherent in the respective roles of the doctor and nurse. The general practitioners highlight the difficulties associated with risk disclosure and prescribing drug therapies, and discuss where they feel the doctor/patient relationship of trust breaks down, further intimating that society must depart from the cultural norms of unquestioning silence in order to facilitate joint

participation in medical consultations. They show a commitment towards encouraging a culture of patient involvement and questioning identifying this is best achieved by targeting the younger generation who seem more willing to engage with health care professionals. On the other hand, the practice nurses highlight the changing nature of their job and how this effects them personally in respect of the problems associated with the consent process both in a legal and in a wider sense.

Perhaps the most notable difference is the way they perceive the importance of communication. Both parties relate to the importance of effective communication within the consent process and, to a certain extent, discuss ways of improving it. This is where some of the differences become apparent. Doctors talk about avoiding the use of technical jargon, listening to the patient and assessing their concentration, whereas the nurses feel one of their specific roles is to actually redress the balance of power and encourage more open communication in this manner. This is where the final, and perhaps most significant, difference becomes evident. It seems the general practitioners seek to improve communication with a view to reaching an accurate diagnosis, whereas the nurses recognise that communication is an integral part of consent itself, and encouraging this is the only way in which consent procedures will improve in general practice.

## 9.13 SUMMARY OF THEMES FROM HEALTH CARE PROFESSIONALS IN PRIMARY CARE

<u>Initial Coding Category in NVIVA</u>	<u>Rank of Medical Practitioner</u>	<u>Number of Coded Entries Within Each Category</u>
Emphasis on Understanding*	General Practitioner	30
	Practice Nurse	12
Informal Consent Procedures*	General Practitioner	24
	Practice Nurse	11
Feelings About the Law	General Practitioner	41
	Practice Nurse	12
Disclosure Trends in Primary Care*	General Practitioner	26
	Practice Nurse	15
Paradigms of Care*	General Practitioners	25
	Practice Nurses	15
Reluctance to Withhold Information	General Practitioners	5
	Practice Nurses	9
Language Problems	General Practitioners	2
	Practice Nurses	6

### IDENTIFICATION OF SUB-THEMES

<u>Initial Theme</u>	<u>Sub-Theme</u>
Emphasis on Understanding*	Different Patient Types
Informal Consent Procedures*	General Treatment
	Minor Surgery
Disclosure Trends in Primary Care*	Less Emphasis on Risk Disclosure
	Willingness to Discuss Treatment Options & Alternatives
Paradigms of Care*	Paternalism & Beneficence
	Paternalism & Beneficence Overlapping with Professional Discretion

\* For the purposes of the discussion section, the sub-themes are analysed in accordance with the primary theme.

## 9.14 SUMMARY OF SPECIFIC THEMES

### 9.14.1 General Practitioners

<u>Individual Theme</u>	<u>Number of Coded Entries Within Each Category</u>
Problems with Risk Disclosure and Drug Therapies	15
Identifying and Redressing the Imbalance of Power	16
Communication Breakdown	28
Changing the Cultural Norms	5

### 9.14.2 Practice Nurses

<u>Individual Theme</u>	<u>Number of Coded Entries Within Each Category</u>
Willingness to Engage with Nurses	5
The Changing Role of the Nurse	4
Nurse Prescribing	2
MMR Vaccination	4

## 9.15 CONTINUING LEGAL REFLECTIONS: *PRIMARY CARE*

### 9.15.1 Theme 1: Informal Consent Procedures

Contrary to what some may think, there is no legal requirement that consent has to be given in writing. It seems both acceptable and practical not to demand too much in the way of formalities in an environment where formality is not necessary. Arguably, documentation and 'red-tape' are derivatives of professional accountability. Whilst this may help in terms of evidential issues should any complaints arise, it is no more conclusive of a valid consent than if expressed orally or by implication. Thus, obtaining consent in this manner seems both legally and professionally acceptable in general aspects of primary care.

In contrast, general practitioners offering surgical procedures need to be aware of the practical evidential problems that may arise should any legal action ensue. The

standard practice of NHS hospitals is now to obtain consent in writing for any type of operation.<sup>4</sup> This is probably due to the fact that there is greater scope for things to go wrong. Whilst it is not necessarily a bad thing that formalities of this kind are ignored for trivial procedures, the only difference between minor operations in primary and secondary care is the clinical setting where the procedure takes place. Presumably the dangers associated with these procedures do not change and it is evident from the interview extracts that these do carry with them at least some element of risk. Thus, in the future it may be worth considering the introduction of written consent for procedures which are akin to those carried out in hospitals. Similarly, a certain amount of caution ought to be exercised in relation to the views expressed by some of the participants. Just because they feel it is reasonable practice not to adopt written consent, this is not conclusive evidence that this would be deemed legally acceptable should it ever come before the courts.

### **9.15.2 Theme 2: Risk Disclosure in Primary Care**

The tort of negligence does not require a duty of perfection;<sup>5</sup> the law can only ever require reasonable disclosure in the circumstances. This is generally understood to mean the disclosure of all risks that the courts deem significant, based on an objective assessment of the reasonable patient.<sup>6</sup> The participants argue the risks in primary care are so infrequent and so slight that, in all probability, the courts would classify disclosure as unnecessary. Moreover, the tort of negligence itself is predicated on harm. Arguably, the consequences of any risks eventuating in primary care may be so

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<sup>4</sup> See appendix [5] for a copy of a standard NHS consent form for all procedures.

<sup>5</sup> See recent comments made by Gummow J. (at 593) and Callinan J. (at 631) in the Australian decision of *Rosenberg v Percival* (2001) 178 ALR 577. They comment about the undesirability of imposing standards of perfection on professionals and the dangers of hindsight reasoning. Moreover, they say the law of negligence is a duty to take reasonable care only.

<sup>6</sup> *Pearce v United Bristol Healthcare Trust* (1998) 48 BMLR 118.

trivial that they do not actually cause harm to the extent where the patient is likely to complain.

However, on reflection, there remains a potential problem. In the absence of written consent the practicalities of establishing liability may turn on evidential issues. Whilst claims against general practitioners are less frequent than against their colleagues in secondary care, there are statistics which demonstrate a steady increase in claims against primary care practitioners.<sup>7</sup> Undoubtedly this increase ought to, and actually has, provided some cause for concern.<sup>8</sup> Whether or not this has affected clinical practice in primary care is a matter for further research. In the present study there is evidence to the effect that the medical practitioners perceive the chances of being subjected to a lawsuit as so small that they do not worry too much about the legal consequences of their actions. However, they do need to be conscious of the fact that, evidentially, in respect of minor surgery, if avenues are left open for patients to argue that no consent was in fact obtained at all, they remain susceptible to a claim in battery.

### **9.15.3 Theme3: Risks and Drug Therapies**

In respect of drug therapies some of the views expressed by medical practitioners, from a legal point of view at least, need to be approached with care. The complexities and legal issues surrounding product liability would provide the basis for a doctoral

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<sup>7</sup> The MPS suggest [in correspondence with the researcher] that there will be 27 claims per thousand GP's arising out of incidents that occur in 2005. See also, Dyer C. "GP's Face Escalating Litigation" (1999) 318 *BMJ* 830. The figures in this study suggest that in 1989 there were 38 claims against GP members of the MPS, compared with 500 in 1998, representing a thirteen-fold increase. See Department of Health Circular "NHS Complaints Reform: Making Things Right" (DoH Publications: London, 2003). For further discussion see RCGP Quality Unit "In Safer Hands" *Issue 6*. Here statistics from the MDU show that in 2003 approximately a 100 GP's were successfully sued. The researcher sought clarification from the MDU and the NHSLA on these statistics. However, they refused to co-operate with this study.

<sup>8</sup> See, for example, Silk, N. "An Analysis of 1,000 Claims Against General Practitioners pt 1" (2000) 7 *Health Care Risk Report* 1; Silk, N. "An Analysis of 1,000 Claims Against General Practitioners pt 2" (2001) 7 *Health Care Risk Report* 3. "Huge Rise in GP Negligence Claims" *The Guardian* 18<sup>th</sup> March 1999.

thesis in itself.<sup>9</sup> Thus, the analysis here will focus exclusively on the issues which may directly affect medical practitioners.

Contractual remedies under this heading are restricted in the sense that usually no privity exists between the patient and the manufacturer.<sup>10</sup> Therefore, any claim has to be levied against those who recommend or supply the drug, such as the doctor or the pharmacist. When dealing with prescription drugs, the problem faced by patients is that it is generally accepted that there is no contractual relationship between the patient and the doctor or pharmacist.<sup>11</sup> The only other protection afforded to patients, outside the negligence framework, is to be found in the Consumer Protection Act 1987. Here a contract is not needed. A claimant may seek compensation from the manufacturer of a product merely by proving the product was defective and that it caused the injury. As this statute renders manufacturers strictly liable it is both easier and fairer for claimants. However, there are two problems with this piece of legislation. Firstly, section 3(2) of the Act makes it very difficult to establish that drugs are 'defective.' As Brazier suggests, drugs are by their nature dangerous and side-effects are often unavoidable. The court has to try to balance the potential benefit against the risk when deciding if an unwanted side-effect renders a drug defective.<sup>12</sup> In addition, there is the section 4 (1) (e) 'development risks' defence. Thus, the manufacturer will not be liable if he can prove that the state of scientific and technical knowledge at the time when he put the product in circulation was not such as to

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<sup>9</sup> For a detailed discussion of these issues see Goldberg, R. *Causation and Risk in the Law of Torts : Scientific Evidence and Medicinal Product Liability* (London: Hart, 1999); Stapleton, J. *Product Liability* (London: Butterworths, 1994). Specifically in the context of informed consent see various comments made throughout Brazier's paper. Brazier, M. "Patient Autonomy and Consent to Treatment: The Role of the Law?" (1987) 7 LS 169.

<sup>10</sup> *Dunlop Pneumatic Tyre Company Ltd v Selfridge* [1915] AC 847.

<sup>11</sup> *Pfizer Corp v Ministry of Health* [1965] AC 512; *Appleby v Sleep* [1968] 1 WLR 948. See also Kennedy, I. and Grubb, A. *Medical Law* Third Edition (London: Butterworths, 2000) at 1612.

<sup>12</sup> Brazier, M. *Medicine, Patients and the Law* (London: Penguin, 2003) at 208.

enable the existence of the defect to be discovered.<sup>13</sup> Secondly, the 1987 Act only applies to products put into circulation after the 1<sup>st</sup> March 1988.

The only other recourse for patients is then within the negligence framework. Here, most commonly, patients will be advised to rely on Lord Atkin's neighbour principle in *Donoghue v Stephenson*<sup>14</sup> and pursue an action against the manufacturer. Despite GP's being insured, this option is more financially lucrative for patients as manufacturers will generally have more money to pay them damages. However, doctors in primary care need to realise that it is still possible for the patient to sue them for drug induced injury caused by an incorrect dosage, for failing to identify and inform the drug posed a risk to the particular patient in question, or where drugs have been recommended in a harmful combination. The problems faced by health care professionals are neatly identified in the research findings. New drugs are frequently entering the market and bring with them new sets of risks. In addition, there is the problem that as research is carried out, and as patients are prescribed drugs already in circulation, further side-effects are identified and fresh risks are subsequently added to an already extensive portfolio.<sup>15</sup> If manufacturers fail to inform either the patient or the doctor about any risks of which they are or should be aware, they may well find themselves liable in negligence. However, manufactures will often seek to inform general practitioners of risks, and in doing so will potentially discharge their liability

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<sup>13</sup> Brazier, *ibid* at 211. For further discussion see Hodges, C. "Development Risks: Unanswered Questions" (1998) 61 MLR 560; Newdick, C. "Developmental Risks" (1991) 20 Anglo-American LR 309.

<sup>14</sup> [1932] AC 562. This in itself is extremely difficult to achieve in respect of drug therapies as although it is clear a duty exists, it is very difficult to establish a breach and a subsequent proximate cause. See Kennedy and Grubb, *op cit* n 11 at 1614.

<sup>15</sup> This is of course subject to the fact that in negligence both drug companies and doctors must not be judged in hindsight; they will be judged on the standards of when the drug was prescribed. See *Roe v Minister of Health* [1954] 2 All ER 131. In addition, the Consumer Protection Act 1987 contains the 'development risks defence' under section 4, discussed above.

by virtue of the 'learned intermediary rule.'<sup>16</sup> The basis for this rule is that it is for the doctor, acting as the expert, to decide whether to prescribe the drug, and if he or she does so, what information to provide to the patient. In respect of most drugs, the risks will be included in the information leaflets provided with the product. However, to further assist medical practitioners a number of extensive 'prescribing manuals' have been developed which detail the risks, side-effects and dangerous combinations of drug therapies,<sup>17</sup> which health care professionals ought to use to help them in prescribing. Legally speaking, some of the statements provided by the medical practitioners in this study are fairly controversial. It is no answer to suggest there are simply "too many risks" to remember and to keep updated with, and it is no defence to claim that the drugs were not in circulation at the time of the doctors' education. It is a slightly complacent, if not cavalier approach, to suggest that the only risks that are disclosed are those which have been encountered and reported by patients in the course of practitioners' personal experiences of prescribing and it seems likely the courts would frown on this. It has long been established that medical practitioners must keep up-to-date with current practice and that doctors equip themselves with the means of doing so by taking the time to familiarise themselves with the necessary literature.<sup>18</sup>

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<sup>16</sup> For discussion of the 'learned intermediary rule' see Kennedy and Grubb, *op cit* n 11 at 1617. They suggest that whilst the rule has never been applied in a medical context within the UK courts, it has been applied in an analogous situation. In the case of *Holmes v Ashford* [1950] 2 All ER 76 the manufacturer discharged liability by warning the hairdresser about properties of a dye. Thus, there is no reason why the courts would not adopt it.

<sup>17</sup> See, for example, the BNF. British Medical Association. *British National Formulary* (Royal Pharmaceutical Society of Great Britain: March, 2004) Vol. 47. Indeed, one of the participants [by correspondence to the researcher] indicated that this manual ought to be heavily relied upon in practice. See also [www.bnf.org](http://www.bnf.org). Also, there are other prescribing manuals. For example, see MIMS website. [www.mims.com.au](http://www.mims.com.au).

<sup>18</sup> 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.'

There are of course two other factors which make it very difficult for claimants to succeed in actions for negligently inflicted injury arising out of defective drugs and negligent prescribing/non-disclosure. These two issues are very complex and the discussion will reflect a theme that was highlighted as problematic by the medical practitioners in this study. Some of the practitioners voiced concerns relating to the MMR vaccine. This illustrates the two further complicating factors in the negligence action. The first is causation. The law of negligence requires that the claimant prove, on the balance of probabilities, that the negligence act or omission caused or materially contributed to the harm.<sup>19</sup> Thus, in respect of the MMR vaccination there is new evidence which suggests the development of autism and bowel disease are not linked to the drug.<sup>20</sup> Thus, medical practitioners can feel reasonably safe in the knowledge that, insofar as the English courts are concerned, it seems highly unlikely that a causal link will ever be established.<sup>21</sup> This is the same for other drug treatments where a range of different factors, quite independent of the drug itself, could have caused the harm suffered by the claimant. The second issue is both a general one in respect of drug therapies and a specific one in relation to vaccinations. In considering the position of the drug, the courts will often engage in an analysis of its social benefit. If the benefits to society on the whole outweigh the small risks to certain individuals, then the courts will consider these factors and will be reluctant to conclude that the product was defective, or that the manufacturer was

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<sup>19</sup> *Wilsher v Essex Area Health Authority* [1988] AC 1074.

<sup>20</sup> *op cit* n 3. In an article in 2003, it was estimated around £10m has been spent in legal aid funding on the cases of 1,000 children in the past 10 years'. However, the Legal Services Commission decided to withdraw public funding, just six months before eight test cases were due to come to court. This was because a science panel concluded there was no evidence to support a link between autism and the drug. Boseley, S. "Parents Lose Cash for MMR Case" *The Guardian*, 2<sup>nd</sup> October 2003.

<sup>21</sup> Despite this, there has been one successful case in Ireland. *Best v Wellcome Foundation* [1993] 2 IR 421.

negligent in circulating the drug or that the doctor was negligent in prescribing.<sup>22</sup> This is particularly the case in respect of vaccines where there is immense benefit to people other than the individual who is on the receiving end of the inoculation. The cause for concern expressed by the medical professionals in this study concerning the MMR vaccine can be written down. Brazier says that any action against them for utilising the vaccine would be unlikely to succeed. Granted there may be a small number of medical practitioners who are opposed to its use, but whilst there remains a substantial body of practitioners who support the treatment, any action in negligence is likely to fail.<sup>23</sup>

#### **9.15.4 Theme 4: Paradigms of Care**

Based on the literature there are essentially there are three models of healthcare which can be identified. The paternalistic model, the autonomy-enhancing model, and the middle ground of the shared decision-making model.<sup>24</sup> At this stage it is important to bear in mind the following assertion made by Beauchamp and Childress:

'...debate about which principle or model should be overridden in medical practice cannot be solved in this streamlined manner by defending one principle against another, or by making one principle absolute. Neither the patient nor the physician has a premier overriding authority, and no pre-eminent principle exists in biomedical ethics.'<sup>25</sup>

Paternalism and autonomy often find themselves in direct conflict. On one view it is possible to suggest that it is here the law and the medical profession clash and cannot exist in harmony as, arguably, the medical profession is a supporter of paternalism whereas the law is a protector of autonomy. Historically, the medical profession has

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<sup>22</sup> See *Loveday v Renton* [1990] 1 Med L Rev 117; *Abouzaid v Mothecare Ltd. The Times*, 20<sup>th</sup> Feb 2001, CA; *Richardson v LRC Products Ltd* (2000) Lloyd's Law Report 280. However, in *A v National Blood Authority* (2001) 60 BMLR 1 the manufacturer was held strictly liable for providing contaminated blood, despite the social utility the 'product' provided. Here the courts drew a clear distinction between negligence and strict liability.

<sup>23</sup> Brazier, *op cit* n 12 at 218.

<sup>24</sup> Beauchamp, T.L. & Childress, J.F. *Principles of Biomedical Ethics* Fifth Edition (Oxford: Oxford University Press, 2001) at 177.

been associated with a paternalistic standard of care and, as described in the literature review, the law has traditionally supported this. In the wake of recent decisions such as *Bolitho*,<sup>26</sup> *Pearce*,<sup>27</sup> *Chester*<sup>28</sup> and *Wyatt*<sup>29</sup> courts have demonstrated a commitment towards patient rights and have gradually departed from supporting the paternalistic view of medicine. Thus, in respect of information disclosure, although the English courts have not fully endorsed the prudent patient standard of care, patients are becoming entitled to more information thereby recognising the importance attached to autonomy. Arguably GP's should not make decisions for patients on any basis, best-interests or otherwise. This however is perhaps an unworkable ideal. Still, GP's ought to be especially cautious when seeking to justify making decisions for patients based on supposed best-interests' and should not rely too much on the common accepted practice of their profession, particularly when it concerns information disclosure.

The health care professionals in this study recognise the importance of autonomy. However, the problem faced by them lies in implementing this model. In practice there may not be enough time to discuss many of the risks with patients, and it would be detrimental to both good medical practice and the patient to demand disclosure of them. In addition, there is the added complication that some patients want decisions making for them and do not want to hear the information about risks and alternatives.

Shared-decision making operates as a compromise and typically involves both the patient and the clinician working together to agree on the best course of action. Clearly, this will involve some disclosure of risks and alternatives from the doctor but will also require some input from patients. From the findings it is evident that these

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<sup>25</sup> *ibid.*

<sup>26</sup> *Bolitho v City & Hackney Health Authority* [1998] AC 232.

<sup>27</sup> *op cit* n 6.

<sup>28</sup> *Chester v Afshar* [2004] UKHL 41; [2005] 1 AC 134.

medical practitioners liked it when patients are willing to become involved in treatment and are more than happy to discuss treatment options with patients. The biggest problem they face is encouraging patients to do this. What is important to remember, particularly in relation to information disclosure in primary care, is that professional discretion is not to be confused with paternalism. A preliminary reading of the interview extracts may blur the distinction between the two. But on reading the transcripts in their entirety this is probably not the intention of the participants, who generally seek to reinforce autonomy, whilst maintaining a certain amount of professional discretion as to what information to give to patients and how this is portrayed.

#### **9.15.5 Theme 5: Communication & Understanding**<sup>30</sup>

The terms *communication* and *understanding* are not interchangeable and should not be used as such. The focus of the law has traditionally been on the former whereas the findings in this study suggest the medical practitioners are more concerned with the latter.

In terms of the law, understanding is a difficult factor to deal with and has not been afforded the same consideration as disclosure. Yet, as Williams suggests, 'unless patients understand the information they are given, arguably they will be no better off and disclosure will have become an empty exercise, a 'rite' rather than a 'right.'<sup>31</sup> Some of the problems are exemplified in this study. Firstly, understanding may often be implicitly assumed. Secondly, understanding is potentially elusive and may be hard to evaluate in some cases. By way of example, the specific problems highlighted in

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<sup>29</sup> *Wyatt v Curtis* [2003] EWCA Civ 1779; [2003] WL 22827037.

<sup>30</sup> Communication and understanding are issues that will be discussed further in the studies concerning both the medical practitioners in secondary care and also patients.

<sup>31</sup> Williams, K. "Comprehending Disclosure: Must Patients Understand the Risks they Run?" (2000) 4 *Med L Int* 97 at 97.

this study concern patients whose first language is not English. Here it becomes extremely difficult to communicate effectively and in turn hard to assess patient understanding. The participants in the study confirm that understanding varies from patient to patient; it is not directly linked to age, but is more affected by the educational background of the patient. As these factors vary greatly, the capacity to understand what is disclosed has to be judged by reference to the individual before them. The participants elaborate some steps that can be taken to assess, enhance and maintain patient understanding. Whilst these are by no means a complete solution to the complex problem of understanding, in a legal sense they could be used to formulate the reasonable steps that ought to be taken to allow the patient to understand the information that is imparted. This argument is developed in the legal reflections component of the medical practitioners in secondary care study.

Poor communication by patients causes problems for doctors and nurses. It can increase the difficulty in diagnosing illness and identifying patient objectives. Poor communication on the part of the doctor leads to poor understanding on behalf of patients. Drawing on some of the issues presented by the doctors and the practice nurses in this study, it may be helpful that health care professionals generally implement some of the methods which are suggested to enhance communication. Indeed, as Weinman says, failure to present information in a manner which can be understood 'is not merely bad communication, it may effectively be non-communication.'<sup>32</sup> However, one of the problems faced by medical practitioners is how to encourage effective communication amongst patients.

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<sup>32</sup> Weinman, R. *An Outline of Psychology as Applied to Medicine* Second Edition (London: Wright Publishing, 1987) at 164.

### **9.15.6 Theme 6: Encouraging Patient Involvement**

The issue of encouraging patient involvement was raised by a number of participants in this study. As has been suggested in the above section, it is desirable that patients communicate with the doctor and take an active role in their healthcare decisions. This is linked to the consent process insofar as patient input undoubtedly paves the way for a more interactive 'process' whereby the patient will inevitably become more 'informed.' Yet, this only represents a small piece in a much bigger jigsaw concerned with ignorance, poverty, class, education and life-style. These matters are legally quite distinct from consent, but sociologically are critical.<sup>33</sup>

Patients often remain silent during medical consultations. One of the reasons may be fear and anxiety. Another identified by some of the participants, relates to the culture that patients are brought up in. Patients may perceive themselves in a hopeless situation; they are less educated than the doctor and may well come from a lower social class. This can create a feeling of dependency.

The law is arguably taking some steps towards correcting this problem by empowering the patient. The courts now seem prepared to recognise the importance of individual autonomy.<sup>34</sup> Yet, the law's power to improve consent is limited to a prescriptive and symbolic nature. Practically it can have very little effect. Thus, Jones has suggested we must look beyond the courts to improve consent in clinical settings.<sup>35</sup> In order for consent to be a truly reciprocal process underpinned by a concept of shared-decision making, we must look to ways of encouraging patient involvement. This will take time and will ultimately involve a change of culture in

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<sup>33</sup> For an interesting post-modernist perspective on the doctor/patient relationship and a critique of how the medical profession has manipulated the knowledge of medical science to elevate doctors to a position of superiority within society see Foucault, M. *The Birth of The Clinic* Sheridan, A.M. (Trans.) (London: Tavistock, 1976). Critiqued by Tallis, R., *Hippocratic Oaths: Medicine and its Discontents* (London: Atlantic, 2004) at 81.

society and amongst patients generally. Perhaps a starting point for this is, as suggested by the participants, is to encourage a culture of openness and continual questioning amongst patients. Meanwhile, if health professionals cannot wait for patients to improve, they may have to take the lead in helping patients to help themselves.

### **9.15.7 Theme 7: The Changing Role of Nurses**

To date, the changing role of nurses remains untested in the English courts. Without doubt the rationale behind expanding the professional repertoire of nurses is encouraging and with the correct training and infrastructure it will inevitably bring great benefits.<sup>36</sup> The comments which follow should not be interpreted as being derogatory or demeaning to nurses in anyway.

Doctors have many years of extensive training, both academic and practical. One of the privileges of this training is that it equips doctors with the ability to diagnose illness and prescribe appropriate drugs. Nurses are not educated or trained to the same extent. In short, nurses are simply not qualified to perform similar prescribing duties to doctors.<sup>37</sup> This surely calls into question the validity of a system which allows nurses to prescribe drugs. Patients may understandably have some concerns about this; it does place a lot of power and discretion to prescribe very potent drugs in the hands of professionals who are relatively inexperienced in this field. If doctors are unaware of many of the risks associated with drug therapies, as

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<sup>34</sup> See *Chester v Afshar*, *op cit* n 28. For detailed discussion see section 2.1.9 in the Literature Review of this study.

<sup>35</sup> Jones, M. "Informed Consent and Other Fairy Stories" (1999) 7 *Med L Rev* 103 at 123.

<sup>36</sup> For further discussion on nurse prescribing see Bradley, P. *et al.* "Primary-Care Opportunities and Threats: Developing Prescribing in Primary Care" (1997) 314 *BMJ* 744; Miller, C.A. "Inappropriate Prescribing Practices and Implications for Nurses" (2003) 24 *Geriatric Nursing* 244; Banning, M. "Nurse Prescribing, Nurse Education and Related Research in the United Kingdom: A Review of the Literature" (2004) 24 *Nurse Education Today* 420.

they admit in this study, then it is both unlikely and unrealistic to expect nurses to be aware of them. This may have a bearing on the level of information that is disclosed to patients prior to the commencement of any drug therapies and, in some circumstances, the legal duty to provide reasonable information may be left unfulfilled. The only way that this can operate effectively is if extensive training is provided for nurses partaking in the scheme, which is comparable to that which doctors receive. The findings in this study suggest that the current system is working and the training provided for nurses is both detailed and extensive allowing them feel confident in prescribing.

The legal position is unsettled. Nurses do need to be aware however that they are on potentially dangerous ground insofar as the law is concerned. It is possible that when undertaking these extended roles they will be judged in reference to a standard of care higher than that which is ordinarily expected of a nurse. The only authority pertaining to the standard of care expected of the inexperienced practitioner resides in *obiter* comments made in the case of *Wilsher*.<sup>38</sup> Here the Court of Appeal rejected the argument that the defendant doctor in this case had done his best in light of his experience. The law requires all medical staff to adhere to the standard of competence to be expected of an experienced professional occupying that specific post. It is possible that if an error is made in the course of nurse prescribing, they will be judged by the standards of doctors in that role. Thus, the practical advice has to be, if unsure about anything, seek the advice of a senior doctor. Once nurses recognise their

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<sup>37</sup> The exception to this is of course consultant specialist nurses who are trained and qualified to perform certain specific surgical procedures such as colonoscopies. For discussion see Dimond, B. *Legal Aspects of Nursing* Fourth Edition (Essex: Pearson Longman, 2005) at 547-555.

<sup>38</sup> *Wilsher v Essex Area Health Authority* [1987] QB 730.

inexperience, they will discharge their liability in negligence which subsequently switches to the general practitioner consulted.<sup>39</sup>

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<sup>39</sup> See *Jones v Manchester Corporation* [1952] 2 QB 852.

## **10 STUDY 3: INFORMED CONSENT IN SECONDARY CARE**

### **PART 1 - INTERVIEWS WITH HEALTH CARE PROFESSIONALS IN SECONDARY CARE**

#### **10.1 INTRODUCTION**

This section of the study explores informed consent in secondary care from health care professionals' perspectives. It employs qualitative interview methods to investigate what actually happens in respect of consent in practice and elicits the views and opinions of health care professionals who are actively involved in the process. It looks at the dynamics of the consent transaction and identifies how consent is obtained, whilst at the same time ascertaining what is important to the health care professionals in their everyday practice when they are dealing with patients. Eight consultants, three registrars, three house officers/senior house officers and six nurses were interviewed. The interviews were transcribed and uploaded into NVIVA for computer-assisted analysis. A thematic analysis was conducted on all the interview transcripts and the findings are discussed in the context of the identified themes.

The study begins by providing a brief justification for the work and then progresses to discuss the procedure, participants and methods of analysis. It then moves on to provide the substantial discussion of findings and, finally, in keeping with the philosophy which underpins the qualitative methodology, there is a reflexive section which reflects on the findings in a legal context.

## **10.2 JUSTIFICATION**

Consent procedures in secondary care are more formal than in primary care. The questions that remain poorly understood are what are the dynamics of these procedures in secondary care and how do they relate to legal theory and practice? As there is little in the way of empirical research concerning the above, this study investigates these issues using qualitative research methods to develop an understanding of informed consent in secondary care from the health care professionals' points of view.

## **10.3 RESEARCH QUESTION**

To investigate and develop a clearer understanding of consent procedures and issues amongst health care professionals in secondary care settings. Please see chapter 7.3 for a full list of research questions.

## **10.4 SUMMARY OF PARTICIPANTS**

Participants in this study included:

a) Consultants (N=8)

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

b) Registrars (N=3)

These participants were based in general and colorectal surgery and endoscopy. The medical input into the study advised consultants and registrars perform similar duties. As such, for the purposes of thematic analysis, the consultants and registrars' interviews were combined.

c) Senior House Officers and House Officers (N=3)

There were only a limited number of senior house officers and house officers who 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.

d) Nurses (N=6)

These participants were various different grades including consultant nurse practitioners in endoscopy/colonoscopy, ward sisters in general surgery and staff nurses in general surgery.

## **10.5 METHODS**

This component of the study employed semi-structured qualitative interviews. Please see chapter 4.8 for further discussion.

## **10.6 ANALYSIS**

The interviews were transcribed and uploaded into the software package NVIVA. The findings were then analysed using the computer-assisted software to identify recurring themes. Please see chapter 8 for further discussion. As this is a qualitative study, within the discussion there are no references to numbers of participants or percentages. However, for a summary of figures relating to the number of themes and the importance attached to each, please see the tables at the end of this study. (See section below for further details).

## **10.7 ORDER OF THEMES**

As the studies started out with no pre-defined themes, the themes are presented in the order in which they developed from the base upwards within each particular study. Within the findings below, the importance attached to each theme is noted in brackets underneath the relevant heading. The level of importance was assessed by the number of times each theme occurred within the transcripts. However, for a complete summary, and to identify the importance attached to each particular theme, refer to the table providing the summary of themes in section 10.14 of this study.

## **10.8 STUDY LIMITATIONS**

This study was based in only one hospital within the UK. Thus it is impossible to generalise in relation to the findings. The research itself was extremely concentrated in the sense that it targeted only one hospital, yet this was the aim of the question. Despite this, the work cut across a number of specialisms at a prestigious hospital whose practices undoubtedly accord with national standards. Thus, in all probability, it can be said to be a fair reflection of what takes place across the country in respect of consent practices in secondary care. In addition, what the study lacks in representativeness, it makes up for in terms of depth, boasting some very detailed qualitative findings.

## FINDINGS

### **10.9 THEMES FROM HEALTH CARE PROFESSIONALS IN SECONDARY CARE**

#### ***10.9.1 Researcher' Note***

As noted in the previous qualitative study, due to the nature of the semi-structured interview format not all the answers provided by the participants were directly related to the initial question posed by the researcher. Often a topic was introduced and then the participant would elaborate on this in great detail. Thus, a number of themes overlapped and this was drawn out in the analysis. Accordingly, within the discussion section, the extracts provided as evidence sometimes do not marry up with the precise nature of the question asked and, in some instances, the initial question posed by the researcher is not displayed. Also, in the findings which concern the common themes across all health care professionals, extracts provided are a mixture of consultants, registrars, house officers and nurses.

#### ***10.9.2 Theme 1: The Importance of Consent as a Shared-Decision Making Process***

\* (There were 36 occurrences of this theme in the consultants/registrars' interviews, 6 occurrences within the SHO/house officers' interviews and 18 occurrences in the nurses' interviews. A total of 60 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

Within this study, it is apparent that issues pertaining to informed consent are at the forefront of the medical practitioners' minds, probably to a greater extent than their colleagues in primary care. The findings suggest that consent is taken very seriously in hospitals.

**Researcher:** As a medical practitioner what is your definition of informed consent?

**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 it 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.

Moreover, one of the common themes appearing from the interviews centred on consent being a process in which both the doctor and patient should be involved.

Thus, the results suggest the real importance of consent is bound up in the needs of the patient. It is viewed as a two-way transaction.<sup>1</sup>

**Researcher:** What is your definition of informed consent as a consultant?

**Consultant No 2:** Getting agreement from a patient, or in certain circumstances from a relative or responsible person...if the patient themselves is unable to give informed consent... and which requires a signature on a pre-designed pro-forma, consent form. The informed part about it is explaining to the patient prior to signature the nature of the operation, the possible significant risks adding percentage risks where appropriate and adding personal data with percentage risks...so that the patient can then make a balanced decision whether or not to proceed with surgery. And together we have to discuss the benefits or otherwise of the procedure that we are doing, so it is a balancing act for the patient to make an informed decision about their health.

It seems that, within the remit of this study at least, consent is seen as vital, not for the protection of medical practitioners, but for the protection of patients.

### **10.9.3 *Theme 2: Problems with the Consent Form***

\* (There were 48 occurrences of this theme in the consultants/registrars' interviews, 9 occurrences within the SHO/house officers' interviews and 25 occurrences in the nurses' interviews. A total of 83 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

The findings indicate the main type of consent in secondary care is written, it appears the medical practitioners within the study seem to suggest the process has become to formalised and bureaucratic. A number of the health care professionals seem to link this problem with the issues identified in the opening section of this study. They acknowledge and perceive the most important basis for consent as being an ethical

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<sup>1</sup> In support of this model of healthcare and decision making see, Feldman-Stewart, D. *et al.* "Practical Issues in Shared Decision Making" (2000) 3 *Health Expectations* 46.

imperative grounded upon the wants and needs of the patient. This is about much more than obtaining a signature on a form. These findings suggest the danger with introducing lengthy and elaborate forms is that the concentration and time that is needed to fill them out, detracts from the actual process itself. This process should include interaction between the doctor and patient to discuss the options available to the patient and the risks and benefits therein. Using more complex and legally orientated forms does not enhance this in any way and in a sense may be doing more harm than good.

**Consultant No 3:** ...You see in the old days we were always told that consent was not worth the paper it was actually written on and now they are becoming so complex in legal forms that we have to do that they are becoming an absolute nightmare. What is important to me is what is important to the patient and what is important to the patient is that the patient is adequately informed about any procedure, what advantages they may gain from it and what the disadvantages are.

Also there are a number of sub-themes which developed under the blanket of this general category. Firstly, there is evidence which suggests the form attempts to standardise consent. Harmonising consent procedures may well be appealing insofar as it provides some consistency and certainty for both patients and doctors. Doctors have mapped out for them, via the medium of the form, what they ought to be discussing with patients, and likewise patients will have clear expectations about what level of information they can expect. Yet, attempting to impose some level of harmonisation on consent procedures that span across a range of specialisms is virtually impossible. Flexibility and ingenuity provide the key to effective consent procedures and it appears the participants here feel a generalised consent form has the potential to fetter this.

**Researcher:** How would you define informed consent?

**Consultant No 1:** Now I object in many ways to the standard consent form that this hospital has...So the consent form is a generic consent form, which is actually misleading but the Trust, as advised by the pernickety lawyers, have

said that we have to use this ridiculous consent form. So in a sense the consenting is a number of events...but because of the silly form, and I have always felt that it is silly, I think it is nothing to do with consent. It is to do with some bureaucrat who doesn't understand the law, sitting in an office who wants to see a form...and it has got to the point now that the radiographers here won't treat a patient unless they have signed a consent form. 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...but the bureaucracy here is as long as you have a signed consent form and whatever is around that they don't care a bugger.

Secondly, as demonstrated above, there is some criticism of those who have designed the form. Whilst not all the participants were as vocal as the above consultant, there is definitely a theme centring on the problems with bureaucracy and 'red-tape' in the consent process. The feeling is that this is driven by the law. The contention is grounded in the fact that most people involved in the consent process, medical practitioners, NHS trust managers, lawyers, and to an extent even patients, are happy to proceed with treatment based on the fact that there is a mere signature on a form. This signature is not conclusive evidence that any discussion whatsoever has taken place between the doctor and the patient about the proposed procedure.

#### **10.9.4 *Theme 3: Disclosure, Openness and Transparency***

\* (There were 18 occurrences of this theme in the consultants/registrars' interviews, 12 occurrences within the SHO/house officers' interviews and 6 occurrences in the nurses' interviews. A total of 36 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

It has to be said that the primary care medical practitioners' within this study, on the whole, recognise the importance of openness and transparency within the NHS. Also, the general consensus in secondary care is that emphasis should be placed on disclosure with a view to keeping the patient fully informed. The findings suggest a commitment towards openness and disclosure; they indicate this has always been the case.

**Researcher:** Do think it is an important part of medical practice nowadays?

**Consultant No 5:** Always has been...obviously if I am going to do something surgical to you then you have to be asleep, when I do it is your body I am playing with and you have to feel comfortable with what I may do in terms of risks/benefits. I mean in my lifetime the surgeon has always taken this seriously even though now it is a more formalised procedure.

The participants indicate a willingness to talk through the risks of procedures with patients.

**Researcher:** As a medical practitioner what is your view of informed consent and how would you define it?

**Surgical Registrar No 3:** It is extremely important. The process of informed consent is integral to our practice and is one of the reasons why patients who undergo procedures need to be informed fully of the risks of the procedure, which covers the gastroscopy. 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.

Based on the empirical findings in this study, it seems that the only occasions on which risks are not disclosed are through mere inadvertence on the part of the medical practitioners, or out of the genuine exercise of what is perceived to be professional discretion. The latter is problematic as the assumption is paternalistic in nature and is undoubtedly underpinned by considerations pertaining to 'best-interests.' Whether or not medical practitioners are aware of the potential significance and danger associated with this is somewhat uncertain. Nevertheless, there remains recognition of the importance of informed consent, openness and honesty.

#### **10.9.5 Theme 4: Problems with Risk Disclosure**

\* (There were 55 occurrences of this theme in the consultants/registrars' interviews, 8 occurrences within the SHO/house officers' interviews and 11 occurrences in the nurses' interviews. A total of 74 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

The findings demonstrate there is confusion and uncertainty surrounding what risks to disclose. It appears that the common perception amongst the medical practitioners within this study is that risk disclosure varies depending on the precise nature of the

procedure and the severity of the consequences should the risk transpire. Thus, in some situations where there is an extremely small risk, where the chances of it eventuating are low, and if it does so the consequences are only mild, then there is a suggestion that this would not be disclosed.

**Researcher:** What sort of risks would you disclose...?

**Consultant No 3:** I think that there is a lot of discussion in the medical profession as to what kind of incidents you should inform the patient of. For example if you had a 0.01% incidence of something extremely rare and very minor then I think I wouldn't mention it otherwise you would never get consent from anybody it would take too long. On the other hand if you had a 1% incidence but it is extremely serious then you really must mention that, and if you had something totally trivial but it occurs in 50% you must mention that too. So it is a balance between total triviality and seriousness and percentage incidents.

In contrast, if there is a risk that is totally trivial and it occurs quite frequently it is indicated that this should be mentioned. Therefore, it seems that risk disclosure is very much a balancing act. What to disclose is judged in reference to the precise nature of the procedure and the chances of the risk developing, balanced against the severity of the complications should it arise. Arguably this is how it should be.

A further pattern emerged concerning the amount of attention that was paid to percentages and statistical precision as a marker for disclosure. In particular the figure of between 1 to 2 per cent was mentioned by nearly all of the participants. The majority of practitioners within this study stress the importance of using percentages to calculate what to disclose. It is evident the perceived threshold for informed consent stands at risks within the range of 1-2 per cent and it appears the rule of thumb is to work within the boundaries of disclosing all risks at around this figure.

**Researcher:** Do you think the law would pose an obligation to disclose more information than you actually would to some patients in some circumstances?

**Consultant No 2:** Yes I mean let us say for example that consent for a hernia operation, maybe the threshold, I can't remember...the threshold in percentage terms for informed consent is something like 4%. I can remember...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 that as well. Moving away from

hernias for the moment I will come back to it later. 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.

### **10.9.6 Theme 5: Disclosure Beyond Risks**

\* (There were 39 occurrences of this theme in the consultants/registrar's interviews, 3 occurrences within the SHO/house officers' interviews and 10 occurrences in the nurses' interviews. A total of 52 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

In order to meet the legal obligations relating to consent, the nature of the information provided to patients centres mainly on risks and the inherent dangers associated with any operations. However, it appears within the dynamics of medical practice this is perceived as being insufficient if performed in isolation. The participants indicate the desirability of disclosing not only the risks, but also the benefits of procedures. The findings suggest this is the only way in which patients can conceptualise the importance of treatment, helping them to rationalise their predicament and to weigh things in the balance in order that they can 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 will block and 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.

It seems that the complexity of modern medicine makes it very difficult for patients to understand the information that is being portrayed to them. Whilst patient understanding in consent is an issue in its own right, clearly the worry for a number of the participants is that in disclosing just the risks of the procedure the patient may not appreciate the true worth of the treatment and may become confused, frightened and anxious. Within this study, the majority of surgeons were involved in cancer

treatment; they suggest that because surgery is often the only option, the patient needs to be told the consequences of failing to go ahead with the procedure.

**Consultant No 1:** On the other hand there is a very interesting dilemma. I had a patient who was a royal marine commando, a big boy, tough boy, with Hodgkin's Disease which gave him big lumps in his neck. A very curative condition, had a wife and a baby and he was pretty ill when he first came in. We gave him a course of chemotherapy and I spoke to him before his second course and said "how was that" and he said "well it was not too bad, I felt a bit queasy, lost a bit of hair, but fine." After the next course I said "how was that" and he said "not too bad I felt a bit iller and have lost all my hair but all the lumps have almost gone." After the third lot "how was it", "fucking not having anymore of that" really bolshie and his disease had disappeared but all he could then think of was the side effects because he could see only the side effects. He couldn't see the benefits at all because as far as he was concerned his disease had gone. We produced his wife and his baby and persuaded him to go through the 6 courses and told him that if he didn't do it for this it would just come back again. If you go through this it will be a bad memory in a few years. A horrible memory you know, you lost your hair, you felt sick, you got mouth ulcers, you felt crap, but in 6 months time that is it. It has all gone and it will gradually fade.

There are two ways in which this can be achieved. For example, health care professionals could frame this in a negative way suggesting 'if you do not have this procedure you may die.' However, this draconian approach may do more harm than good. The common practice of the medical practitioners appears to involve firstly explaining what is wrong with the patient, then explaining why the treatment is necessary, and finally, discussing the potential drawbacks in the form of risks. It is within the middle component where the medical practitioner's attempt to frame things in a positive light in order to provide the patient with the opportunity to visualise the benefits of what they are proposing.

**Researcher:** ...That is interesting because a lot of the way in which the law has gone has not paid a great deal of attention to alternatives and advice about alternatives. Do you discuss alternatives with your patients?

**Consultant No 8:** Yes I do because I start with saying "what if we do nothing? If we do nothing and I put you a desert island your back problem will probably go away and you will get better. If you have got a back problem and it lets lie you on the beach in the Bahamas, feed you gin and tonics all day long, tell you to swim 3 times a day, your pain will go away. Can you afford to do that? No, you have a wife you have got 2 kids and you have a manual job...of course you

can't." So there is an option to do nothing and then if there are other procedures such as physiotherapy or other alternative procedures like radiotherapy I will discuss them in detail, and if necessary I will refer them to other people.

The underlying issue here is clearly one of balance. It would be fair to suggest, on the present findings, that a great deal of emphasis is placed on keeping the patient informed about risks. However, it is possible to conclude that the feeling is disclosure should not be based solely on risks and that other types of information are equally important to allow the patient the opportunity to express informed consent.

In continuing this trend, one of the sub-themes which developed under this general heading concerns the disclosure of alternatives. It appears there is a general agreement as to the theoretical desirability of disclosing alternative treatments to patients thereby allowing them freedom of choice. However, an underlying concern is that it is not always practical to do so. There are a number of reasons offered as justifications. Firstly, because the study focuses mainly on general surgery, with cancer patients, the consensus was that more often than not surgery is the only option open to the patient. Thus, there simply are not any alternative options available to the patient and medical practitioners are reluctant to engage the patient for fear of creating false hope. A further concern centred on the possibility that if the patient is provided with too many options, they become confused and this affects their decision making process. In situations like this medical practitioners openly acknowledge that they will 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 on leading them into the operation which you think is best for them. Because if you give them the facts they will pick the same one as you usually.

Moreover, the study demonstrates that in certain situations medical practitioners do actually decide what treatment to offer patients based on their own personal

preferences. Indeed, the indication is that in the limited circumstances where alternatives are available, the decision to opt for one course of action over another is left to the professional judgment of medical practitioners. When quizzed as to how these decisions are reached the results show that it is often determined in reference to evidence-based data as to what is in the best-interests of the patient.

**Researcher:** Something I picked up on, because I have been doing a lot of work with Mr....and Mr....is the Barium Enema and the Colonoscopy. Is the patient given a choice between those two?

**Consultant No 7:** No I don't usually offer them a choice. I usually tell them the message that I think it is best for their symptoms. It is fairly clear-cut in patients who have bleeding or diarrhoea; they are better with a colonoscopy. If they have got functional disorders, bad liver disease or abdominal pain they may be better with Barium. So there is sort of medical information that pushes you in one or other direction and I tend to advise them. There is the odd patient who says "oh I have had a bad experience I can't face this, that and the other" and then we could negotiate and say "well you can have a Barium even though it is less good." But no generally I don't offer them a choice.

**Researcher:** Do think perhaps you should do?

**Consultant No 7:** No I very much feel that they should have what the evidence says is the best test.

**Nurse Practitioner No 6:** I do clinics and I have sat in clinics particularly with the gastroenterologists and they generally say to them "this is the best test to define this and whilst there are other tests they are not as good." And again they pitch it at whomever they happen to be talking to. To be honest no I don't really go through the alternatives. I think if you have just signed the consent form you really don't want to be told at that point that there is actually a barium enema that you could have had. And it seems a pointless exercise to do that when they have got that far down the road and are sitting opposite you with an empty bowel.

### **10.9.7 *Theme 6: Underlying Paternalism & Best-Interests***

\* (There were 23 occurrences of this theme in the consultants/registrars' interviews, 1 occurrences within the SHO/house officers' interviews and 7 occurrences in the nurses' interviews. A total of 31 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

Throughout the majority of the interview transcripts there were some underlying connotations which could be associated with paternalism and best interests. The true extent to which medical practitioners realise they are becoming embroiled in these

two paradigms of care is somewhat unclear and, in any event, the two are somewhat interchangeable.

**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 throughout the participants in secondary care is the paternalism is no longer acceptable. However, it seems some of them suggest they would always act in the patient's best interests and they thought this was acceptable, perhaps not realising or associating this with the paternalistic paradigm. There is evidence to the effect that decisions are sometimes made for patients where there is more than one treatment option available.

**Consultant No 2:** ...very occasionally, it is perhaps best not to spell out things otherwise you might make them miserable, quality of life is an issue. There is also, which is perhaps even more important, whereby if you go into too much detail you frighten the patient from having surgery and they go off and decline and that is not in their best interest. So you have to have a balance of judgement in how much information you disclose. In fact in day-to-day practice that is pretty uncommon. Most people are able to take it on the chin.

Moreover, it appears medical practitioners sometimes may try and guide the patient towards what they feel is the best course of action and, in some circumstances, discretion is invoked as to what is said and how it is couched. Therefore, even though the results favour a transparent and open relationship in terms of information disclosure, there are still some circumstances in which the doctor may be economical with the truth depending on the perceived wants and needs of the individuals before them.

**Researcher:** Are you aware of therapeutic privilege that allows you to withhold information from patients which you feel would be detrimental to their health?

**Consultant No 4:** Yes 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, this is where we differ from the Americans. It is my judgement where I draw the line, but the

American rule says that all risks must be disclosed. Every consent form outlines some kind of risk.

The medical practitioners here do not perceive this conduct as being paternalistic in nature, even though in some circumstances it could be. One interpretation suggests this is no more than a professional judgment call, which is deemed acceptable under the circumstances.

**Consultant No 7:** Yes I do breach the law in the terms of the haemorrhoidectomy one in that I specifically don't warn my patients about urinary retention. And I have got a paper that shows that this effect in my patients is low so I think that if I ever got to go to court on it I could stand up in court and say "I did this because..." and I have got the back-up. I do say to the trainees that it is important that they must inform the patients about it because they haven't got that back up so therefore they have to tow the line. Does that make sense?

**Researcher:** So it is working on the best interests of the patient?

**Consultant No 7:** I hope so. I can't see any other reason why you would do something really.

#### ***10.9.8 Theme 7: Communication Breakdown***

\* (There were 20 occurrences of this theme in the consultants/registrars' interviews, 14 occurrences within the SHO/house officers' interviews and 11 occurrences in the nurses' interviews. A total of 45 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

Every participant acknowledged good communication skills provide the key to effective consent procedures. However, the findings suggest that in order for the consent process to work, and to make it a truly reciprocal process, good communication is needed from all parties; both medical practitioners and patients. Nevertheless, a number of the participants demonstrate anxiety over the fact that the communication process does seem to break down within the course of medical consultations. Apparently there two perceived reasons for this.

First and foremost, one of the most noticeable themes is the emphasis that is placed on different patient types and the indirect effect this has on the communication process. The findings show that there are two patient types. The ones that actively

seek out information and who are willing to become involved in their healthcare, and the ones that do not want to know anything about their treatment preferring to disenfranchise themselves from the shared-decision making.

**Researcher:** So you need to find something out about the patient then?

**Consultant No 4:** Yes I mean a lot of what I personally do is based on a basic psychological appraisal, which you look at any basic psychological assessments of patients in information gathering they do 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.

Evidently the willingness of a patient to communicate is not linked to their age, but ultimately turns on the individual personality and intelligence of the patient rather than being intrinsically related to age.

**Researcher:** Do the patients tend to ask you a lot of questions in practice when you are having a consultation?

**Consultant No 8:** The more educated the patient the more questions they will ask. The less educated the patient usually the less questions they ask which is at least that is my perception of their education. No certain types of patients you know will ask lots of questions you can usually pick those out.

Communication levels fluctuate depending on the type of patient the doctor or nurse is dealing with, this has a knock-on effect on how 'informed' the patient actually wishes to be. Different patients require different methods and levels of encouragement to communicate, and different patients require different approaches to information disclosure. Thus, it is evident medical practitioners perceive the need to tailor the information to individual patients.

**House Officer:** ...Yes because you need to think what the patient needs to know as opposed to what you tell them. I mean the problem is that when you invite patients to ask questions it is difficult to know what they want to know.

You often have to make the decision what you think they need to know because they don't necessarily ask.

The second sub-theme is connected to an issue that has featured greatly in terms medical-legal analysis, that of the imbalance of power within the doctor/patient relationship. It seems clear that in the opinion of the health care professionals here the power relationship does have a bearing on the patient's willingness and desire to communicate and engage with the doctor within their treatment.

**Researcher:** Do you think patients do get scared? Why is that is it for a number of reasons?

**House Officer:** Yes because of the environment that we are in. Because 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 findings illustrate that the medical practitioners are conscious that patients may sometimes feel intimidated due to the disparity in expertise and because of perceived vulnerability. The feeling is that the patient, playing the role of the novice, is sometimes overawed in the face of both illness and the doctor as an expert. This leads to a reluctance to ask questions for fear of embarrassment caused by lack of understanding, worry of not being able to articulate questions in an appropriate manner, or a reluctance to engage with the practitioner deriving from the old fashioned notion that the 'doctor knows best.' This may have created a situation where patients are indifferent to taking an active role in their own healthcare as the preference is for the doctor, as the expert, to make any decisions. There is, of course, another explanation. Cancer patients may be reluctant to ask for fear of hearing the worst. Whilst there is literature in support this<sup>2</sup>, the findings in the patients' study

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<sup>2</sup> For discussion what consultants feel ought to be disclosed to cancer patients see, Gordan, E.J. and Daughhery, C.K. "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, Marwit, S.J. & Datsun, S.L. "Disclosure Preferences about

seem to suggest otherwise as the majority of participants suggest they would want to know everything.

### **10.9.9 Theme 8: Tailoring Information to Suit Individual Patients**

\* (There were 26 occurrences of this theme in the consultants/registrar's interviews, no occurrences within the SHO/house officers' interviews and 27 occurrences in the nurses' interviews. A total of 53 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

Even though the health care professionals recognise the benefits of keeping the patient informed about risks and benefits of treatment, the participants still stress the importance of exercising some clinical discretion in the consent process. It has already been demonstrated that there are different types of patients and this has the potential to cause communication problems, which may lead to the consent process breaking down. However, this also causes problems in the actual process of providing the patient with the necessary information. It seems the medical practitioners recognise that different types of patients need different approaches to information giving.

**Consultant No 1:** ...but I think that when you are dealing with a life threatening illness, you have to be aware of how much that patient wants to know and you have to tailor the information to that. And that means you have to tailor the information when obtaining the consent to that as well.

Thus, they acknowledge willingness and desirability to discuss risks and other treatments with patients, although they intimate the law sometimes encourages disclosure beyond that which is sensible in the particular circumstances. In these situations, whilst it appears they are fearful of abstaining from talking about risks altogether, it would seem they are still prepared to tailor the information to the wants and needs of particular patient.

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Terminal Illness: An Examination of Decision-Related Factors" (2002) 26 *Death Studies* 1; Yardley, S.J. *et al.* " Receiving a Diagnosis of Lung Cancer: Patients' Interpretations, Perceptions and Perspectives" (2001) 15 *Palliative Medicine* 379.

**Researcher:** Do you find that you have to find out a little bit about a particular patient before you can make an assessment?

**Nurse Practitioner No 5:** Yes I suppose you would do. I mean this is the thing about consent particular 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. And also you can get things like maybe anxiety state...you know...you have got to try and consider lots of different factors about the information that I give them. I would never really be put off by giving any of that kind of information, say for instance there were two patients one of whom was particularly anxious, it wouldn't stop me from disclosing the same information I would give to the patient who wasn't anxious. Because I still feel that the anxious patient needs to have all that information in order to make an informed choice...but maybe I wouldn't be quite as blunt as I might have been with someone who doesn't seem as anxious.

In a sense this exercise of clinical judgement is a necessary part of the consent process as it allows disclosure to be defined by reference to the individual.<sup>3</sup> The real danger is that the threat of the law erodes this discretion when it is undesirable for it to do so. This point is discussed further below at section 10.7.12 in relation to defensive medicine.

#### **10.9.10 Theme 9: Methods of Enhancing Patient Understanding**

\* (There were 34 occurrences of this theme in the consultants/registrars' interviews, 6 occurrences within the SHO/house officers' interviews and 30 occurrences in the nurses' interviews. A total of 60 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

Clearly, whilst the legal emphasis is on disclosure, the information imparted is meaningless unless the patient has the capacity to understand what is being said.

Every medical practitioner in this study flags up understanding as being an important issue in informed consent. It can be seen that understanding is clearly a

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<sup>3</sup> For recent a discussion on the desirability of disclosing information in reference to the individual see Brooks, *et al.* "Information Required to Provide Informed Consent for Endoscopy: An Observational Study of Patients' Expectations" (2005) 37 *Endoscopy* 1136; Quill, T.E. "Autonomy in a Relational Context: Balancing Individual, Family, Cultural, and Medical Interests" (2002) 20 *Families, Systems and Health* 229.

problem. Previous sections highlight it is commonly accepted there are different types of patients and these needs are to be taken into consideration when tailoring information to suit individuals. This also affects understanding, which is also a very subjective concept. It is evident the real worry for medical practitioners is in regard to divulging the risks to patients and how they subsequently comprehend this information. The perception amongst the participants seems to be that, in some circumstances, upon hearing risks patients will be unable to comprehend what is being said and will become confused, frightened and anxious. Without understanding their condition and why it is needed, the patient cannot conceptualise and weigh the information in the balance. This renders any disclosure and subsequent consent procedures a meaningless exercise.

**Consultant No 3:** ... I always speak to my patients personally because you are not always there when other people do it. I always say now "firstly do you agree to undergo this operation having had it all explained to you?" "Do you understand what we are going to do and why we are going to do it and what the procedure entails?" They can't understand the detail of it, they can't understand all the ins and outs of the anatomy and that it is a big operation and that some of the joints are very difficult and they occasionally can leak. They can't realise this. They are not health care professionals, so you have got to put it in layman's terms in a way that hopefully they will have a perspective of understanding. But I can't explain to you the intricacies of a pancreatectomy. I wouldn't expect to, I wouldn't expect you to try and take it on board. I would try and explain in simple language the implications of it.

A number of the health care professionals focussed on how to enhance understanding. Clearly, a host of factors affect this. For example, in the face of severe illness and bad news, the patient may quite reasonably find immense difficulty in retaining and comprehending any information regardless of what steps the doctor employs to assist them. Moreover, some patients may pretend to understand when they actually do not; undoubtedly the relative education and intellectual ability of patients has an effect on what they take in. What is certain is that there is no sure way to test this and any attempt to ensure complete understanding is an unobtainable goal.

Therefore, above all else, the emphasis is on allowing the patient an opportunity to conceptualise the treatment by giving them a chance to balance the benefits against the risks. It is these different methods of placing treatment in context which are most prominent within the results.

**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?" and 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.

As is demonstrated above, a suggestion is made that the most effective way to facilitate patient understanding of the risks associated with treatment and the necessity of a particular course of action is to use analogies. Something patients can relate to in every day life. For example, comparisons are often drawn between the chance of a risk materialising and being involved in a plane crash, and between percentage risks and the likelihood of winning the lottery. A fair amount of attention was paid to the way in which things are said, the key being that phraseology has a marked effect on the way information comes across to patients and how it is subsequently interpreted. For example, risks can be framed against a positive backdrop rather than just the negative connotations ordinarily associated with information of this kind. In addition, a particular technique was advocated which, although relatively simplistic in nature, is from all accounts incredibly effective and innovative. A number of practitioners suggest they use illustrations and diagrams to enhance patient understanding. Drawing things for patients allows them to visualise their body, see what is wrong with them and how it is going to be rectified.

**Consultant No 8:** All I try and do is give as much information as I can and give diagrams. I know it is similar to teaching medical students. You teach medical students just by talking to them they will retain 25%. If you use slides with

pictures they will retain 50%. If you use sound i.e. moving pictures and so on and so forth they will retain nearer 60-70%. If you do something idiotic in front of them they will remember it even more, so if you make a fool of yourself you know he's the daft twit who did this, that and the other. So trying to give handles for people to retain information is the key and keeping it simple. Now you can apply those techniques when you are taking consent from patients but you have to tailor it each patient and that is very difficult.

There was also evidence that use of written information is of particular use in explaining things to patients in a simplistic manner which they can take away from the consultation with them. This allows them time to gather their thoughts away from the intensity of the consultation process when they have had time to recover from the shock of hearing bad news. From here patients can articulate further questions without feeling the direct pressure from the imbalance of power within the doctor/patient consultation.

**Researcher:** So do you give them eg like you said written information do you think that this enhances their understanding?

**Nurse Practitioner No 5:** Yes it has all just been recently adapted and you know we have looked at patient information again to try and make it as user friendly as possible. But I do think that the written information we give out on endoscopy is very good in the sense that it goes through all the risks that we talk about as an endoscopist. So it gives them lots and just reiterates what has already been said. What you will often find is that they will come in and you will start to talk about risk and they will say "oh yes I read about that in the booklet" which I suppose is a clarification that they at least know something about it...which can only be a good thing.

### **10.9.11**      ***Theme 10: Distaste for Withholding Information***

\* (There were 15 occurrences of this theme in the consultants/registrars' interviews, 3 occurrences within the SHO/house officers' interviews and 9 occurrences in the nurses' interviews. A total of 27 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

One issue that all the medical practitioners agreed on was the reluctance to withhold information. There seems to some confusion over the actual existence of the therapeutic privilege defence and the true nature of its operation. This subject was initially introduced by the researcher as a component of withholding information. The participants often asked whether, legally speaking, they were allowed to do this.

At this stage, the researcher introduced the specific term 'therapeutic privilege' and, on hearing this, many of the health care professionals asked the researcher to explain this defence. It was generally frowned upon. The medical practitioners find it difficult to think of examples where they would use this defence or where the information would be so damaging so as to justify complete avoidance of disclosure under this legal mechanism.

**Consultant No 3:** ...But withholding information 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. For example some people say "well I don't want dad to know that it is cancer or whatever" however if the patient does ask me "is it cancer?" I will always say "yes". I can't lie to a patient, they need to have someone they can trust. On the other hand there maybe a time when I would not give the whole picture to certain patients particularly if I thought that that was going to be detrimental to them or at the express request of relatives but even then my responsibility is to the patient. So I would hope that I would always believe what is best for the patient. Sometimes you would not give the complete or total picture you might be looking at a picture, which you believe to be in the patient's best interest. I don't commonly and regularly withhold information.

There is another problem. Nearly all the medical practitioners flag up the issue of relatives' requests to withhold information. The findings demonstrate that this is a major worry for health care professionals and something they are frequently asked to do. There is also some confusion as to whether this is where therapeutic privilege kicks in.

**Researcher:** Do you think that in any situation you would be justified in withholding information from a patient?

**Consultant Nurse:** I think back to the times when the patients relatives may have asked that their relative was not informed that they had cancer and I have nursed through the problems that that can cause. I remember one occasion when a patient was not informed of the seriousness of his illness and he kept coming back wanting to know why he wasn't getting any better, why was it happening. I understand that relatives feel the need to protect relatives who have terminal illnesses, but I feel that it prevents nurses for undertaking their jobs properly. I feel that the patient should be informed but without taking away all hope.

Whilst relatives' requests to withhold information are a grey area in terms of medical ethics, they are not in respect of the law. It is indisputable that this is not a sufficient ground for withholding information.

Irrespective of the legal intricacies the data suggests that medical practitioners are disinclined to withhold information and the presumption is in favour of disclosure. They are unsure as to the precise nature and applicability of the defence of therapeutic privilege and it is only in the most extreme circumstances where they feel justified in not telling the patient something. Whether this is an accurate reflection on actual day-to-day practice remains open to speculation. Yet, it is possible that medical practitioners do withhold some information but do not perceive it as being under the therapeutic privilege, rather they view it as merely professional discretion and as a component of having to tailor information to the wants and needs of patients as individuals.

#### **10.9.12 Theme 11: Willingness to Delegate**

\* (There were 17 occurrences of this theme in the consultants/registrar's interviews, 5 occurrences within the SHO/house officers' interviews and 8 occurrences in the nurses' interviews. A total of 30 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

In actual fact the willingness to delegate in consent proved to be a very difficult theme to deal with. Potentially there is an overlap here. It represents a general theme common across all the medical practitioners, whilst at the same time there are also issues falling under the scope of individual themes based the rank of medical practitioners. Due to its prominence it is worthy of mention under both.

The general attitude to delegation in the consent process is that it is acceptable. Common sense decrees that in practice it can only be senior medical practitioners who are in a position to delegate consent and thus it is evident consultants and registrars

provide opinions that are probably an accurate reflection of what takes place in reality, based on their experiences and practices. The findings indicate that consent is delegated in practice and is used as a mechanism for saving time and for teaching purposes.

**Consultant No 4:** Oh yes I do I think it is very important to delegate consent if it is appropriate 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 which 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 hey hang on a minute 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.

The only caveat to this, which all the participants emphasise, is that delegation for surgical or invasive procedures can only be carried out if the person taking the consent is capable of performing the procedure or has sufficient understanding of the procedure in question. Clearly this understanding must encompass things such as risks, benefits and alternatives. The findings in the observational component of this study provide evidence that it is usually the consultant who has overall responsibility for obtaining consent.

**Consultant No 7:** Yes as a general rule if you are able to do the operation you are able to take the consent. So some of the Registrars will sometimes take consent for operations that they are OK with doing. The one exception to that is endoscopy, where the House Officers do take the consent throughout the hospital for endoscopies, although they can't perform endoscopy. And the reason for that is that the patients need to be prepped ahead of time so they can't come down, get the consent and go straight ahead with it. So the House Officers do obtain consent for endoscopy.

### **10.9.13 Theme 12: The Law Encouraging Defensive Medicine**

\* (There were 52 occurrences of this theme in the consultants/registrars' interviews, 21 occurrences within the SHO/house officers' interviews and 25 occurrences in the nurses' interviews. A total of 98 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

It is very difficult to draw any firm conclusions about the influence of the law and whether it does actually encourage defensive medicine. Firstly, as Baker suggests, it is very difficult to identify what is meant by defensive medicine.<sup>4</sup> One possible explanation focuses on unnecessary tests and procedures that squander time and money.<sup>5</sup> This however does not fit neatly with consent practices and information disclosure in clinical settings. Thus, for the purposes of this study, defensive medicine can be defined as exposing the patient to excessive information about risks and alternatives which is detrimental to their physical or mental health, and refusing to acknowledge the patient is entitled to waive their right to certain information. The problem with this is whether or not these practices do actually take place and, if so, how they can be directly attributed to the law. The term defensive medicine automatically suggests that one is 'defending' themselves from something. In a medical environment this could mean changing daily clinical practices in order to protect oneself from legal action. In this sense defensive medicine is not necessarily a bad thing. One of the goals of tort law is to influence doctors and other health care professionals to act differently, and to motivate them to provide higher standards of care in order to avoid patient injuries.<sup>6</sup> Thoroughness in information disclosure is desirable. It is only when this becomes excessive and detrimental to the patient that it becomes problematic. Health care professionals may well feel obliged to tell patients things when otherwise they would not. This is very difficult to measure as it is

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<sup>4</sup> Baker, T "The Goods on Defensive Medicine" in Baker, T. *The Medical Malpractice Myth* (Chicago: University of Chicago Press, 2005) at 118.

<sup>5</sup> McGovern, G & Simpson, A. "We're Reaping What We Sue" (2002) *Wall Street Journal* 17 at 17.

impossible to state categorically if and when this happens, and to what extent it affects patients. What is 'excessive' is a matter of individual interpretation. Yet, as each patient is an individual, it is foreseeable that certain disclosure practices may be unwarranted and adversely affect *some* patients. To what extent then can this change in practice be described as 'defensive' and how does it relate to the law? The immediate question is precisely what are health care professionals defending themselves from? It is demonstrated at a later stage of the thesis that clinical negligence claims are decreasing and the actual chances of a medical practitioner becoming the subject of a successful lawsuit are few and far between. (See section 13.17.1 Solicitors' Study). Thus, it seems that the legal rules themselves do not directly impinge on medical practice.

Despite this research does tell us that malpractice lawsuits probably do affect how doctors practice medicine, and some of what they do may not help patients.<sup>7</sup> This begs the question why is this happening? One suggestion is that doctors have anxieties about medical malpractice lawsuits that go well beyond the real risks they face.<sup>8</sup> Thus rather than the legal rules having any direct effect, it is the perceived threat of the law which, in some situations, alters clinical practice. What do the findings in the current study tell us about this in relation to excessive risk disclosure and failure to recognise the waiver?

The findings here suggest that there is a certain fear and distaste of the law. A general theme developed that medical practitioners are conscious of the law operating in the background.

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<sup>6</sup> Baker, *op cit* n 4.

<sup>7</sup> Kessler, D. & McClellan, M. "The Effects of Malpractice Pressure and Liability Reforms on Physicians' Perceptions of Medical Care" (1997) 60 *Law and Contemporary Problems* 81; Kessler, D. & McClellan, M. "Do Doctors Practice Defensive Medicine?" (1996) 111 *Quarterly Journal of Economics* 353; Zuckerman, S. "Medical Malpractice: Claims, Legal Costs, and the Practice of

**Researcher:** Do you think that the law has placed an obligation on yourself to disclose too much information to patients sometimes?

**Nurse Practitioner No 6:** Yes I do sometimes. I mean I talk about the risks that are known to be the highest risks so perforation is the highest risk that could happen. I don't talk about death and not every time but occasionally I do say, "the worst scenario is that you could need surgery." But I don't say that to every patient and maybe I should... but I just think that you have to pitch it at the level that they want. And again some of these little old ladies and gentlemen...they just really...you could talk till you are blue in the face and they would be none the wiser than when they walked in the room before you opened your mouth.

**Researcher:** Do you think that is a bad thing then that if they say they don't want to know...and you feel obliged to tell them?

**Nurse Practitioner No 6:** They are the sort of patients that when something goes wrong they would turn round and say "well you didn't tell me that." So I just think tough. I am sorry you know I am not going to stand up in court defending this because you just said I didn't tell you that.

**Researcher:** Do you think that patients should be able to waive their right to informed consent if they say that?

**Nurse Practitioner No 6:** Only if there was a form that was very clearly documented that got you off the hook if it went pear shaped because they will turn the tables so easily...

Whilst nearly all the participants state they are aware of the law and that a lot of emphasis is placed on the legal side of things in contemporary medical care, it is impossible to ascertain how, if at all, this influences their practice. Defensive medicine is more usually discussed in relation to diagnosis and treatment. It may be perceived by some, including of course the participants, that defensive medicine is not associated with consent. However, there is *indirect* evidence relating to what can possibly be classified as defensive medicine and thus some very tentative conclusions may be drawn from the findings.

One of the sub-themes concerns excessive risk disclosure. It is submitted by the researcher that excessive risk disclosure is, in some situations, analogous with defensive medical practice. Whilst there is a general feeling of enthusiasm for openness and disclosure, the majority seem to indicate that in some situations they

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Defensive Medicine" (1984) 3 *Health Affairs* 128. Despite this, there is evidence that the overall impact of this defensive medicine on health care-costs is not very large. See Baker, *op cit n 4* at 134.

<sup>8</sup> Baker, *op cit n 4* at 135.

feel obliged to tell patients about risks where they may not otherwise do so. The underlying connotation being that the law is placing indirect pressure on disclosure trends.

**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." And there are other issues where the relatives say "we don't want him to know that" and I say "well I am sorry but it is just not on the patient has to know and you are not the patient it is him that makes the decision not you."

The research illustrates that, in some circumstances, medical practitioners are being forced to disclose too much information about risks which could be detrimental to both the doctor/patient relationship and the consent process as a whole.<sup>9</sup>

This has to be approached with caution though as a result of one of the above themes. It appears that despite feeling that the law perhaps places an obligation on them to disclose excessive risks, medical practitioners still feel it is important to exercise clinical judgement and discretion in tailoring information to suit the needs of individual patients. In one sense this is almost an inner contradiction. However, on the interpretation of the researcher, it seems they try to maintain clinical discretion but feel the law has eroded this. The health care professionals are conscious of bombarding patients with too much information about risks but now feel obliged to as a result of the law. Therefore, the foundation upon which to base an argument that the law is causing defensive medical practice starts to become evident.

**Researcher:** Do you ever force this information on them?

**Consultant No 4:** Well it is a very difficult point if 30% psychologically of your patients are blockers you then run to the stage of do you have a right to tell them and I think we should. The best way to prevent a lack of understanding is to give them all the information because therefore they see it, they sign for it and you know that they have seen it. For me that is still not quite far enough I want them to know certain risks now eg if you have got a blocker who needs cancer care where it is getting quite complicated you have got to unblock this and make them realise that they need to know.

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<sup>9</sup> For empirical evidence in support of this see Stanley, B.M. *et al.* "Informed Consent: How Much Information is Enough" (1998) 68 *Aust. N.Z. J. Surg* 788.

One of the further issues drawn out related to the patient's desire to waive their right to informed consent. A general opinion common across all medical practitioners within this study is that a patient is not entitled to waive their right to informed consent. Thus, even in situations where the patient explicitly states they do not want to hear information about risks, or where they voluntarily place themselves in the hands of the doctor, the suggestion is that medical practitioners will continue to tell them about the risks regardless of the patient's request not to be informed. This appears to be commonly associated with the law and the fear of being sued should anything untoward happen.

**Researcher:** Yes if for example a patient says, "I don't want to know" would you tell them?

**Nurse Practitioner No 5:** I think it is very difficult. I think there comes a point where I am happy if a patient says to me "I just don't want to know all the details." Then maybe there would be specific things that I would be happy not to tell them...but equally there are things that I would be absolutely adamant that I must tell them. Such as, you know, I keep reverting back to the colonoscopy. I would not really feel comfortable in not telling the patient about the risk of the perforation and bleeding because that is there whether you are doing therapeutic intervention or whether it is just a diagnostic test. So it is there for everybody really and I think to not make somebody aware of that information even if they had said specifically that they didn't want to know. I would not feel very comfortable with that going ahead because if it then happened I suppose under those circumstances it is a kind of self-protection. I think if it then happened you are more likely for the patient to come back and say "well nobody ever said that to me" than them say "well I told them not to tell me." So there are certain things that I am absolutely adamant that I would want to say to them.

**Researcher:** Do you see that the law has made you disclose more to the patient than maybe you would be personally comfortable with?

**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.

If, as a result of the law, health care professionals are continuing to disclose information against patients wishes, surely this strengthens arguments that the law is

encouraging defensive practice in consent procedures that may have a detrimental effect on both the mental and physical health of the patient.

#### **10.9.14 Theme 13: Consent as a Continuing Process**

\* (There were 15 occurrences of this theme in the consultants/registrar's interviews, 3 occurrences within the SHO/house officers' interviews and 20 occurrences in the nurses' interviews. A total of 38 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

Perhaps the major issue which has been overlooked by the law, and one which was perhaps most common throughout all the transcripts, was that consent should not be viewed as a one-off event and should not be carried out in isolation. The findings illustrate a strong feeling that it should be an on-going process consisting of a number of consultations with all levels of medical practitioners involved in the treatment. This was particularly the case for cancer treatments or where the patient suffered from serious bowel complaints. It is evident that, within the day to day practice of the department under investigation, consent is viewed very much as continuing process.

**Consultant No 2:** The way we do it is in outpatients on the consent form, which is kept down there. In the cold light of day I have a patient coming up to surgery usually before a pre-med when I think you might not be in quite a position to give proper informed consent in those circumstances. So the GMC backs this up that it should be obtained in outpatients by a surgeon who is competent to carry out the operation...I will deal with it myself if I am involved in the operation. If a Registrar is going to be involved in the operation I might have done it myself in outpatients. All of the risks will also be gone through in fine detail at the bedside.

For example, upon the patient being referred, at the first stage of their consultation they usually always meet the consultant or registrar, who is accompanied by a nurse. At this time a diagnosis is made or the patient may be referred for further tests. When a diagnosis is made and a particular operation is recommended the usual practice is that the consultant or registrar will sit down with the patient and go through the risks and benefits with the patient at that stage. They may even fill out the consent form in

outpatients. After this, the patient is afforded the opportunity for a further consultation with a member of the nursing staff. This gives them the chance to clarify any issues with the nursing staff and ask any further questions. They are then provided with written information about the procedure and given a contact number for a consultant nurse should they need any further advice. Depending on the severity of the condition they may also be given a further appointment for a meeting with the consultant nurse therefore enabling them to digest the information provided, giving them time to go away and articulate further questions.

**Researcher:** Do you think that it is a process that the patient should be involved in?

**Surgical Registrar No 3:** Oh yes. Informed consent is a process not just for medical practices. The consent procedure is integral to the patient it is a symbiotic relationship between the practitioner and the patient. It is by no means a medical issue it is an issue between the patient and the doctor or the practitioner which is intimate and probably should take place within a consenting clinic. 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 2 minutes before they have the procedure. It is a symbiotic and active relationship between the patient and the physician.

Thus, by the time the patient is actually admitted to hospital on the day of the operation, the majority of the work in terms of obtaining informed consent has already been done. The signing of the consent form is merely perfunctory acting as a small piece of a much larger jigsaw.

#### **10.9.15 Theme 14: Reliance on Professional Guidelines**

\* (There were 16 occurrences of this theme in the consultants/registrar's interviews, 2 occurrences within the SHO/house officers' interviews and 4 occurrences in the nurses' interviews. A total of 22 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

It is evident that whilst some of the medical practitioners are aware of the documentation that is disseminated by the Department of Health and General Medical

Council, and welcome this as a positive step in the consent process, the majority admit to having little knowledge of these protocols.

**Researcher:** There are a lot of guidelines set up by the Department of Health about consent do you think that they are adhered to in practice?

**Consultant No 4:** I think that unfortunately they are no more than representative of what is going on. I think some people are...I mean...I think that I have hardly read anything that comes out from the Department of Health. And I guess that a lot of people like to think that. However, there is no doubt that a lot of people look on these guidelines as being unachievable documentation that has come round. It depends on what they are and what they do. I personally think that they are great in that they define as a professional body of what level we will be judged by them so therefore you really ought to emulate them. This is what society expects. It is not my judgement, I am a doctor and I practice to the level of what that society wants. I don't actually practice to the level I want because this country doesn't want to pay a large percent in tax so therefore anything the Department of Health guidelines specify is currently what we tend to be governed by and what we need to consider in practice.

This is hardly surprising amidst existing empirical evidence that doctors are unaware of the GMC's code mandating emergency treatment.<sup>10</sup> This does however contradict an earlier point made in the literature view that doctors are more likely to know and pay attention to professional regulatory regimes such as the Patient Code of Rights in New Zealand.<sup>11</sup> Some of the health care professionals even indicate that whilst they are aware of the guidelines, the attention paid to them in practice is minimal. This seems to be for two reasons. First, the lack of time medical practitioners actually have to read and ingest the recommendations. Second, because they are over-complex and require so much in terms of information disclosure they become an impractical model of how consent should be obtained, fettering clinical discretion.

**Researcher:** Do you have to adhere the Department of Health guidelines; do you pay a lot of attention to these because they are always sending out policies and guidelines etc?

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<sup>10</sup> See Williams, K. "Doctors as Good Samaritans: Some Empirical Evidence Concerning Emergency Treatment in Britain" (2003) 2 JLS 258 at 268. Here only 54 per cent of doctors recognised that they had a professional obligation to treat patients in an emergency in accordance with a GMC mandate. Failure to do so can result in a charge of serious professional misconduct.

<sup>11</sup> See section 2.1.11 in the Literature Review 1 of this thesis.

**Consultant No 3:** Yes you do, you have to pay attention to them but the trouble is sometimes they are not totally practical, they are not terribly realistic and they come out with bumph this thick and 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 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.

It may well be that the detailed and rather elaborate guidelines serve as a marker for good practice. However, in the absence of any scope for practical application they will remain precisely that. Instead of making inroads into enhancing consent in clinical settings they become little more than an unworkable ideal that ultimately may be frowned upon by the people that need to rely on them most.

#### **10.9.16      Theme 15: Challenges Posed by Patients Getting Involved**

\* (There were 58 occurrences of this theme in the consultants/registrars' interviews, 23 occurrences within the SHO/house officers' interviews and 33 occurrences in the nurses' interviews. A total of 114 occurrences combined across all sets of healthcare professionals. For further details refer to the table providing the summary of themes in section 10.14 of this study).

It appears patients sometimes go away from consultations after being advised to read up about their condition, and upon their return come back with extensive literature on the subject. This may often be irrelevant, excessive and inaccurate. Whilst some of this may have been brought about by the elaborate written information that is given to patients, the indication is that this is not the core of the problem. This patient information is both accurate and pitched at the appropriate level, giving a fair and balanced medical opinion reliant upon evidence-based practice. The real challenge posed seems to be from patients who use the Internet.

**Researcher:** So you mentioned that you should give the patient as much information as possible. Do you use the Internet and give written information to patients?

**Consultant No 8:** I don't use the internet because it is full of garbage. And I say to the patients "you can have a look." I mean patients don't do it so much now, but 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. One are the good sites where they are from University based hospitals in the States giving good information, the other half are private clinics that are actually touting for business. So I am not going to be able to tell which of those two are.

Medical practitioners acknowledge that if guided to the correct sites, the Internet can be a useful tool. However, the findings suggest there is a lot of information contained on the web that is both inaccurate and potentially misleading. When patients access this, subsequently bringing it to the attention of the doctor, a great deal of time has to be spent clarifying patient concerns that may be irrelevant or which should not actually have provided cause for concern in the first place. Moreover, there seems to be a problem which revolves around information originating from different jurisdictions where medical techniques may vary from those offered in this country. The concern seems to be that there is just too much information for health care professionals to be aware of and this has the potential to look bad in the face of patient questioning. Also, some overseas techniques may not be evidenced-based practices and the doctor or nurse is left having to justify to a patient why they will not perform a particular new and innovative procedure that may be on offer in alternate jurisdictions.

**Researcher:** Do you think that the fact that this information has been made available on the internet and that the information is now readily available does that pose a problem to you?

**Consultant No 2:** Well it causes a problem in as much as that they might have minutiae, which I am unaware of. So they have got one up on me and that does cause a problem. Although that doesn't happen very often and then you just have to come clean and say "I will go and look it up what is the website"... Some of it is misleading, some of it is not evidence based and lacking in scientific quality. And so you can gently remind the patient that that really is not hard line evidence and here is the evidence instead, you know go down the standard road.

## 10.10 SPECIFIC THEMES: CONSULTANTS AND REGISTRARS

These consultants and registrars were from a range of different specialisms including general and colorectal surgery, neuro surgery, gynaecology/obstetrics and orthopaedics.

### 10.10.1 Theme 1: Problems with Categorising Risks

\* (There were 17 occurrences of this theme in the consultants/registrar's interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

Common sense dictates that some risks will be classed as general risks associated with all surgery whereas others will be categorised as special risks typical of specified procedures. Both consultants and registrars seem eager to comment on these issues focussing on the ease with which risks can be classified under the two headings and how this affects disclosure in practice. There is evidence to the effect that it is not too difficult to divide risks into these two headings and, in any event, the distinction is largely irrelevant, as both general and special risks ought to be disclosed in practice.

**Researcher:** Is there a difference between what you would class as sort of special and general risks that you would perhaps disclose?

**Surgical Registrar No 3:** There are general and special risks and there are special risks and specific risks to specific procedures. And then there are general risks for any anaesthetic or any big operation, but you should mention both really. For the big operations where the risks are significant then yes both should be mentioned. But with the small operations like a hernia repair...I mean...I have never talked about risks of blood clots in someone who is a standard fit and well person. I would never talk about the risk of heart attack or about not coming round from the anaesthetic to somebody who is having a hernia operation as those risks are minute and I don't think you would ever get anybody to agree to have the operation.

**Researcher:** Does the significance of a particular risk vary from patient to patient?

**Surgical Registrar No 3:** I think the specific risk for a certain operation will probably remain the same. What would change could be the general risks. Say if you had got somebody undergoing surgery who had already got a heart condition then their risk of having a cardiac arrest under the anaesthetic or around the time of the operation is a lot greater. So you would need to place more emphasis on that. Likewise...if you had got somebody who had a blood

clotting abnormality then you have got to place more emphasis on the fact that they may get bleeding after the operation. So yes you have to tailor your consent towards your patient.

However, one interpretation is that the findings demonstrate medical practitioners may perceive a third category exists. These appear to be risks so small that they are classified as neither 'general' nor 'special.' The perception seems to be that these fall into a bracket of justifiable non-disclosure, as they are so slight as to be insignificant. One further point to be flagged up by registrars in particular relates to the interchangeable nature of general and special risks. It is apparent that in some circumstances risks that would ordinarily be of a general nature to most patients may become special, based on the constitution of the individual before them. Hence consideration of this is needed when tailoring disclosure to meet the needs of the particular patient.

#### **10.10.2      Theme 2: Disclosure of Death**

\* (There were 19 occurrences of this theme in the consultants/registrars' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

In addition, a pressing concern is whether registrars and consultants are under an obligation to disclose the risk of death. Some suggest a degree of worry over disclosing this risk, yet it is commonly acknowledged that under certain circumstances patients ought to be informed about this if it is significant in their situation.

**Consultant No 8:** Yes I disclose every risk that is serious that I can remember. The problem is what is a serious risk and that is where it becomes difficult. E.g. I will tell every patient, what I used to do is just say all risks explained including death and paralysis because death and paralysis to me in my field, as a neuro-surgeon, is probably the most serious risk and I always mention death. And the patient looks at me as if I am talking nonsense because sadly people don't appear to understand that if you open the head up and do a brain operation there is a significant chance that you will die.

Some participants even suggest they may disclose it irrespective of its rarity as it is always a possibility with a consequence so severe that patients ought to be made aware of it. Once again this is bound up in what is essentially a balancing act for medical practitioners. Clearly, the consequences should the risk transpire are catastrophic so this is a major determining factor. However, the rate of occurrence must be somehow balanced against this in order to reach conclusion as to whether the patient is told. This is not an easy task and it appears that, whilst some medical practitioners may not feel comfortable with it, when there is a real chance of death, they are prepared to discuss it with patients.

### **10.10.3      Theme 3: Requirement to Quote Personal Statistics**

\* (There were 7 occurrences of this theme in the consultants/registrar's interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

In terms of percentages, a particular concern also seems to be whether or not they are under an obligation to quote their own personal success and failure rates to patients or if the obligation is to quote national figures. The DoH and the GMC remain silent on this issue in their recent guidelines

**Consultant No 2:** ...And I think in the circumstances of serious surgery, I do actually discuss survival in sort of positive terms to make it easier, because in my own figures I have no mortality in an operation. So it is easier to say that it appears to be very safe in my hands. Although there is a mortality risk if you look at the literature.

### **10.10.4      Theme 4: Indifference Towards the Power Relationship**

\* (There were 14 occurrences of this theme in the consultants/registrar's interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

All the participants within the various different studies concede that there is a massive imbalance of power within the doctor/patient relationship. It has already been demonstrated that this has a knock-on effect in terms of the communication

breakdown. Whilst consultants and registrars do suggest a number of useful ways of enhancing understanding, which goes some way towards indirectly redressing the relative disparity in knowledge, many of the consultants acknowledge the power relationship is an inevitable consequence of the doctor patient relationship.

**Consultant No 5:** I have been working with a psychologist. I have had some discussion with them and one of the problems is how you portray yourself. We don't wear white coats anymore...some do...I have got one over there. I have only to put that on when I've done something wrong...It is like the judges wig you want the full panoply of medicine arriving when you have got some really difficult explaining to do. I wear a tie because I think they expect me to wear a tie and there have been some surveys done that the teenage patients don't worry but older patients, adults want the doctors to look conservative. So there is all this stuff which is getting them on your side. "Trust me I am going to put knives into your body I can kill you." I may not be your best friend but I am someone who will do their best and who is good at what they do.

The participants suggest the imbalance of power will always exist, regardless of what steps are taken to remedy it and thus a certain apathy is shown towards actually redressing it. Many consultants focussed on the ways to improve understanding; very few discussed ways to enhance communication by placing the patient at ease in the face of their perceived socially dominant status.

#### **10.10.5 Theme 5: Reforming the Consent Process**

\* (There were 12 occurrences of this theme in the consultants/registrars' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

A number of the consultants and registrars indicate that the most effective way to improve the consent process is to ensure that it remains a continuing process. This is explored in detail above and it seems the best way to achieve this is to undertake the majority of the communication and explaining process in outpatients as opposed to on the morning of the operation where the patient is often understandably anxious.

**Consultant No 8:** ...The whole business of actually taking consent from a patient is somewhat absurd it actually should be the other way around. The patient should be given the information and pointed to any source like the internet, or textbooks or whatever, the library. They should go and get all the

information, and then they should come back to the surgeon and consent the surgeon to operate. The surgeon then signs a form saying I will agree to undertake the procedure. At the moment it is the wrong way round because it puts the onus on the surgeon to impart information to a patient which can never be 100%. It really ought to be the other way round. A person going to buy a car hopefully does a bit of research before they go and buy it. People don't buy anything, medicine is a commodity it is bought and sold it may not be very pleasant and anyone listening to this tape will think that I am a complete so and so but the fact of the matter is that health care is a commodity. The patient should be able to buy it from the best purchaser or the best provider and therefore the patient has to be the best informed.

In addition to this, as highlighted above, a number of other potential improvements are highlighted. A suggestion was made that consent process should be reversed and it should be the patient who approaches the surgeon with a consent form which is made up of a number of terms and conditions. The onus is then on the surgeon to agree to undertake the operation when he or she is satisfied that the patient has made some effort to make themselves aware of the procedure and its implications, and can also demonstrate some level of understanding in relation to the treatment. This is explored in greater depth in the legal reflections component of this study.

#### **10.11 SPECIFIC THEMES: SENIOR HOUSE OFFICERS / HOUSE OFFICERS**

There were only a limited number of senior house officers and house officers who 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.

### **10.11.1 Theme 1: Recognition of their Role in the Consent Process**

\* (There were 4 occurrences of this theme in the SHO/house officers' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

The findings illustrate a number of issues in relation to senior house officers and house officers' involvement in consent in practice. For example, an argument can be made out that the junior doctors do actually recognise the importance of consent. The admission is that they are not supposed to take consent for major invasive surgery. There is also confirmation that they are not actually asked to do this, and even if they were, quite encouragingly they suggest they would refuse to do so, or at the very least seek advice from a senior colleague.

**Researcher:** So they tend to ask you questions as a junior doctor?

**House Officer No 1:** I think more so, I mean some people have a list of questions and they will ask the consultant when they are there...but not usually. Mostly what will happen is that when it is quieter later they might ask you then but I do think that the nurses get the most of it. If it is about operations and things I don't tend to have the information there to give them so I leave that to the Registrar.

The very fact that junior doctors are able to discuss issues pertaining to consent shows that, despite having little experience in practice, they perceive themselves as having an active role in the process. Just because they are not as actively involved as senior colleagues are they do not think they have no part to play or that they should not concern themselves with consent issues. For example, they acknowledge the types of consent they are involved in such as blood tests, injections, and physical examinations stressing the importance of obtaining the patient's permission before undertaking any type of treatment. Moreover, for some procedures such as colonoscopies where they are directly involved in the consent process, the participants indicate the importance of explaining the treatment to patients via the risk/benefit ratio thereby highlighting the importance of keeping the patient fully informed.

In addition, the participants at this level perceive themselves as playing an important role in communication. The findings illustrate that the perception amongst junior doctors is that patients may sometimes feel intimidated by the consultants and the swarm of doctors that surround them during ward rounds. Accordingly, the suggestion is that the patients are more willing to engage with the junior doctors once the senior members of staff have moved on. Hence, they assist in the communication process in the sense that patients will converse with them in order to ask questions and clarify concerns which in turn improves levels of informed consent.

### **10.11.2      Theme 2: Emphasis on the Law in Training**

\* (There were 4 occurrences of this theme in the SHO/house officers' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

The second theme identified in relation to senior house officers and house officers relates to the amount of legal training they receive. In comparing this to the results of the quantitative study with medical students, it appears they receive more instruction in terms of the legal issues upon entering practice than they do in their early years as undergraduates. It appears a fair amount of attention is afforded to the legal issues in the continuing professional development of their training.

**Researcher:** Is there a lot of emphasis placed on the legal side in your training?

**House Officer No 1:** 'I think we had some lectures, we definitely had some lectures on points of the law and as House Officers we are supposed to have teaching every week. But so far we have had 2 sessions. We don't get teaching that often because we are supposed to have it every week but they do cancel a lot. So maybe we will have teaching 1 in 4 sessions and 2 days have been devoted to legal aspects so that is a large chunk.

**Researcher:** So what sort of things do they talk about to do with the legal aspect?

**House Officer No 1:** We have had 2 lectures on consent and legal issues given to us by the medical protection society, which was obviously quite interesting because they defend the medical profession. And the other one was here and they just talked about not obtaining consent for things that you don't know how to do.

Legal training seems to be welcomed as it prepares them for when they may need to exercise this acquired knowledge as, in practical terms, legal issues are important across all levels of medical practice. It also prepares them for when they take on senior roles such as registrars or consultants and become involved in more complex procedures bringing with them a greater sense of both responsibility and legal accountability.

## **10.12 SPECIFIC THEMES: CONSULTANT NURSES / NURSES**

These participants were various different grades including consultant nurse practitioners in endoscopy/colonoscopy, ward sisters in general surgery and staff nurses in general surgery.

### **10.12.1 Theme 1: Emphasis on Understanding**

\* (There were 16 occurrences of this theme in the nurses' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

The first issue noticeable from the research findings is that nurses seem to place much more emphasis on the requirement of patient understanding in the consent process.

**Nurse Practitioner No 5:** ...Yes...I think it is really. Because I mean you are often in a situation when you are consenting a patient for a procedure, they are already in the room, they are surrounded by the equipment, obviously they are hyper anxious and you are having a conversation with them which they seem to be absorbing and everything. But unless you sort of say to them "well what does that mean to you" or "repeat that back to me" you really haven't got any concept of whether or not they have taken that information in. Like for instance when we are talking about sedation options. So I will talk to them about the different processes and then I will ask them "what do you think, have any preference?" and they will be like "I don't know." And sometimes I think is it just because that you have not absorbed anything of what I have said or is it just that you don't know what to decide. So it is difficult to know whether they have understood it.

Understanding for them forms an integral component of informed consent and there is less emphasis on disclosure of risks and statistics and more on the underlying ethical

importance attached to understanding and why this is so important from a patient's point of view.

### **10.12.2      Theme 2: Importance of the Role of the Nurse in Consent**

\* (There were 20 occurrences of this theme in the nurses' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

Ordinarily one may imagine that the role of the nurse is merely ancillary in the consent process; technically speaking they should not be obtaining consent if they are not qualified to perform the procedure. Thus, the majority of the focus within consent has traditionally been on the consultant or registrar and the importance of their role in obtaining informed consent. This is no longer an accurate reflection on contemporary medical practice.

**Nurse Practitioner No 4:** ...I have worked as a nurse practitioner so patients come to see me in the usual manner that they would go to see a doctor so there is a changing role there, it a different role to the traditional nurse. When a patient first comes in say for a test etc that is really the start of the consent process.

It is evident that a number of the nurse practitioners interviewed within this study do actually perform invasive procedures involving risks. As a result, they are responsible for obtaining consent for these procedures. Nurses do consent patients for procedures such as colonoscopies and endoscopies and this is evident from the findings in the observational study. Also, and perhaps more importantly, irrespective of whether or not they are qualified to perform procedures, nurses at all levels see themselves as bridging the gap in communication between the patient and the consultant and, as such, their feeling is that they play an important part in the consent process.

### **10.12.3      Theme 3: Bridging the Gaps in Communication**

\* (There were 18 occurrences of this theme in the nurses' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

It is evident that the majority of nurses in this study perceive the importance of their role in consent as bridging the gap in communication. They feel patients are more willing to communicate with them and it is their role to clarify any concerns and questions once the consultant has left the room. The problem is, of course, this is very difficult to do if they only have a limited understanding of the risks themselves. However, it appears that the nurses under investigation here do appreciate the risks associated with a range of medical procedures, evidenced by the fact that they talked about them in relation to what they disclose to patients earlier on in the study.

**Researcher:** Do you think there is ways you could enhance the understanding of the patient?

**Nurse Practitioner No 4:** I am a nurse and I think often nurses are the buffer between doctors and patients. You obviously still have some constraints on you because of the hierarchy but nurses generally speaking act as advocates. When a patient say is too frightened to say to a doctor "I don't understand that" they might say to the nurse afterwards "I didn't have a clue what he is talking about." So often the nurses bridge that gap.

This demonstrates not only the importance of the nurse's role in consent, but also the significance that is attached to effective communication acting as being a prerequisite to all professional/patient relationships. This again is linked very much to consent being a continuing process and the benefits therein become self-evident when viewed in this context.

#### **10.12.4      *Theme 4: Distaste for Delegation***

\* (There were 7 occurrences of this theme in the nurses' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

The findings suggest that the nurses are extremely averse to delegation in the consent process. They indicate that consent should never be delegated, and for the nurses who are responsible for carrying out invasive procedures, the indication is that this represents bad practice.

**Ward Sister:** I would hope not. I am all for team working and I am all for extended roles but I do think that generally speaking nurses should nurse and I think that if it comes down to a procedure that a doctor is going to perform then the doctor should do the consent. Because even sometimes I know about co-elective surgery but I am not a surgeon so even now sometimes the patients will say “well what exactly is he going to do” well I can say “well he is going to reset part of your bowel and you are going to have a colostomy” say for instance because I know that but to actually what he is going to do well then it is the surgeon who should talk about it.

The underlying impression is that the participants concede that historically consent used to be delegated. However, they feel it no longer happens. It is possible to view this as a direct contrast to what the consultants intimate earlier in the study that they are happy to delegate consent to anyone with adequate knowledge and experience of the procedure.

#### **10.12.5 *Theme 5: Reluctance to Disclose Risk of Death***

\* (There were 4 occurrences of this theme in the nurses' interviews. For further details refer to the table providing the summary of themes in section 10.15 of this study).

Finally, there is a strong reluctance to mention the risk of death where the chance of it materialising is particularly low so as to render it trivial. This is seemingly out of concern for the patient insofar as they may become unduly frightened and anxious upon hearing this which may have a detrimental effect on their mental and physical health. There is also attention drawn to the fact that it may also put them off treatment that may be both necessary and of benefit to them.

**Researcher:** Are you conscious of the fact that you might put them off the procedure if you divulge too much information?

**Nurse Practitioner No 5:** Yes I think so because I think I tend to give them a lot more information than probably some of my colleagues would do. I tend to go through all the potential pros and cons with the exception of...I don't sort of talk to them about things like death which is a potential complication really but it is such a small risk. I wouldn't necessarily go into sort of the risk of death as I think you can then start to scare people...but yes I think I perhaps do give too much information.

## **10.13      COMPARING AND CONTRASTING THEMES IN SECONDARY CARE**

It has to be said that, in the main, medical practitioners within secondary care actually agreed with each other on the majority of issues hence the discussion and analysis focuses on the many common themes recurrent across different grades of personnel.

For example, there are few discrepancies between consultants, registrars and junior doctors. In relation to junior doctors, whilst the results draw out some specific issues which are just relevant to their role, this never appears in direct conflict with what registrars and consultants say. This may be of no surprise given that junior doctors may share similar agendas with senior colleagues. As both senior house officers and house officers operate under the tutelage of consultants and registrars, opinions and practices will undoubtedly rub off on them.

However, it is evident that even though there are some similarities between the views and opinions shared by doctors and nurses, there is also some definite conflict. For example, the consultants place a fair amount of emphasis on risk disclosure whereas the nurses tend to focus on understanding as being the most important component in the obtaining of informed consent. Similarly, nurses do not think delegation is appropriate in consent and they do not think this goes on in practice. Compare this to what the consultants suggest about being happy to delegate consent to an appropriate person and that it does actually happen in practice. It is apparent the nurses perceive the importance of their role in consent as being good communicators. They see themselves as being more approachable thereby going some way towards redressing the imbalance of power and bridging the gap between patients and doctors. Consultants, on the other hand, do not necessarily seem to view the imbalance of power as a negative thing. Finally, the nurses are reluctant to disclose the risk of death

to patients for fear of affecting the mental state of the patient and it has been noted that many of the surgeons do this regardless of the consequences.

Here we begin to see a pattern emerging that is illustrated neatly by the latter two points. The role of the nurse in contemporary medicine is that of the patient advocate. Advocacy has become an accepted and integral attribute of nursing practice. Many codes of ethics for nurses state that they ought to act as the patient advocate.<sup>12</sup> Thus, amongst other things, they are supposed to protect patient rights. This includes value-based decision making, the patient's human and legal rights and the right of autonomy. It seems that whilst this is a positive aspect of nursing, in some situations, it has the potential to cause conflict with senior colleagues, especially if doctors attempt to act paternalistically. Thus it is possible to attribute the importance they attach to understanding, communication and not unnecessarily overburdening the patient with excessive risks as being directly linked to the way in which they perceive their overall role as a nurse. That is, representing and protecting the rights and interests of patients in a much wider sense, which some doctors may interpret from a much narrower perspective.

## **10.14 COMPARING SECONDARY CARE THEMES WITH PRIMARY CARE THEMES**

In comparing some of the themes identified in this part of the study, with the findings of the previous study concerning primary care, it appears there are both similarities and differences. One common theme throughout both studies is the importance of consent and shared-decision making, yet both sets of clinicians highlight difficulties in implementing this model of care. Nearly all the practitioners in both studies

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<sup>12</sup> For discussion see, O'Connor, T. & Kelly, B. "Bridging the Gap: A Study of General Nurses' Perceptions of Patient Advocacy in Ireland" (2005) 12 *Nursing Ethics* 453; Holley, S. *et al.* "Pain Resource Nurses: Believing the Patients, Believing in Themselves" (2005) 32 *Oncology Nursing*

highlight and stress the ethical imperative which underpins informed consent. Directly following on from this there was agreement about the difficulties inherent in the communication process and the ability of patients to understand. These problems are perceived to be as a result of individual traits of patients and are not concerned with merely age and illness, but are perhaps more affected by their relative educational background. Whilst some of the consultants in secondary care show an indifference towards redressing the imbalance of power, most of the other participants, in particular the nurses, highlight ways of developing communication. Also, and perhaps most encouragingly, the majority of clinicians across both studies demonstrate steps that ought to be taken with a view to enhancing patient understanding and some of these included some very innovative techniques.

In addition, the findings illustrate that both sets of practitioners recognise the importance of openness and transparency suggesting that the majority of complaints are a result of a breakdown in trust between the doctor and patient. For example, the emphasis is mainly on disclosure, except in some situations where both doctors and nurses inadvertently slip into what could almost be likened to indirect paternalism, albeit out of concern for what they perceive to be in the patient's best-interests. Therefore, it is fair to conclude that whilst medical practitioner's at all levels are reluctant to purposefully or intentionally withhold information from patients, they are still prepared to invoke clinical discretion in some circumstances regarding precisely what to say and how to say it.

There is a clear acknowledgement from both sets of practitioners that they are conscious of the law and that it does operate very much in the background in contemporary medical care. Yet, medical practitioners do not perceive this as having

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*Forum* 843; Altun, I. & Ersoy, N. "Undertaking the Role of Patient Advocate: A Longitudinal Study of Nursing Students" (2003) 10 *Nursing Ethics* 462.

a *direct* effect on their everyday practices. They are still happy to rely on clinical judgement. This is fine as there is no reason to fear the law; it is highly respectful of clinical judgement. This is particularly the case in relation to the medical practitioners in primary care. This may be related to the dynamics of general practice where arguably the scope for legal challenge is lower thereby causing less concern for practitioners in this field. Yet, in the same breath, GP's acknowledge medical practitioners in secondary care may have greater cause to feel threatened by the law as a result of the complex treatment in which they are involved. The findings do show the *indirect* effect the law is having on practice within secondary care. The medical practitioners admit they sometimes engage in excessive risk disclosure and fail to recognise the waiver and, despite the fact they seem to have difficulty making the connection, this can be linked to defensive practice.

The real difference to be found when comparing the results of both the primary and secondary studies resides in the nature of the consent process itself. There is evidence to the effect that within primary care consent is very informal and is expressed mainly verbally or by implication even where minor operations are involved. The opposite is true of secondary care. Whilst the medical practitioners are aware the dangers with this, consent procedures are extremely formal and emphasis is placed on written consent and appropriate documentation. Moreover, it is evident that much greater significance is placed on risk disclosure. Once again, this difference may lie in the fact that procedures in secondary care are likely to be more invasive and complex thereby increasing the risks and the chances of something untoward happening.

## 10.15 SUMMARY OF THEMES FROM HEALTH CARE PROFESSIONALS IN SECONDARY CARE

<u>Initial Coding Category in NVIVA</u>	<u>Rank of Medical Practitioner</u>	<u>Number of Coded Entries Within Each Category</u>
The Importance of Consent as a Shared-Decision Making Process	Consultant / Registrar	36
	Senior House Officer / House Officer	6
	Consultant Nurse / Nurse	18
Problems with the Consent Form*	Consultant / Registrar	48
	Senior House Officer / House Officer	9
	Consultant Nurse / Nurse	25
Disclosure, Openness and Transparency	Consultant / Registrar	18
	Senior House Officer / House Officer	12
	Consultant Nurse / Nurse	6
Problems with Risk Disclosure*	Consultant / Registrar	55
	Senior House Officer / House Officer	8
	Consultant Nurse / Nurse	11
Disclosure Beyond Risks*	Consultant / Registrar	39
	Senior House Officer / House Officer	3
	Consultant Nurse / Nurse	10
Underlying Paternalism & Best-Interests	Consultant / Registrar	23
	Senior House Officer / House Officer	1
	Consultant Nurse / Nurse	7
Communication Breakdown*	Consultant / Registrar	20
	Senior House Officer / House Officer	14
	Consultant Nurse / Nurse	11
Tailoring Information To	Consultant / Registrar	26

Suit Individual Patients		
	Senior House Officer / House Officer	N/A
	Consultant Nurse / Nurse	27
Methods of Enhancing Understanding	Consultant / Registrar	34
	Senior House Officer / House Officer	6
	Consultant Nurse / Nurse	30
Distaste for Withholding Information*	Consultant / Registrar	15
	Senior House Officer / House Officer	3
	Consultant Nurse / Nurse	9
Willingness to Delegate	Consultant / Registrar	17
	Senior House Officer / House Officer	5
	Consultant Nurse / Nurse	8
The Law Encouraging Defensive Medical Practice*	Consultant / Registrar	52
	Senior House Officer / House Officer	21
	Consultant Nurse / Nurse	25
Consent as a Continuing Process	Consultant / Registrar	15
	Senior House Officer / House Officer	3
	Consultant Nurse / Nurse	20
Transferability of Professional Guidelines	Consultant / Registrar	16
	Senior House Officer / House Officer	2
	Consultant Nurse / Nurse	4
Challenges Posed by Patients Getting Involved*	Consultant / Registrar	58
	Senior House Officer / House Officer	23
	Consultant Nurse / Nurse	33

## IDENTIFICATION OF SUB-THEMES

<u>Initial Theme</u>	<u>Sub-Theme</u>
*Problems with the Consent Form	Problems with Standardising Consent Contempt for the designers
* Problems with Risk Disclosure	Problems with Confusion Problems with Statistics
*Disclosure Beyond Risks	Placing Things in Context: Risk v Benefits Disagreement over Alternatives
*Communication Breakdown	Power Relationship Different Patient Types
*Distaste for Withholding Information	Problems with Requests of Relatives
* The Law Encouraging Defensive Medical Practice	Consciousness of the Law Excessive Disclosure Failing to Recognise the Waiver
*Challenges Posed by Patients Getting Involved	Problems with the Internet

\* For the purposes of the discussion section, the sub-themes are analysed in accordance with the primary theme.

## 10.16 SUMMARY OF SPECIFIC THEMES

### 10.16.1 *Consultants / Registrars*

<u>Individual Theme</u>	<u>Number of Coded Entries Within Each Category</u>
Problems with Categorising Risks	17
Disclosure of Death	19
Requirement to Quote Personal Statistics	7
Indifference to the Power Relationship	14
Reforming the Consent Process	12

### 10.16.2 Senior House Officers / House Officers

<u>Individual Theme</u>	<u>Number of Coded Entries Within Each Category</u>
Recognition of their Role in the Consent Process	4
Emphasis on the Law in Training	4

### 10.16.3 Consultant Nurses / Nurses

<u>Individual Theme</u>	<u>Number of Coded Entries Within Each Category</u>
Emphasis on Understanding	16
Importance of the Role of the Nurse in Consent	20
Bridging the Gaps in Communication	18
Distaste for Delegation	7
Reluctance to Disclose Risk of Death	4

## 10.17 CONTINUING LEGAL REFLECTIONS: SECONDARY CARE

### 10.17.1 Theme1: Problems with 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.'<sup>13</sup> Reflecting on the findings of this study, it is apparent that the medical practitioners do not perceive consent as being just a 'medico-legal requirement.' They demonstrate a commitment towards keeping the patient informed and look positively on the concept of shared-decision making.<sup>14</sup> However, worryingly, it appears the elaborate and detailed nature of the consent form stifles some of the creativity and discretion that is needed in order to render consent a

<sup>13</sup> Jones, M. "Informed Consent and Other Fairy Stories" (1999) 7 Med L Rev 103 at 126.

<sup>14</sup> For discussion see Feldman-Stewart, *op cit* n 1.

'true' process in which the patient is involved. The medical practitioners perceive the over-complex nature of the form as being driven by the law and identify that this has turned consent into a regimented procedure that takes something away from the patient. This serves as detrimental to the consent process. Evidence of a correctly filled out form, accompanied by a mere signature, does little to prove the patient has expressed a valid and informed consent. If anything, it has the potential to mislead clinicians into thinking that they have when, in actual fact, they have not.

Despite the fact that the clinicians under investigation suggest that consent should be a reciprocal process, the opinions expressed, in conjunction with the later observational findings, suggest that the consent form has the undesirable effect of making the process unnecessarily bureaucratic. Thus creating the danger, as identified by Jones, that medical practitioners are left "consenting the patient", a term which in itself 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 in, or indeed controls.<sup>15</sup>

### **10.17.2 Theme 2: 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.'<sup>16</sup>

As the law of negligence is predicated on harm the requirement to provide necessary information preceding any operation has inevitably focussed on the risks inherent in treatment. As a result, medical practitioners' perceptions of consent have been

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<sup>15</sup> Jones, *op cit* n 13 at 125.

coloured and, despite the fact the consent should not be solely about risks, the development of the law has undoubtedly encouraged prominence to be attached to this side of things, effectively turning clinicians into agents of disclosure. This is problematic as Beauchamp and Childress remind us that although the term informed consent was born in a 'legal context, from a moral viewpoint, it has less to do with liability of professionals as agents of disclosure and more to do with the autonomous choices of patients and subjects.'<sup>17</sup>

The problem for the law has been reaching a consensus on how to judge the adequacy of clinicians' disclosure. The various approaches were analysed in the literature review of this study and it is arguable, though by no means certain, that the law has yet to come to a firm conclusion on how best to do this. The findings suggest doctors are also unsure about what to disclose in practice. Whether or not this confusion is caused by the law remains uncertain. For clinicians to be influenced by the law's uncertainty, they would normally have to know something about it. The findings indicate the clinicians actually know very little about the law and how it operates. Thus it is possible, and perhaps more likely, *their* uncertainty stems from uncorroborated collegial anecdotes.

The findings in respect of this study illustrate two things. Firstly, risks are disclosed by reference to the probability of them materialising, and secondly, some attention has to be given to the patient as an individual and the seriousness of the procedure's side effects. This is because the gravity of risks fluctuates depending on the individual. In addition, as well as considering what *ought* to be disclosed to the patient, there must also be some scope for taking into account what *should not* be

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<sup>16</sup> Berry, D. *Risk, Communication and Health Psychology* (Berkshire: Open University Press, 2004) at 23.

<sup>17</sup> Beauchamp, T.L. & Childress, J.F. *Principles of Biomedical Ethics* Fifth Edition (Oxford: Oxford University Press, 2001) at 81.

disclosed in relation to their particular circumstances. How then does this reflect on the various legal standards of care?

Presuming, as most academic and practising lawyers would, that disclosure is no longer dictated solely by the *Bolam* standard, it seems that medical practitioners are under an obligation to disclose all risks that the courts would deem significant based on what the reasonable patient would want to know. However, what constitutes a significant risk cannot be defined by reference solely to the percentage chance of it transpiring. 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 highlights the further 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.<sup>18</sup> The courts have recognised these dangers but have often become embroiled in referring to percentages by way of example.

Understandably, the medical profession, which operates within the positivist framework of the natural sciences, has clung to this as a method of providing a benchmark against which disclosure can be measured. The major difficulty for patients is how to interpret these statistics. Recently the Secretary of State for Trade and Industry was quoted as saying 'fifty per cent of the public doesn't actually know what 50% means.'<sup>19</sup> Research has shown that over a third of a sample of a 1,000 Germans were unable to interpret the term 40 per cent correctly, mistakenly believing

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<sup>18</sup> Kennedy, I. "The Patient on The Clapham Omnibus Postscript: The House of Lords' Decision" In Kennedy, I. *Treat Me Right : Essays in Law and Medical Ethics* (Oxford: Clarendon Press, 1988) at 200.

<sup>19</sup> Patricia Hewitt (Secretary for State for Trade and Industry) quoted in the *Independent*, 30<sup>th</sup> November 2002).

that it meant one in four or every fortieth person, rather than four out of every ten.<sup>20</sup>

In order to combat this problem, Gutteling and Wiegman proposed that the principal 'ground rule' of risk communication is that the information should be customised to the receiver's needs.<sup>21</sup> 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, as opposed to addressing the irrelevant questions, and must also be comprehensible and not add to further confusion.<sup>22</sup> As such, 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. This is based not only on the seriousness of their condition and the overall state of their general health, but also the wider social factors that effect the lifestyle of the patient. Medical practitioners should not rely too much on statistics as a marker for what to disclose and the law should not judge the significance of a risk solely by reference to this.

One of the further problems for the law is from whose point of view the significance of a risk ought to be judged. Based on Lord Woolf MR's interpretation in *Pearce* this appears to be a matter for the courts to decide based on an objective assessment.<sup>23</sup> Very recently Maclean has identified the problem with this suggesting 'the question of a risk is a subjective issue coloured by the individual's character,

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<sup>20</sup> Gigerenzer, G. *Reckoning with Risk* (London: Penguin, 2002) at 45.

<sup>21</sup> Gutteling, J.M. & Wiegman, O. *Exploring Risk Communication* (Dordrecht: Kluwer Academic Publishers, 1996) at 121.

<sup>22</sup> *ibid.*

<sup>23</sup> *Pearce v United Bristol Healthcare Trust NHS* (1998) 48 BMLR 118 (CA) at 124.

experiences and goals.<sup>24</sup> Therefore, the problem resides in the fact that an objective test is applied to what is essentially a subjective matter. Maclean further argues that if the test were subjective it would be more sensitive towards patient autonomy.<sup>25</sup> However, it appears Maclean thinks this test would never work<sup>26</sup> and as such the basis of his paper is to call for some empirical evidence to 'give a voice to the reasonable patient.' This thesis goes some way towards providing some empirical evidence. Yet, what Maclean is calling for is a contradiction in terms. If the findings in this thesis tell us one thing, it is that there is no such thing as a 'reasonable patient.'<sup>27</sup> 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', an argument can be made out for refining the standard of care to account for the needs of individual patients in risk disclosure. This argument is developed and explained in the solicitor's study

### **10.17.3 Theme 3: Excessive Disclosure: Perceptions of the Law**

Kennedy famously suggested that 'one doctor's defensive medicine may well be another's idea of good practice.'<sup>28</sup> This is true. Diligence in risk disclosure can only be a good thing. However, at this point it is worth pausing to consider Kennedy's other famous assertion:

'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.'<sup>29</sup>

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<sup>24</sup> Maclean, A. "Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence" (2005) 7 Med L Int 1 at 12.

<sup>25</sup> *ibid* at 11.

<sup>26</sup> *ibid*. The reason offered for this is a well versed argument by both academics and the courts. This centres on the danger of self-serving testimony coloured by hindsight and the effect this could have on increasing litigation trends. However, the hypothesis seems somewhat unsubstantiated.

<sup>27</sup> See the various comments made by the medical practitioners in this study accompanied by the comments made by patients, that the information a patient wants varies depending on the individual.

<sup>28</sup> Kennedy, *op cit* n 18 at 190.

<sup>29</sup> Kennedy, *op cit* n 18 at 189.

Whilst it appears that there remains some confusion amongst medical practitioners over exactly what to disclose, the results demonstrate that clinicians operate within a framework of disclosure that is dictated by a benchmark figure of one per cent. There appears to be agreement that all risks around this mark ought to be divulged. Thus, Kennedy's statement may no longer be an accurate reflection on contemporary medical practice; there does indeed appear to be some harmonisation over disclosure. However, the courts have never stipulated that all risks have to be disclosed around the one per cent mark. Whilst in some circumstances this may represent good practice<sup>30</sup>, it may also have the reverse effect. Particularly if, as the findings suggest, clinicians feel the law is placing an obligation on them to disclose more than they think they should.<sup>31</sup> Disclosure is very much a subjective issue and some consideration has to be given to the level of information the particular patient wants. For example, Miller has suggested that patients differ in the amount and type of information that 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.<sup>32</sup> This is confirmed by a number of practitioners within this study. There is strong evidence to the effect that

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<sup>30</sup> Interestingly, 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 "Seeking Patient's Consent: The Ethical Considerations" (1998); Department of Health Circular "Good Practice in Consent Implementation Guide: Consent to Examination or Treatment" (2001). However, in a recent article it was suggested the standard level of disclosure in modern medicine encompasses all risks within the region of 1-2% and above. See Hussain, W. *et al.* "Consent and Invasive or Interventional Cardiology" (2001) 7 *Clinical Risk* 127 at 129. Interestingly enough, in the most recent House of Lords decision *Chester v Afshar* [2004] UKHL 41; [2005] 1 AC 134 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.

<sup>31</sup> For a general discussion of how excessive disclosure affects medical practice see Heywood, R. "Excessive Risk Disclosure: The Effects of the Law on Medical Practice" (2005) 7 *Med Law Int* 93.

<sup>32</sup> See. Miller, S.M "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."

not all patients want to be kept informed about all risks, and regimented disclosure of all risks around the one per cent mark in every situation removes an element of clinical discretion.<sup>33</sup> The law supports professional discretion in terms of either the *Bolam* test or the therapeutic privilege, depending on which standard of disclosure is in operation. (See section 3.1.8 in the Literature Review 2). The findings in this study illustrate that medical practitioners are unaware that this is a viable option when considering the individual needs of patients. Indeed, they seem to relate it mainly to relatives' requests to withhold information and this is not really what clinical discretion in disclosure is all about. It is also submitted that the law must take into account the patient's ability to waive their right to informed consent in order that their right to self-determination is truly respected.<sup>34</sup> If the above two factors are overlooked this could be detrimental to the patient thereby endorsing a culture of 'excessive risk disclosure', or, on an alternative interpretation, defensive medical practice.<sup>35</sup> The findings in this study support the notion, as previously suggested in section 10.9.13, that this is not caused by the legal rules themselves; instead it is 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

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<sup>33</sup> See recently see Beresford, N. *et al.* "Risks of Elective Cardiac Surgery: What Do Patients Want to Know?" (2001) 86 *Heart* 626. For further empirical evidence see Lidz, C.W. *et al.* "Therapeutic Misconceptions and the Appreciation of Risks in Clinical Trials" (2004) 58 *Social Science & Medicine* 1689-1697; see also Fraser, A.G. "Do Patients Want to be Informed?" (1984) 4 *Br Heart J* 468.

<sup>34</sup> For discussion on how the waiver can be tied into the therapeutic privilege defence in order that the law can account for the passive patient see Heywood, *op cit* n 31.

<sup>35</sup> A classic example of defensive medicine brought about by the potential threat of consent litigation is for the treatment of anal fissures. The standard and most effective surgical procedure to cure this is called a lateral sphincterotomy. The most common risk, although very slight, is soiling. A generation ago this was not divulged. However, this is now divulged to the patient; the problem is the evidence provides a varying degree of soiling rates which patients interpret differently. Thus, surgeons are recommending treatments which are known to be not as effective as surgery and that can take up to a year to complete. The majority end up having to have surgery anyway and in the interim period they may well have been harmed as a result of failing to resort to surgery in the first place. See. Brown, S.R *et al.* "The Management of Persistent and Recurrent Chronic Anal Fissures" (2002) 4 *Colorectal Disease* 226.

to understanding mal-practice law suits that we would like them to take to medical practice.<sup>36</sup> This reinforces the idea the medical practitioners ought to receive more extensive training in relation to the law as is suggested at various points throughout this thesis. (See section 13.17.4 in the Solicitors' Study).

#### **10.17.4 Theme 4: Disclosure Beyond Risks**

Looking beyond the mere disclosure of risks to consider discussing the benefits of treatment is, in the opinion of the researcher, an example of good practice and should be viewed as such.<sup>37</sup> There is evidence to the effect 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.<sup>38</sup> This is an inevitable consequence of medical consultations; more often than not patients will always look to the positives. Also, is it not a small price to pay if it affords the patient the opportunity to place into context the need for the proposed treatment so they can make a more balanced decision?

Moving on to alternatives, there is a lack of English authority on this issue.<sup>39</sup> Interestingly enough, Kennedy and Grubb suggest that in *Sidaway* none of their Lordships referred to any duty to advise patients of alternatives.<sup>40</sup> With respect this is wrong. Lord Scarman clearly suggests that his interpretation of the duty to disclose

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<sup>36</sup> Baker, *op cit* n 4 at 135.

<sup>37</sup> Edwards has suggested the balancing risks and benefits is a very 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. Edwards, A. *et al.* "Concepts in Risk-Benefit Assessment: A Simple Merit Analysis of Medicine?" (1996) 15 *Drug Safety* 1.

<sup>38</sup> Hekkenberg, R.J. *et al.* "Informed Consent in Head and Neck Surgery: How Much do Patients Actually Remember?" (1997) 26 *J. Otolaryngology* 155; Smith, D.K. *et al.* "Informed Consent to Undergo Serum Screening for Down's Syndrome: The Gap Between Policy and Practice" (1994) 309 *BMJ* 776.

<sup>39</sup> 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.

should encompass alternatives to treatment.<sup>41</sup> Clearly, 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 the findings there is some disagreement over this. Some of the clinicians intimate it is appropriate to discuss treatment options with patients. Nevertheless, in the same breath, examples are 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 standpoint they need to be wary of doing this. Despite the fact that little attention has been paid to this component of the duty, there is evidence of late that patient rights generally are being afforded greater protection by the courts.<sup>42</sup> Thus, if clinicians fail to discuss and offer different treatment options to patients, and risks transpire, it is possible they could be held liable for withholding this information about 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 should this happen, as opposed to an alternative procedure carrying considerably less risk.<sup>43</sup> Denying patients' choice based on evidence-based practice has the danger of becoming a euphemism for paternalism. In addition, justifying procedures on the grounds of personal preference, convenience and allocation of resources may be frowned upon by the courts and is likely to play second-fiddle to considerations of patient autonomy.

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<sup>40</sup> Kennedy, I. & Grubb, A. *Medical Law* Third Edition (London: Butterworths, 2000) at 711.

<sup>41</sup> See *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 at 876.

<sup>42</sup> Most notably in the cases of *Chester v Afshar* (*op cit* n 30) and *Pearce* (*op cit* n 23). See also *Bolitho v City & Hackney Health Authority* [1997] 4 All ER 771. For discussion on the changing nature of the law and its attitude towards patient's rights see Lord Irvine "The Patient, The Doctor, Their Lawyers and the Judge" (1999) 7 Med L Rev 255.

<sup>43</sup> Classic examples of this may include the decision to opt for a colonoscopy as opposed to a barium enema (discussed in the observations section) or the various procedures available for the treatment of the 'pilonidal sinus' (discussed in the observations section). See also the treatment of anal fissures, *op cit* n 35.

### 10.17.5 Theme 5: Enhancing Understanding & Communication

In contemporary medical care, more often than not, it seems patients are provided with adequate information about treatment. Thus, in the future we may see more attention, in a legal context, towards the 'understanding' component of consent. The focus of the patient's argument may switch towards the fact that despite the information being provided, they were unable to understand and were not given an adequate opportunity to do so. This problem will be compounded if risk disclosure takes the form of regimented and uniform process whereby the patient is just bombarded with information. However, to date, little attention has been paid by the courts to the duty to facilitate understanding. In *Smith v Tunbridge Wells HA* 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.'<sup>44</sup> [emphasis added].

Whilst this remains only a decision at first instance, it is the only case where any great consideration has been given to the understanding element of consent. Grubb suggests this does not represent the law as it places too onerous a duty on the doctor and goes beyond the reasonableness standards of negligence. Accordingly, the suggested interpretation is there is a requirement for the doctor to take *reasonable steps* to make the information intelligible and understandable.<sup>45</sup> The problem is that the courts are yet to articulate what those reasonable steps ought to be. What this study does provide is some examples of the good practice that can be used to facilitate

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<sup>44</sup> *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 334 at 339.

understanding. Over time the courts could develop these into guidelines, which could assist them in determining whether a doctor has done enough to enhance this aspect of consent. The first thing to note is that good communication leads to higher levels of understanding. Patients prefer it when doctors are good communicators and this undoubtedly improves what the patient digests and assimilates. Moreover, the use of diagrams and visual aids enhances comprehension, as does the use of analogies to allow patients to contextualise the severity and the need for treatment. Similarly, the findings suggest that advances in electronic resources provide a useful resource as long as patients are directed to appropriate web-sites. This, coupled with the dissemination of written information, provides valuable methods of enhancing knowledge.<sup>46</sup>

Nonetheless patient appreciation remains very subjective and is difficult to assess. Thus, in the future, it may be worth implementing a section on the consent form which allows the doctor to elaborate, for evidential purposes, the steps which have been taken to assist understanding. This would work as an addition to the already existing system whereby the patient signs to say they have some level of understanding because this, in isolation, remains somewhat of an empty gesture. Achieving complete understanding is an unobtainable goal; doctors could never make this happen and the law would never be able to judge them against this idealistic

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<sup>45</sup> See Grubb, A. "Medical Negligence: Information and *Bolam*" case note (1998) 3 *Med L Rev* 198 at 201. Others also support this standard. See, for example, Williams, K. "Comprehending Disclosure: Must Patients Understand the Risks They Run?" (2000) 4 *Med L Int* 97.

<sup>46</sup> There is various empirical evidence relating to the benefits of decision-aids and written information in the consent process. See Barrett, R "Quality of Informed Consent: Measuring Understanding Among Participants in Oncology Clinical Trials" (2005) 32 *Oncology Nursing Forum* 751; Barratt, A. *et al.* "Use of Decision Aids to Support Informed Choices about Screening" (2004) 329 *BMJ* 507; Feldman-Stewart, D. "A Decision Aid for Men with Early Stage Prostate Cancer: Theoretical Basis and a Test by Surrogate Patients" (2001) 4 *Health Expectations* 221; Schapira, M. & VanRuiswyk, J. "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 Taylor, E.M. *et al.* "Patients' Receipt and Understanding of Written Information about a Resuscitation Policy" (1998) 12 *Bioethics* 64.

standard. However, this is not to say that the law cannot assess the reasonable steps that should be taken. This would encourage clinicians to create a culture where patients comprehend treatment to an extent where they can express a more 'informed' consent.

#### **10.17.6 Theme 6: Consent as a Continuing Process**

Williams identifies the shortcomings of the law in respect of its ability to act as a watchdog over consent in practice. He suggests '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.'<sup>47</sup> Thus, the functional nature of any legal inquiry tends to view consent as an 'isolated process', rather than looking at the bigger picture of whether the patient was afforded the maximum opportunity to make a considered choice. This opportunity is restricted if consent is seen as a one off event that is performed the morning before any procedure. If consent is obtained at this stage, it may be perceived by patients as something that is just necessary and the rationale underpinning consent itself may be ignored. In contrast, the opportunity to exercise one's self-determination is advanced if consent is viewed as a continuing process which begins the moment the patient is referred to hospital. Even if the procedural side of consent, that is, the signing of the form, is not performed until a later date, the regular communication of information still forms part of an on-going consent process. It seems the clinicians under investigation here realise that what they do prior to the formalities associated with consent still forms an integral part of consent being viewed as continuing process, the purpose of which is to keep the patient as 'informed' as possible. The functional nature of the legal inquiry

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<sup>47</sup> Williams, *op cit* n 45.

will not change. However, evidentially, if it can be proved that the patient was provided with information about risks, benefits and alternatives at many different levels and was afforded to opportunity to ask questions of different clinicians, it may go some way towards allowing the courts to reach the conclusion that the patient was indeed kept 'reasonably' informed.

This brings us neatly to the next point. This concerns delegation. Legally speaking delegating consent makes no real difference as the focus remains on what is actually said rather than who says it. Clearly, if medical staff are unaware of what the procedure entails then they should not take the patients consent insofar as the legal formalities are concerned. However, if it is to be viewed as an on-going activity this is not to say they should not be involved in the process at all. It has been demonstrated quite extensively 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 as to the importance of consent.<sup>48</sup> Thus, as long as there remains adequate supervision, in order to facilitate consent as a continuing process, it is essential to involve medical practitioners at all levels.

#### **10.17.7 Theme 7: Professional Guidelines: Setting a New Standard?**

Reflecting on Jones's comments that 'as professional attitudes to the question of information disclosure change...patients will become entitled to more information under the *Bolam* standard,<sup>49</sup> it seems this assertion is correct. The standards of the profession have changed, demonstrating a commitment towards keeping the patient more informed; this is evident from the extensive guidelines issued from the

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<sup>48</sup> Soin, B. *et al.* "Informed Consent: A Case for More Education of the Surgical Team" [1993] 75 *Ann. R. Coll. Surg. Eng.* 62.

<sup>49</sup> Jones, *op cit* n 13 at 125.

Department of Health and the General Medical Council.<sup>50</sup> Nevertheless, the question as to whether or not the guidelines can be used to define a new standard of care in respect of information disclosure is uncertain. Firstly, the standard set by these guidelines is in advance of what the law requires, and secondly, the courts are under no obligation to follow these standards; legal and professional standards are two matters that are quite distinct. Undoubtedly, they will provide some guidance and the courts may often be inclined to adopt 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 here that whilst many are aware of their existence, they are unaware of their substantive content. Legally speaking ignorance is no excuse;<sup>51</sup> still the goals set by the protocols must be obtainable. The participants here suggest that some of them are idealistic and fail to account for the realities of the consent process. If compliance with the guidelines is unachievable in practice, and can never realistically be met by clinicians, there is an inescapable difficulty in allowing them to influence the legal standard of care.

#### **10.17.8      Theme 8: Reforming Consent**

In analysing some of the suggested ways to reform consent, legally speaking, perhaps the most interesting idea concerned the reversal of the process itself. This would operate in such a way that the patient approaches the medical practitioner and it is for the doctor to agree to undertake the procedure once they are satisfied that the patient has made themselves reasonably aware of the necessary details. What effect would this have on consent from a legal point of view? Firstly, does it deny the patient the

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<sup>50</sup> See guidelines by DoH and GMC, *op cit* n 30.

right to self-determination? Not really, this would only be the case if the patient was denied the opportunity for treatment altogether based on their failure to become involved or their inability to understand what is proposed. This is not what the participants were suggesting. The rationale behind reversing the consent process serves two purposes. First, it places emphasis on patients to take more responsibility for their own decision making and, second, it provides a fail-safe system for protecting the medical practitioner. Thus, the answer to the above problem is to provide a different consent form for those patients who do not have the 'capacity' to consent. Under these circumstances both parties would agree to continue with the treatment on the understanding that the patient has not got the ability to express an appropriate 'informed consent'. Alternatively, for those patients who just do not wish to make themselves reasonably aware of what the treatment entails, the consent form could include a disclaimer that the patient signs effectively confirming that they have relinquished their right to informed consent. Evidentially, this may make medical practitioners feel more safe and protected. Initially it may seem at odds with the concept of patient self-determination, something that the law strives to protect. However, legally speaking, it does not deny the patient the opportunity to decide and they would still have to give their permission at some point and agree to whether or not they want treatment. However, two things are worthy of note here.

Firstly, a system like this does have the potential for abuse. Medical practitioners theoretically would have the power to deny medical treatment and could conceivably 'pick and chose' their patients. Also, in some situations, both parties may reach a 'stalemate' where the patient declines to sign the disclaimer and the medical practitioner refuses to proceed in the absence of this. This could be based on the

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<sup>51</sup> 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

perception that the patient has the capacity to make himself or herself aware of the treatment, but is just unwilling to do so. Under these circumstances clinicians may find themselves subject to close scrutiny, in both a legal and professional sense.

Secondly, one may be forgiven for questioning how different this system is from the one currently in operation. Effectively it still involves a form with both parties signatures present on it, the purpose of which is to provide documentary evidence that consent has been obtained. Merely switching the onus onto the consultant to agree may have little effect, especially if it is just another process where the medical practitioner agrees all the time. If anything its practical significance could be to slow the process down; both medical practitioners and patients may frown upon this rather than welcoming the move. Irrespective of this, a compromise could be reached which involves amending the consent form currently in use. This could be done by including a disclaimer and tick-box verifying the patient wishes to waive their right to informed consent, and a section which confirms that, in the opinion of the clinician, this particular patient does not understand and does not have the capacity to express a valid and informed consent. This would be for both the clinician and the patient to tick and sign.

This suggestion for reform is certainly different, and represents an idea that has never been picked up in academic sense. It does have its drawbacks, but then again so does the present system. If it were to be implemented it would be at its most effective in outpatients, were it could be used to facilitate the desirable option of maintaining consent as a continuing process. The patient could be given an explanation of the proposed procedure, this could be supplemented with some written information and the actual consent form. The consent form itself could then be taken

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technique.'

away to be filled out by the patient, and at the next appointment the consultant could complete their section of the form after they are satisfied the patient understands what is going to happen. At this stage, the consultant can decide whether or not the patient ought to sign an alternative consent form, or if the disclaimer should be signed dealing taking into account the acquiescent and apathetic patient. If the only disadvantage is that this would take more time then there is no reason why the system could not work. It is certainly no answer to suggest this cannot work because it has never been done before. What it would certainly go some way towards is cultivating an environment where patient involvement is expected by encouraging them to read up on proposed treatments and the risks and side effects therein. For those that do not want to engage in this process, the answer is catered for in this system, but for those that do, it would allow them the opportunity to foster a deeper understanding of the treatment they are agreeing to. There is of course a counter-argument to this. The consultants in the study who perceive the existing system as unnecessarily bureaucratic would undoubtedly be hostile towards such an approach. They are unlikely to embrace a system which, in their eyes, may have the potential to introduce more 'red-tape' into the consent process. This should not be used as an excuse to write this idea off without at least some further consideration. Perhaps this may provide the forum for further research into the benefits and drawbacks of implementing such a system.

# **11 STUDY 3: INFORMED CONSENT IN SECONDARY CARE**

## **PART 2 - INTERVIEWS WITH PATIENTS**

### **11.1 INTRODUCTION**

This section explores informed consent from patients' perspectives. It employs qualitative interview methods to investigate the views and opinions of those who have been treated in hospital, by the clinicians in the previous study. It looks at the dynamics of the consent process and identifies how consent is obtained; whilst at the same time ascertaining what is meaningful and important to patients in everyday practice. Eight patients were interviewed who had all been treated, or were currently receiving treatment, in the department of general surgery. The interviews were transcribed and uploaded into NVIVA for computer-assisted analysis. A thematic analysis was conducted on all the interview transcripts and the findings are discussed in the context of the identified themes.

The study begins by providing a brief justification for the work and then progresses to discuss the procedure, participants and methods of analysis. It then moves on to provide the substantial discussion of findings and, finally, in keeping with the philosophy which underpins the qualitative methodology, there is a reflexive section which reflects on the findings in a legal context.

### **11.2 JUSTIFICATION**

Consent ought to be a shared-decision making process of a reciprocal nature. The questions that remain poorly understood are how do patients perceive consent, what is important to them in this process and how does this relate to legal theory and practice? As there is little in the way of empirical research concerning the above, this

study investigates these issues using qualitative research methods to develop an understanding of informed consent from the patient's point of view.

### **11.3 RESEARCH QUESTION**

To investigate and develop a clearer understanding of consent procedures and issues amongst patients in secondary care settings. Please see chapter 7.3 for a full list of research questions.

### **11.4 SUMMARY OF PARTICIPANTS**

The number of participants in this study included:

Patients (N=8)

The patients in this study were a mix of both males and females. There were five females and three males. The participants were middle-aged and above and had all received treatment at some time from the health professionals who were interviewed in the previous study. This was in the department of general and colorectal surgery. They had suffered from a range of illnesses such as cancer, Crohn's, ulcerative colitis, IBS and had undergone different forms of invasive and non-invasive treatment.

### **11.5 METHODS**

This component of the study employed semi-structured qualitative interviews. Please see chapter 4.8 for further discussion.

### **11.6 ANALYSIS**

The interviews were transcribed and uploaded into the software package NVIVA. The findings were then analysed using the computer-assisted software to identify recurring themes. Please see chapter 8 for further discussion. As this is a qualitative study, within the discussion there are no references to numbers of participants or

percentages. However, for a summary of figures relating to the number of themes and the importance attached to each, please see the tables at the end of this study. (See section below for further details).

## **11.7 ORDER OF THEMES**

As the studies started out with no pre-defined themes, the themes are presented in the order in which they developed from the base upwards within each particular study. Within the findings below, the importance attached to each theme is noted in brackets underneath the relevant heading. The level of importance was assessed by the number of times each theme occurred within the transcripts. However, for a complete summary, and to identify the importance attached to each particular theme, refer to the table providing the summary of themes in section 11.11 of this study.

## **11.8 STUDY LIMITATIONS**

The patients in this study were approached using only one hospital in the UK, and due to the difficulties associated with gaining access, only a limited number of participants were interviewed. Thus it is impossible to generalise in relation to the findings. The research itself was extremely concentrated in the sense that it targeted only one group of patients who had received treatment from one specialism. Despite this, what the study lacks in representativeness, it makes up for in terms of depth, boasting some very detailed qualitative findings.

## **FINDINGS**

### **11.9 THEMES FROM THE PATIENTS IN SECONDARY CARE**

#### ***11.9.1 Researcher's Note***

As noted in the previous qualitative studies, due to the nature of the semi-structured interview format not all the answers provided by the participants were directly related to the initial question posed by the researcher. Often a topic was introduced and then the participant would elaborate on this in great detail. Thus, a number of themes overlapped and this was drawn out in the analysis. Accordingly, within the discussion section, the extracts provided as evidence sometimes do not marry up with the precise nature of the question asked and, in some instances, the initial question posed by the researcher is not displayed.

#### ***11.9.2 Theme 1: Difficulty in Relating to and Understanding Consent***

\* (There were 29 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

Many participants struggled to provide definitions of consent and demonstrate a very sketchy understanding of what it is actually about. There is some evidence to suggest that the patients perceive it as being important to medical practitioners as it is a method of 'covering their backs.'

**Researcher:** What is your understanding of consent?

**Patient No 2:** I thought it were more or less for if there was any come back if anything went wrong with the operation it clears them of any liability. Because some past years ago, in the old Royal Hospital, which used to be on West Street, they have pulled it down now, I went in for an operation on my polyps on my nose. And while I was down at a theatre, unbeknown to me, the anaesthetist was a trainee, which is fair enough, and she must have hit a nerve in my arm and it partly paralysed my arm. I finished up being off work for 7 weeks when I should only have been off a week as my job at that time involved the use of my arm. So I had to have a claim against them for loss of earnings you see. That's what I thought these things that you had to consent for were...to alleviate the

profession from these counter claims and one things and another. Is that what they are really for?

Few patients mentioned or even implied that consent was about their right to self-determination. The perception seems to be that consent is viewed as a means to an end. That is, something that is *necessary* and something they have to do in order to get to the next stage, which is the treatment.

**Researcher:** So what sort of happened in the consent procedure?

**Patient No 2:** Well he just asked me to sign a consent form. I had a heart bypass as well 3 years ago and that was the same thing and you sign this paper thinking well "I have got to sign it to get the operation." I mean if I had refused would they have refused the operation that is one thing that they never explain you see.

**Researcher:** Would you prefer it to be the consultant who took your consent or are you not really bothered?

**Patient No 4:** No I was not really bothered it could have been just anybody. I would have consented to. I mean you either want an operation or you don't. It's as simple as that and in my case I didn't really have a choice. They do their best and that's all they can do it's as simple as that.

Later, however, the findings do show willingness from the patients to receive information about risks and alternatives, the benefits of openness and transparency, effective communication and problems with understanding. They also portray an eagerness to engage with medical practitioners and enthusiasm for becoming involved in their treatment. The real reason for this may be slightly different than first envisaged.

### **11.9.3 Theme 2: Willing to Receive Information and Become Involved**

\* (There were 19 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

The patients in this study seem quite enthusiastic about receiving information and becoming involved in their treatment. It seems that the participants under investigation like to be kept informed. They are happy to receive information about

risks and see the desirability of this, further intimating that they would feel aggrieved should anything be deliberately withheld from them.

**Researcher:** ...Would you have been upset if the consultant hadn't told you about some perhaps important major risks and these risks had developed afterwards?

**Patient No 2:** Oh yes because they know the risks don't they? I mean we only know so many risks don't we? I mean if you are informed of the side effects I mean if you go on a tablet there is always notes telling you of the side effects because when I had had my bowel operation naturally they sent me up to Weston Park with it being cancer to see Mr xxxxxxxx. Now Mr xxxxxxxx is a wonderful man. He asked me what I wanted to know and I said "I want to know everything." So he wrote it me all down and he said "now you are 30% cured of cancer and I can give you another 5% with chemotherapy." He explained all the side effects of what that chemotherapy would give me and how long it would be for and I sat there and looked at things and I said "I am not going to go through the risk of having all them side effects just for 5%." So I refused it and he admitted that that would have been the decision that he would have taken but it was my decision.

Nonetheless the majority of participants also seem to recognise that there are different types of patients, some of whom may not want to receive information about risks. The findings suggest that the perception amongst the patients is that some individuals may like to 'bury their heads in the sand' and may not want to be told about risks, instead preferring to hand themselves over to the care of the doctors letting them get on with making them better. Also, there are further suggestions that some patients may become unduly anxious, confused, scared and put off by over exposure to risks. In these circumstances there is acknowledgement that there may be some grounds for withholding some information.

**Patient No 3:** ...I think it is up to the individual person. I mean like you said if somebody says "I definitely don't want to know" then that is their right...but I mean if you sit there are you say "I want to know it all" then they should not be allowed to hold anything back at all.

The findings provide some insight into the type of information that patients require and are ultimately willing to receive. It seems it is not enough to receive information about risks in isolation. Indeed, if this happens the view is this has a negative effect

on the doctor/patient relationship. Emphasis is placed on the need to spell out the benefits of the treatment in conjunction with the risks, with particular reference to the consequences of not having the treatment.

**Patient No 8 [Husband]:** ...It's one thing to say what are the risks of the operation, but surely you really need to also think, well what are the risks if I don't have the operation?

**Researcher:** Yes

**Patient No 8:** You need both sides of that.

**Researcher:** Yes I think that is a really important point. Do you think they actually discuss those in practice nowadays?

**Patient No 8: [Husband]** ...And then you look at us you might think that we will operate but these are the risks, if it's not a success you will not be with us in three months time. And say in that case I am not going to have it. I would rather carry on and just see how long I have got.

**Researcher:** Yes. I mean I think you are absolutely right. That's the way. I have spoken to some of the consultants as I am interviewing consultants as well and they have said that nowadays they try to explain in terms of the risk/benefit ratio, which is the right way to do it. You are not going to get anywhere by just disclosing risks.

**Patient No 8 [Husband]:** You don't want to put them off, and yet without the operation you have not got much chance at all, so I think you do need to have the information to balance do I or don't I?

This is in order that the patient can weigh in the balance the potential need for their treatment against the consequences of refusing it and is the only way they can conceptualise their situation.

#### **11.9.4 Theme3: Overall Satisfaction with Consultations and Information Received**

\* (There were 48 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

The findings illustrate that despite the fact that some of the participants feel some decisions are already made for them, they still trust the doctor and are happy for this to happen.

**Researcher:** No...that is the real difficulty I mean we have talked about consent and the fact that it is about making a decision and obtaining the full facts. Did you ever get the impression that the doctor has already made the decision for you?

**Patient No 7:** Oh definitely. Yes Yes. I mean it is like you will have this operation and you know that it is really and 99% of people will go along with what they say won't they, they won't go away and say "well wait a minute I will go away and think about that." I suppose it depends on what is wrong with you. I mean in our case where we had cancer...I mean at the end of the day there was only one option wasn't there, to go with what he said and you trust that doctor. Well I think you would probably would do more now they are specialised...

Overall the patients seem satisfied with both the consultation process and the information they received prior to any operation with this particular hospital. They say the information received is adequate and that both the consultants and the nursing staff provide an excellent service. Furthermore, the clinicians are happy to answer questions and engage with them enabling patients to feel at ease within the consultation process.

**Researcher:** Do you think he spent enough time with you so that you could say "I have consented to this operation and I know what it is about?"

**Patient No 2:** I felt that way yes. And at the same time I know the amount of time he spent with me was as much as he could give me because he is very busy. He had a lot more people waiting to see him I mean he told me that I would need to have an endoscopy, which I had, and that is when they told me I had got cancer. And 2 weeks after that they sent back for me because they had seen these 2 cancerous polyps in my bowel and apparently at the end of every week all the team have a discussion.

**Researcher:** So do you think you were given enough information so that you could make an informed choice?

**Patient No 2:** Yes I think they did very well. Like in my first examination they told me I had these polyps and they were chatting to me, having a bit of a laugh and a joke. Then they told me they had found something else and I had to go in and then this other lady she had me and my wife in and explained it to us both. I think they have been very good I have had no problem at all.

However, there are some problems with this which became evident in the analysis. These centre on patients' feelings towards the medical practitioners. It is evident that the perception of the participants is that both the doctors and nurses can do no wrong. They are loath to criticise the work of the consultants and their staff and there is a strong undertone of satisfaction and gratitude towards the people that have cared for them.

**Researcher:** Part of the consent process is about explaining the risks to the patient. Did Mr xxxxx explain the risks to you?

**Patient No 4:** There was a lady, I forget her position, she came to me the night before the operation and she explained all the risks to me and at finish up I just got a few tablets but I never used one when I came out. They did a remarkable job on me and I will be honest with you, I made a donation to cancer research because that is how pleased I was with the treatment I had. From the first examination to the staff who looked after me whilst I was in hospital and even now I go for different tests and that.

Herein lies the problem. In the main, the patients interviewed in this study consisted of cancer sufferers who have been operated on by the consultant surgeons who were also interviewed. Two things can be said about this. Firstly, the patients may understandably feel reluctant to criticise medical practitioners who may have saved their lives. Secondly, as their operation was successful, this will undoubtedly have a bearing on how they perceive the quality of the consultation and the information provided to them beforehand. They may be inclined to look on it more favourably than if say an adverse event had taken place subjecting them to some type of damage. For this reason many of the patients did truthfully acknowledge that they could only comment on *their* direct experiences and that these opinions may differ from patient to patient. Hindsight reasoning is a danger, yet it is an inescapable consequence of any post-operative research. Still, as long as this is accounted for, there is no reason to suggest that some tentative conclusions cannot be drawn from this work. Thus, it is possible to conclude that the majority of patients within this study remain happy with both the consultation process and the amount of information that is disclosed in practice.

#### **11.9.5 Theme 4: Unwillingness to Complain and Resort to Legal Action**

\* (There were 58 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

A common pattern emerged relating to the patient's unwillingness to complain and resort to legal action. Again, it is easy to suggest this with hindsight, when everything has been a success. These views may well have been different if something untoward had happened. This needs to be accounted for when attempting to make any generalised statements about the research findings.

It is evident the patients here do not feel it is appropriate to actively look to penalise and seek redress against medical practitioners for omissions and mistakes that may be made in course of their professional duties. It would not be an accurate assertion to suggest none of the patients admitted to raising complaints; indeed some actually did. Yet, there is a general feeling of sympathy towards the position of medical practitioners and the challenges they face within everyday practice. Whilst there is an acknowledgement that it is very difficult to mount a complaint within the internal mechanisms of the NHS, the general feeling is that very few patients would consider going beyond this. This is coupled with a strong theme, which suggests the patients dislike those who resort to legal action.

**Researcher:** Would you ever have considered legal action?

**Patient No 7:** No.

**Researcher:** Why is that?

**Patient No 7:** I don't know. Probably because it is too much trouble and that sounds awful but when you have had what you have had and you are recovering you don't want the hassle anyway and you don't. Also it was a pure mistake nobody did it on purpose.

This seems to be attributed to a number of things. For example, there are connotations that could be associated with the ever-increasing notion that we are living in a litigious society which is being encouraged by such things as television advertising. There appears to be a feeling of anger towards those who are perceived

to be nothing more than money grabbers attempting to make a 'fast-buck' out of the NHS. This is linked to the idea that doctors and nurses, in the main, do an excellent job and should not feel threatened in their work as a result of exposure to the law.

**Researcher:** Just hypothetically if they had not told you about the major risk and this was to have happened would you have been really upset then and would you have considered complaining to anybody?

**Patient No 4:** I don't think I would personally perhaps now because I now what a good job they did, but I don't think I would have complained because they did a marvellous job and explained everything to me. I know I have had one or two friends who have had the same problems as me, one died with it you know that were unfortunate he had of those bags on him, everything doesn't always go right they are not perfect. I accept that you know things can. I mean with this friend of mine it must have been that serious things just didn't go right for him and unfortunately he died. It is just one or those things you have got to accept it is part of life. I mean there are young people who are PE teachers, really fit and they can die from heart failure it happens.

**Researcher:** Is that true of all patients do you think or do you think some are more willing to complain than others?

**Patient No 4:** They do yes. You know in life its like you know you are waiting 5 minutes for a bus and what is the chance that you get somebody complaining about it. Bus has probably been caught in traffic but you will always get somebody blaming the bus driver but its not his fault. Some people complain about slightest little thing you will find that in life, if you are at work, or anywhere, if you are having a drink you will get certain people. I mean I have a friend like that he will grumble about anything.

**Researcher:** It doesn't lead to a solution does it?

**Patient No 4:** In fact we were on holiday once in Turkey and he got the wrong change. It were I would say about 10 or 15p and he went complaining and this young man got the sack. This young man made a mistake and he got the sack. He should have been ashamed of himself. He thinks everything should be perfect but its not, that's not life is it?

**Researcher:** That is the sort of thing from my point of view, these people complain but 9/10 the doctors is always going to try and have your best interests at heart.

**Patient No 4:** I know you will always get people complaining and you hear about these judges and doctors who have been on the Internet. I am on about these cases that get publicised. They forget about all the 100s and 1,000s of cases that they have done well for they only publicise when summat has gone wrong. It's always headlines... they forget about time when it is has gone right, like in my case that has gone right.

Some of the patients do actually identify that this may have a negative effect on the work of medical practitioners. Moreover, and perhaps more significantly, the findings suggest that as with any walk of life, medical practitioners do make mistakes, and it is

not fair to penalise them to a greater extent than other professionals just because of the nature of their particular job.

#### **11.9.6 Theme 5: Problems with Understanding**

\* (There were 26 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

In relation to the understanding component of informed consent, all the participants acknowledge that it is problematic. This however seems unrelated to the imbalance of power and the potential for intimidation. Furthermore it does not seem connected to medical practitioners' lack of ability to communicate information about the treatment in an effective manner. The source of controversy seems linked to the patient's ability to comprehend information at the time it is disclosed.

**Researcher:** Did you get the opportunity to speak to your consultant about your operation?

**Patient No 2:** Yes but you see when they tell you that you have got to have this big operation, like a heart bypass or bowel cancer, your mind goes blank. And I believe now that I don't really know what they told me because in goes in one ear and out of the other. But now I believe they are doing an audio tape and this has been discussed at our meetings and the consultants are going to do these audio interviews for the patients to take away with them and have a listen to them in their own home. Which is a good thing and I think there should be more of that done. I think they are pushing through with it more to have these audio tapes for people to take home with them.

The findings suggest it is extremely difficult for patients to understand what is being said to them in the direct face of illness, and after being told bad news. They say they are often so frightened and preoccupied with their own thoughts they often just 'shut off' from what is being said. It appears this is particularly relevant to the specialism under investigation, which is predominantly concerned with cancer treatments. The minute 'cancer' is mentioned the participants suggest many will not listen to anything else the doctor or nurse has to say as that word is the only thing they will focus on.<sup>1</sup>

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<sup>1</sup> For patient perspectives on the amount of information desired about terminal illnesses see, Marwit, S.J. & Datson, S.L "Disclosure Preferences about Terminal Illness: An Examination of Decision-

**Researcher:** That is the difficulty with it I mean I think perhaps two ways, and you have already mentioned one is in terms of the drawing that helps doesn't it?

**Patient No 7:** Yes you know it only take a couple of minutes for them to do that but even so some patients don't want to know. They really don't want to know and I know that because I have brought a patient into surgery with a suspected lump and a suspected bowel cancer. He got in there and they said what they wanted to do and he just walked out and came out "they are not messing about with me." He wouldn't even let them go near him you know and I mean you are talking about different ages, different people and intelligence is everything isn't it?

In situations like the above, the process of information disclosure becomes an empty gesture.

However, of further significance are the personal feelings of the participants towards understanding. Many of the interviewees rely on personal experiences by way of example and whilst many suggest understanding is a general problem, the findings indicate that the participants under investigation here imply they actually found little difficulty in understanding what was said to them in the course of their personal consultations.

**Researcher:** In terms of the consent process itself what is not paid attention to, in terms of the law, or not much attention is this issue of understanding and arguably you have got to understand what it is that you are consenting to. Do you think it is very difficult to understand what a consultant is saying to you?

**Patient No 7:** Well in truth no because I have always understood what they have said so it is difficult isn't it to say in general for everybody else. I have to say that I have understood what they have meant.

On one interpretation, this can be viewed as a contradiction as, on one hand they seem to identify a potential problem, then on the other deny it exists based on their personal experiences. There is of course the possibility that the participants are loath to admit that they do not understand things through fear of sounding unintelligent. This seems unlikely as the majority of the participants did seem genuine.

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Related Factors" (2002) 26 *Death Studies* 1; Yardley, S.J. *et al.* " Receiving a Diagnosis of Lung Cancer: Patients' Interpretations, Perceptions and Perspectives" (2001) 15 *Palliative Medicine* 379.

It is evident the patients do seem to rely on their personal experiences. That being said, whilst they do warn about the dangers of generalising about individuals other than themselves, it appears they are prepared to speculate about how understanding is very much dependant upon the individual. The findings highlight that understanding is subjective and does vary from patient to patient. For example, the participants suggest that some individuals may not be very intelligent and their understanding will be affected by this. Moreover, it is highlighted that some patients more than others will be affected by the fear of illness; once again this will effect the ease with which information can be understood.

**Researcher:** Do you think it varies very much from patient to patient?

**Patient No 7:** Yes I mean, it sound awful doesn't it, but not everybody is intelligent. I mean if some elderly person goes in, as I have observed from some of my clients, and they explain it to them and they haven't a clue have they? And if they don't take somebody with them then yes it depends on the situation really the level of intelligence, the age it could be anything really.

Finally, although understanding is a major problem, it is stressed this should not be used as an excuse to ignore this important factor. As a result, a number a themes developed based on methods of enhancing understanding. Some of these ideas, as illustrated in the above extract, include the effective use and distribution of written information, the use of diagrams in consultations and the development of audio tapes to be given to patients allowing them to playback what is said in a consultation at a later date.<sup>2</sup> There is a also evidence to the effect that nurses play an important role in

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<sup>2</sup> There is various empirical evidence relating to the benefits of decision-aids and written information in the consent process. See Barrett, R "Quality of Informed Consent: Measuring Understanding Among Participants in Oncology Clinical Trials" (2005) 32 *Oncology Nursing Forum* 751; Barratt, A. *et al.* "Use of Decision Aids to Support Informed Choices about Screening" (2004) 329 *BMJ* 507; Feldman-Stewart, D. "A Decision Aid for Men with Early Stage Prostate Cancer: Theoretical Basis and a Test by Surrogate Patients" (2001) 4 *Health Expectations* 221; Schapira, M. & VanRuiswyk, J. "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 Taylor, E.M. *et al.* "Patients' Receipt and Understanding of Written Information about a Resuscitation Policy" (1998) 12 *Bioethics* 64.

developing understanding and that this is best achieved by maintaining consultations as continuing processes.

### **11.9.7 Theme 6: Importance of Communication**

\* (There were 39 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

All the patients stressed the importance of effective communication. It is indicated that this is one of the most important aspects of the doctor/patient relationship. This is based on the premise that both doctors and nurses who are skilled communicators are the ones that know how to offer the relevant information and explain it in a manner which is easy to understand. These practitioners are also the ones who are able to tailor information, or phrase things in a certain way in order to take into account the needs of individual patients.

**Researcher:** Do you think they are reluctant to discuss with patients what is going on and things like that from your experience?

**Patient No 3:** I think sometimes doctors don't listen, they don't listen enough, they look at a textbook and say "this says this, that and the other" and they don't listen. Everybody is different as to how they react and they should listen to each individual and I don't think they do.

The participant's views on communication are further divisible into two distinct sub-categories.

In one sense the findings illustrate a strong inclination towards openness and transparency between doctors and patients. This is personified within the very first theme where the findings suggest patients are more than happy to receive information and like to be kept informed. Similarly, many participants stress the importance of honesty within the doctor patient relationship. There is a preference for medical practitioners who communicate honestly with patients. Indeed, honesty seems to be viewed as a prerequisite to developing relationships of trust between the doctor and the patient.

**Researcher:** So you are the sort of person that very much likes to be involved in the treatment?

**Patient No 1:** Oh yes definitely and I like to ask questions and I like to be answered honestly.

The findings conclude that patients are aware of the importance of effective communication. Patients are more at ease with medical practitioners who are good at communicating because this leads them to being better equipped and prepared to deal with illness.

**Patient No 1:** ...I think with some people they have a natural gift to be able to communicate with people. I think others haven't and they should have some form of tuition.

**Researcher:** So some education in terms of the communication side because a lot of doctors training the emphasis is on diagnosis and treatment and things like that perhaps a little bit more on the communication side?

**Patient No 1:** It is the same with young doctors you know. The stream of doctors that surgeons bring around with them, there are some of the younger ones who can really communicate with patients and they are wonderful really for young men. But others they seem to be aloof, who can't talk to you.

**Researcher:** So a change in attitude?

**Patient No 1:** Well they need to be probably told how to communicate. I don't think some of them...it is probably due to the way that they have been brought up.

However, it appears the general consensus amongst the interviewees is that historically clinicians have been poor communicators and that this is an aspect of their job which needs improving. There are indications, of late, that doctors are getting better at this and perhaps more emphasis should be placed on this important aspect in their training.

**Researcher:** Do you think patients sometimes feel intimidated about speaking to consultants?

**Patient No 6:** Yes I do think that some of the doctors do need to improve their communication skills.

**Researcher:** Do you think that this needs to come from their training? or do you think it is inherited?

**Patient No 6:** Sometimes yes but I think now in this day and age I don't think it is as bad. You still get it because there are still some doctors about who do, but now I do feel that a lot of them are a little bit more human. I have been coming to hospital and having operations since I was 30 and back then they didn't used to speak to you. They used to speak at you but now I do think they have learnt a little bit I think.

### **11.9.8 Theme 7: Feelings about the Power Relationship**

\* (There were 37 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

The findings indicate that whilst most of the participants acknowledge there is an imbalance of power within the doctor patient relationship, this may be less of a problem than initially envisaged. Once again this was a theme where the participants relied heavily on their direct experiences and how the power relationship affected them personally in conjunction with some generalised views as to how this may vary from patient to patient.

A pattern emerged which suggests an imbalance of power does exist and the patients recognise this. This is no real surprise as it is fairly clear that patients and medical practitioners operate at different levels within the context of medical consultations. What may be of greater significance is the effect that this has on the consultation process. Based on the participant's opinions it appears this is minimal. Many of the interviewees state that personally the imbalance in power between themselves and medical practitioners does not perturb them in the sense that they still wish to be kept informed about the operation and receive the necessary information. Moreover, it does not lead to a reluctance to ask questions and seek out further information should they feel the need. In fact, nearly all the participants suggest that, from a personal point of view, they would always feel confident in asking questions.

**Researcher:** I think one of the things might be that patients can feel intimidated about asking questions. Did you ever feel that in terms of the consultant/doctor situation?

**Patient No 2:** To a certain extent yes because our age group, and this is going back years, when you went to your local doctor and sat in the waiting room no one spoke. It was deathly silence, but now it's branched out hasn't it? But even so I think that feeling is still there. But I mean personally myself I can speak to them now but I can understand some people having that attitude that they would like to talk to them. But they are afraid and they don't feel as if they are equals.

The findings suggest that this will vary depending on individual personalities. For example, a common suggestion was that historically doctors have always been viewed as 'god-like' by many of the older generation and this may have led to a culture of silence amongst patients.

**Researcher:** Do you think that is the case with all patients? Do you think some are intimidated about asking questions?

**Patient No 7:** Oh yes I mean some of the consultants think they are Gods don't they? They are put on a pedestal and in actual fact they are only human beings themselves aren't they.

**Researcher:** Do you think sometimes that the lower level/junior doctors are better at the communication than the consultants?

**Patient No 7:** Well yes I think they probably...well I think perhaps. Because the training has included that more for the younger ones and also because they are not quite up there they are not God yet are they?

The participants however stress that they could not speak accurately for others and were adamant that this was a view that was not held by them personally and it would not affect their ability to communicate with the doctor. Thus, arguably there is evidence of a culture shift. The findings portray an image that medical practitioners are generally becoming more friendly and approachable and are increasingly happy to try and discuss issues with patients at their level. In particular, the important roles of the nurse practitioners and consultant nurse specialists are highlighted in that they are extremely friendly and approachable and provide an effective mechanism for bridging the gap between patients and doctors. In addition, there also appears to be concern that not enough attention is being paid to communication and bedside manner skills in medical training. The findings suggest it is essential that junior doctors are made aware of the importance of this when it comes to everyday practice and should not be concerned merely with diagnosis and treatment.

**Researcher:** Do you think that it is easier to communicate with the nursing staff perhaps than ask questions to the consultants?

**Patient No 8:** Erm yes maybe. You see the consultants these days, are very different to what they use to be, they talk to you and Mr xxxxxxxx is especially good. When you are talking to xxxx she treats you like a friend. She is very

good indeed and er, after I had had this operation I had a swelling and I said "what is it?" it was xxxx that found it out. I came one day to see xxxx for an appointment. She said "is everything all right?" I said I had got a swelling and she examined me and said "Mr xxxxxxxx is next door, I'll fetch Mr xxxxxxxx to see you." And he came through and it was an incisional hernia from the operation.

Finally, and in order to preclude any concerns about these findings, it is necessary to note the relative age of the participants. The participants were middle-aged and above and there was an equal split between males and females. Unfortunately due to the nature of the specialism it was very difficult to interview any candidates from the younger end of the spectrum. It may well be that the patients are affected more so than they actually recognise or care to admit, yet it appears this is more related to personality than to age. Some patients may well feel intimidated and anxious; whilst this may effect their ability to ask questions and digest information effectively, this is not the case all the time. Clearly the perception is that generally the imbalance of power does not necessarily prevent patients from asking questions and engaging with the medical practitioners, though it could do in certain circumstances.

#### ***11.9.9 Theme 8: Identifying the Therapeutic Benefits of Being Informed***

\* (There were 39 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

The theme that is perhaps most noticeable within the patient findings is the manner in which all participants identify the therapeutic benefits of informed consent. The suggestion is that patients want to be kept informed as this stands them in better stead to deal with subsequent developments after their operation.

**Patient No 4:** ...I think everybody would like to know...I don't know percentage wise but I do know it is much better. But I do think that people would like to know. I mean they could make arrangements at home and one thing and another and the only thing I was bothered about when I was told I had cancer. I wasn't frightened for my own sake but it meant leaving my wife you know she is 77 and I look after her, she is quite capable of looking after herself but that was the only fear I had got for my wife...I wasn't afraid but it weren't a

matter of being afraid. It was just that I enjoy being active you know. I mean I go dancing now 3 or 4 times a week I had to be a bit careful after the operation. I took my time I am sensible I have cut my drinking out and I go walking... I do still have a drink because I used to be a very heavy drinker but I am just sensible now. Like this weekend I am going to a dance Saturday night I will go out on Sunday and sink 2 or 3 pints at the local.

Moreover, patients want to be kept informed prior to the operation so they know what to expect and in order that they can instigate appropriate and necessary mechanisms for post-operative care.

**Researcher:** Do you think some patients just don't want to know?

**Patient No 1:** Yes I do definitely.

**Researcher:** Do you think that is problematic?

**Patient No 1:** I do for them the patient.

**Researcher:** Why is that?

**Patient No 1:** Well I think that if you ask questions, want to know things, you know what you are able to do afterwards. Because after a serious operation you want to know all sorts of things like if you need to be on a diet, if you need aftercare nursing and what you should do and what you shouldn't do about certain things.

The participants say it is much better for medical practitioners to remain open and honest with patients, as if they are informed about what pain and suffering to expect after the procedure they will have time to mentally attune and prepare themselves. In contrast, if they are kept in the dark, and wake up from an operation suffering from a lot of pain and discomfort that they did not originally expect, the reverse happens. The mental state of the patient switches from one of being ready to cope with certain issues, to one of anxiousness and fear of the unexpected; two characteristics which may have a detrimental effect on the healing process.

**Researcher:** In terms of the consent process and the way it is going, it is about disclosing risks and things like that to patients, if they have got the opportunity. Obviously it is slightly different if it is an emergency. Do you think that it is important that they disclose risks to patients about operations?

**Patient No 8:** Yes.

**Researcher:** Why?

**Patient No 8:** Well if they don't know, I mean they come out of the operation and everything is not going, as it ought to go, if they are told about it before they have a rough idea of what is happening. I would want to know. Definitely.

The same example can be carried over into drug therapies. If patients are informed beforehand of the beneficial outcomes of a particular drug regime they may be prepared to co-operate with the medical practitioner and complete the course of antibiotics. If the benefits of these drugs are not spelt out to the patient and they are not told why it is important to complete the dose, then the temptation may be for them to ignore the advice of the doctor or nurse.<sup>3</sup> This is particularly the case with drug therapies as it often it is difficult to look beyond the immediate to foresee the long-term benefits they provide. Thus, it becomes essential for medical practitioners to inform the patient that in order to see end results it may take time. If this is omitted patients may not recognise this, which may once again have a detrimental effect on the healing process.

It is possible to interpret the research findings as providing a valuable insight into what patients perceive as being the true rationale behind the requirement of being kept informed. It seems different from the traditional point of view that the obligation to provide information to the patient is underpinned by the ethical imperative of bodily integrity and self-determination. It has already been illustrated that patients struggle to relate to this in the context of consent. These findings tell us that the real reason that patients wish to be kept informed is not out of concern for their autonomous rights as individuals, but out of their concern to assist the healing process. In a sense this may also be linked to the way in which they actually perceive consent itself; as a means to an end. Something that has to be done to allow them to get to the next stage, the treatment needed to get them better.

**Patient No 7:** ...I mean there are things I mean if somebody didn't tell you that you are terminal and you are still clinging on there are things that you might want to sort out before you die. You know things that you want to arrange and

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<sup>3</sup> For discussion see Simon, R.I. "Prescribing and Monitoring Medications: Clinical-Legal Issues" (2004) *Psychiatric Times* 17; Cooper, C. "Keep Taking the PILS" (2001) 357 *Lancet* 1720; Editorial "Chemotherapy and Informed Consent" (1997) 22 *Health Facts* 1.

things you want to sort out with your relatives and friends. So in a way I don't think they should withhold anything.

### **11.9.10      Theme 9: Improving the Consent Process**

\* (There were 33 occurrences of this theme in the patients' interviews. For further details refer to the table providing the summary of themes in section 11.11 of this study).

The findings provide a valuable insight into how patients perceive the consent process can be improved.

Firstly, in respect of the waiver there were varied opinions. It has to be said that the majority of patients initially frowned on allowing people to forego their right to the information needed in order to give an effective consent. However, when questioned a little further some actually recognised the dangers with providing the patient with too much information. Whilst they were keen to stress that *they* would never wish to do this, the participants did concede that some patients may become scared and anxious and that forcing information on them may damage the doctor/patient relationship. Under these circumstances the findings suggest that the waiver may be acceptable, but should be the exception rather than the rule, and that ultimately the decision should rest with the individual. It seems however there is a concern for the patients that simply wish to bury their heads in the sand and this is frowned upon by those who see the therapeutic benefits of being kept informed.

**Patient No 3:** I mean I learnt more from the meetings I had with different people. That there is no need to be afraid of cancer. It can be treated if it is caught early enough...we need to push this awareness. I mean some of my friends I think they are a bit fed up of me because I said "if you have got any symptoms or it is just something that you think is wrong in your mind go to your GP and ask for some tests."

A number of participants suggest the benefits of patients who have already undergone medical procedures voluntarily attending hospitals to discuss the treatments with future patients. The findings indicate this can be achieved effectively by either

attending ward rounds or outpatients clinics and is a way of placing waiting patients' minds at ease by explaining what they can expect to happen before, during and after the treatment. They may often be able to relate to confused, anxious and frightened patients at an appropriate level.

**Patient No 8:** I think that more could possibly be done, by introducing Cress group members to people who are waiting. I mean we had a different experience obviously, so we didn't have any time to worry in a sense, but I think if they had said, we will put you on the waiting list for 4 or 5 weeks and I think in that time you would have appreciated talking to somebody else who had maybe had the experience. I know how you feel, even if it works out smashing like us. If you look on it from the inside, someone maybe not so professional, the other layman idea, you are the layman and you are thinking what is it. You are not only wanting a scientific explanation, it's just nice if someone who has experienced it and says I know how you feel.

This is clearly an innovative way to improve both patient understanding and the levels of information they receive in practice. However, it only works if people are willing to volunteer. Some may say they will; yet when it comes down to it many may not, or at least this is the danger. This should not be used as an excuse to write this off completely as a number of approaches can be adopted to minimise this problem, the most important of which is connected to the type of patients targeted to help. As many of the participants suggest, because they fall within the upper age bracket they do have a little flexibility and seem willing to give over some of their time to this scheme if the appropriate infrastructures are put into place. This is not to suggest the younger generation have nothing to contribute as, if their circumstances allow and if they are prepared, it is clear they have something to offer. Yet, in order to implement this effectively it becomes essential to target the older generation. Contrary to what many sceptics may think, the evidence here is that many ex-patients, if asked, would be more than happy to offer their services.

The final theme can be identified as improving the consent process through the development of patient help groups.<sup>4</sup> For example, within the department under investigation one of the consultant nurses ran a group that meet on a monthly basis where ex-patients and medical representatives can discuss issues of concern.

**Patient No 3:** ...They just wrote to me and said they were setting this group up and would I be interested and we all met at the City Hall. And there was quite a lot of it and then it dwindled after a bit because the first meeting wasn't a very good meeting because a lot of people all they were doing was moaning and they didn't want that. But I think you have got to listen to the moans if they want to put things right for other patients that are coming through they have got to listen to those complaints if you don't you can't put it right.

The researcher was fortunate enough to be invited to attend one of these meetings. The interviewees stress the significance of these help groups. They afford patients the opportunity to ask questions about treatment; both pending and post-operatively. They also focus on considerations such as the information patients should be provided with generally, and the risks, pain and side effects to be expected. The patients communicate their experiences of treatment and discuss important points such as how best to construct written information leaflets. Although these groups are mainly attended by older people, they are open to all patients and there is a strong perception amongst the participants in this study that these are extremely beneficial and that all patients, both young and old, should be encouraged to participate in these sessions.

## 11.10 SUMMARY OF PATIENTS' THEMES

Within the individual patient interviews, there were no particularly strong exemplars that stand out as being worthy of discussion as specific themes. None are sufficiently recurring so as to have any bearing on the overall findings of the research. For example, some of the patients discussed past experiences in respect of their medical

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<sup>4</sup> See Editorial "Registrar: How to use Support Groups" (2005) 5 *General Practitioner* 78; Bishop, F. & Yardley, L. "Constructing Agency in Treatment Decisions: Negotiating Responsibility in Cancer"

care generally, but these were not always related to consent. In addition, some patients commented on things such as private care, the position of relatives and wider issues such as first impressions and how they are important. Some of these individual issues did however blend in with the wider categories and were thus combined and discussed within the remit of the overall themes.

### **11.11 COMPARISON OF HEALTH CARE PROFESSIONALS' THEMES WITH PATIENTS' THEMES**

In comparing the findings of the patient study with the findings of the medical practitioners' study it is apparent there is not a great deal of difference between the two. Ironically one of the inherent differences is actually the way both parties perceive the rationale behind consent. Medical practitioners view consent as being important from the patient's point of view; in contrast patients perceive consent as being important from the medical practitioner's point of view. Likewise, it is evident that medical practitioners identify the importance of keeping the patient informed and the patients in turn are willing to receive information and see the benefits of this. Both parties recognise the importance of effective communication, honesty and transparency and concede that understanding is a major problem that needs to be improved. A number of methods are offered as a means of enhancing patient understanding by both patients and medical practitioners.

The research shows that patients predominantly view consent as a means to an end and something that is *necessary*. They fail to make the link between the process of receiving information and consent. Until patients are encouraged to move away from this perception, towards understanding that it is about their choice and right to decide, it is difficult to envisage any way of improving consent.

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(2004) 8 *Health* 465.

A further difference resides in the way in which patients see the importance of being kept informed as directly linked to therapeutic benefits, as opposed to medical practitioners who, in the main, suggest keeping the patient informed is underpinned by ethical imperatives and professional obligations.

On final point is worthy of discussion here. In the medical practitioners' study a tentative argument was made relating to excessive risk disclosure encouraging defensive medical practice. To a certain extent this is rebutted by the evidence provided by the patients that they are more than happy to receive information about risks. Whilst this may be true, it is important to remember that a number of patients indicate that different individuals may become anxious, scared and confused if subjected to excessive information even though they themselves were not directly affected this way. They further suggest that this is of detriment to the patient, implying that if individuals state categorically they do not want to hear information about risks, and this becomes clear to the doctor, under these circumstances they should be allowed to waive their right to certain information. This appears to be in conflict with some of the clinician's views about the waiver, where it seems there is some reluctance to recognise this as a component of the patient's right to self-determination.

## 11.12 SUMMARY OF THEMES FROM PATIENTS IN SECONDARY CARE

<u>Initial Coding Category in NVIVA</u>	<u>Number of Coded Entries Within Each Category</u>
Difficulty in Relating to and Understanding Consent	29
Willingness to Receive Information*	19
Overall Satisfaction with Consultations and Information Received*	48
Unwillingness to Complain and Resort to Legal Action	58
Problems with Understanding*	26
Importance of Communication*	39
Feelings About the Power Relationship*	37
Identifying the Therapeutic Outcomes of Being Informed	39
Improving the Consent Process*	33

### IDENTIFICATION OF SUB-THEMES

<u>Initial Theme</u>	<u>Sub-Theme</u>
*Willingness to Receive Information	Personal Feelings of Patients Identification of Different Patient Types Type of Information Wished to Receive
*Overall Satisfaction with Consultations and Information Received	Feelings Towards Medical Practitioners
*Problems with Understanding	Personal Feelings Problems with Different Patient Types Ways to Enhance Understanding
*Importance of Communication	Emphasis on Openness and Transparency Importance of Honesty
*Feelings About the Power Relationship	Personal Feelings Different Patient Types Intimidation and Anxiousness
*Improving the Consent Process	Feelings on the Waiver

	Patient Involvement
	Patient Help Groups

\* For the purposes of the discussion section, the sub-themes are analysed in accordance with the primary theme.

## 11.13 CONTINUING LEGAL REFLECTIONS: *PATIENTS*

### 11.13.1 Theme 1: Understanding of Consent

It is evident that the patients found it very difficult to talk about the consent process and what they perceive to be its underlying purpose. This allows us to note two things in relation to their understanding of consent. Firstly, they seem to view the procedure as a wholly separate issue from the process of information disclosure which, as is demonstrated below, patients seem to welcome. Secondly, and perhaps more significantly, it seems patients under investigation in this study perceive consent as something that is just necessary and something that they have to do.<sup>5</sup> This is completely at odds with the very purpose of consent and what the legal rules governing the process seek to protect. That is, the patients right to make a choice. However, this does reflect existing research that many patients do not actually read the consent form before signing it and would often give their name to anything in order to get an operation.<sup>6</sup> Despite patients looking favourably on openness and disclosure, there is some evidence to suggest any information provided is not used in the decision-making process or the context of the consent procedure itself. Research suggests patients have made their decision long before they reach the 'consenting stage.'<sup>7</sup> In which case, as is discussed below, it appears the information patients

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<sup>5</sup> In a recent empirical study carried out by Maclean, it was suggested that some patients saw consent as something that was just 'necessary.' This is supported by empirical evidence suggesting there is a weaker desire for information on the day of the operation. See Kain, Z.N. "Parental Desire for Perioperative Information and Informed Consent: A Two-Phase Study" (1997) 84 *Anesthesia and Analgesia* 299. Cited in Maclean, A. "Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence" (2005) 7 *Med L Int* 1 at 12. Clearly, the severity of the condition may also effect this bringing into play the limitations stressed throughout this study due to the fact the majority of the patients were cancer patients who were interviewed post-operatively.

<sup>6</sup> Lavelle-Jones, C. *et al.* "Factors Affecting Quality of Informed Consent" (1993) 306 *BMJ* 885.

<sup>7</sup> For example, a study conducted by Faden and Beauchamp suggested that although 93 per cent of patients surveyed believed they benefited from the information disclosed, only 12 per cent used the information in their decisions to consent. See Faden, R.R. and Beauchamp, T.L. "Decision-Making and Informed Consent: A Study of the Impact of Disclosed Information" (1980) 7 *Social Indicators Research* 313-36. See also Fellner, C.H. *et al.* "Kidney Donors - The Myth of Informed Consent"

desire is not used to facilitate the decision making process, but rather is a prerequisite for assisting their recovery. In other words the patients in this study fail to make the link between the consent procedure *per se* and the process of information disclosure.<sup>8</sup>

### **11.13.2 Theme 2: Willingness to Receive Information**

The findings in this study add to the already existing body of empirical evidence, which suggests that patients do actually prefer to be kept informed about the risks and benefits of treatment.<sup>9</sup> The catalogue of potential justifications for non-disclosure is endless. Disclosure increases anxiety; information about risks will cause excessive worry for patients; patients will not be able to understand what is said; it will cause confusion having a negative effect on the decision making process. This is by no means an exhaustive list. However all of the above, and indeed any other arguments of a similar nature, are all highly tenuous, particularly amidst evidence that doctors underestimate patients' desire for information.<sup>10</sup> This precludes any suggestion that a paternalistic standard of disclosure is appropriate, and dispels any argument that the professional standard of care should remain the predominant basis for establishing or denying liability for negligent failure to provide information. The arguments for

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(1970) 126 *American Journal of Psychiatry* 1245. Thus there is an indication that patients make their decisions prior and independent of the process of receiving information.

<sup>8</sup> Other empirical evidence supports this. For example, Sutherland found that whereas the majority of cancer patients felt that they did not receive enough information about their condition, only 23 per cent wanted to have more say in terms of the actual decision making. Sutherland, H.J. *et al.* "Cancer Patients: Their Desire for Information and Participation in Treatment Decisions" (1989) 2 *Journal of the Royal Society of Medicine* 260.

<sup>9</sup> See, for example, Donovan, J.L. & Blake, D.R. "Patient Non-Compliance: Deviance or Reasoned Decision Making?" (1992) 34 *Social Science and Medicine* 507; Also Blanchard, *et al.* "Information About Decision Making Preferences of Hospitalised Cancer Patients" (1988) 27 *Social Science and Medicine* 1139. Here it was found that 92 per cent of cancer patients wanted to receive all relevant information about their disease, irrespective of whether it was good or bad. See further, Kerrigan, D. *et al.* "Who's Afraid of Informed Consent?" (1993) 306 *BMJ* 298; Sculpher, M. *et al.* "Patients' Preferences for the Management of Non-Metastatic Prostate Cancer: Discrete Choice Experiment" (2004) 328 *BMJ* 382.

<sup>10</sup> See, amongst others, Turner, S. *et al.* "What are the Information Priorities for Cancer Patients Involved in Treatment Decisions? An Experienced Surrogate Study in Hodgkin's Disease (1996) 73 *Br J Cancer* 222. Indeed Professor Jones in his article cites various studies in support of this assertion. Most notably 'Doctors are demonstrably poor judges of patient preferences for the involvement in their

adopting such a standard are well versed and perhaps best demonstrated by Lord Diplock in *Sidaway*.<sup>11</sup> His suggestion that providing patients with information about risks would have the effect of making the patient's physical and mental health worse rather than better is simply not true of most patients. If anything it is the opposite; patients perceive the need for this information in order that they can improve the healing process and speed up recovery time post-operatively. Moreover, any suggestion that warning patients about risks acts as a deterrent and would encourage them to refuse treatment is an embodiment of classic paternalism which can no longer be supported by the law.<sup>12</sup> Thankfully the pace and development of the law in recent times has, in theory, reflected this; it has started to recognise the importance that ought to be attached to keeping the patient informed.<sup>13</sup>

Clearly some patients may become anxious, unduly worried and as such may not welcome the information that clinicians should provide. The patients in this study acknowledge this. The key is that these patients are regarded as the exception rather than the rule. The law must be able to account for the acquiescent patient as, under these circumstances, excessive disclosure can exhaust the therapeutic benefits of keeping the patient informed. Here it is important that medical practitioners should not interpret the law as eroding their clinical discretion to an extent where they feel backed into a corner with regard to what they tell a patient in terms of risk factors. The law recognises that discretion still plays a key role in modern medical practice and can (and should) be relied upon in some circumstances in order to protect the

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healthcare.' (1986) *Institute of Medical Ethics Bulletin*, Supplement No.3 cited in Jones, M. "Informed Consent and Other Fairy Stories" (1999) 7 *Med L Rev* 103 at 128.

<sup>11</sup> [1985] AC 871 at 895.

<sup>12</sup> Per Lord Diplock, *ibid*.

<sup>13</sup> This is evidenced from the recent decisions in *Chester v Afshar* [2004] UKHL 41; [2005] 1 AC 134; *Wyatt v Curtis* [2003] EWCA Civ 1779; [2003] WL 22827037; *Pearce v United Bristol Healthcare NHS Trust* (1998) 38 BMLR 118 and *Bolitho v City and Hackney Health Authority* [1998] AC 232. The implications of these decisions are reflected upon in the Literature Review and the Solicitors' Study components of this thesis.

patient from unnecessary over-exposure. The law allows this to happen firstly via the means of the therapeutic privilege defence, and secondly, by recognising the patient's ability to waive their right to informed consent. If these two are implemented and monitored correctly, a happy medium is reached which on the one hand provides adequate protection to the patient who wishes to be informed, whilst in the same breath protects the needs of patients who do not want to exercise this right.

### **11.13.3      Theme 3: Unwillingness to Complain**

Brazier has suggested that a lawsuit is a 'clumsy and inadequate' means of investigating medical error. However, some patients will be inclined to sue simply to find out what really happened.<sup>14</sup> The findings in this study relate to previous empirical evidence suggesting patients are not primarily concerned with compensatory redress when something untoward happens. For example, a recent survey suggested that only 30 to 39 per cent of aggrieved patients wanted monetary compensation when they initially instigated a complaint. Yet, 50 per cent of patients primarily sought an admission of fault, a thorough investigation of their complaint and action to prevent what happened to them happening to others.<sup>15</sup> The findings in the present study reflect these views. The patients seemed very reluctant to complain and frowned upon those who sought to make money out of clinicians who had simply made mistakes. Patients do understand that doctors and nurses can make mistakes just like anyone else, and in reflecting on this in a wider sense, it seems likely most rational people would accept this. The general consensus in this study seems to be the patients are very reluctant to resort to the law. There is some recognition that this is because of the time and financial implications of seeking legal redress. These are not the main reasons though.

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<sup>14</sup> Brazier, M. *Medicine, Patients and the Law* (London: Penguin, 2003) at 221.

<sup>15</sup> Mulcahy, L. *Mediating Medical Negligence Claims: An Option for the Future* HMSO, 2000.

It seems simply that the patients in this study perceive it as being unfair to hold clinicians legally accountable and also identify the effect of doing so could be harmful to medical practice. This confirms two things. Firstly, it unites the statistics cited in the literature review of the study that informed consent cases are few and far between and that the law of informed consent 'does not work.'<sup>16</sup> Secondly, it provides further empirical evidence that we are not living in a compensation culture. Both these issues are developed in the solicitors' study.

It appears that the time when patients do want to complain is where they feel they have been treated with lack of respect by the clinician. Under these circumstances they are more inclined to pursue complaints through the hospital's internal mechanisms. However, there is perhaps some difficulty if patients do not know how to instigate these complaints and who to actually complain to. After the report of the Wilson Committee in 1994, hospital complaints procedures are now supposedly streamlined.<sup>17</sup> The report's recommendations were largely implemented in 1996 with the aim of making the complaints procedures more accessible and open to patients.<sup>18</sup> Despite this, there is some debate over their effectiveness,<sup>19</sup> and it appears patients are largely unaware of how they operate. This is where the exercise of caution is needed. Drawing on Brazier's earlier assertion, if something has gone wrong then the majority of patients will simply want to know what has happened. Here honesty and transparency is the key. It is essential in order to prevent any claim from manifesting itself in the first place. If patients perceive there has been some sort of cover up, that they are being 'fobbed off', or worse still that they are been treated

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<sup>16</sup> Jones, *op cit* n 10 at 107.

<sup>17</sup> *Being Heard* - The Report of a Review Committee on NHS Complaints Procedures (London: DoH, 1994).

<sup>18</sup> *NHSE Complaints - Listening - Acting - Improving: Guidance on Implementation of the NHS Complaints Procedures* (London: DoH, 1996).

with disrespect, they may well be entitled to feel aggrieved. Honesty in admitting mistakes could perhaps prevent this. Secondly, honesty and transparency is needed within the complaints procedure itself. This is to prevent recourse to the law. If, for whatever reason, patients do feel it is necessary to pursue an internal complaint they must know how to do this and must feel the system is efficient enough to afford their reproach the attention it deserves. If they do not see this, they may well be tempted to resort to the threat of legal action as a last resort when, in actual fact, this could have been prevented at a much earlier stage in the proceedings.

Interestingly, Richards reported that most complaints about doctors by patients concerned poor communication rather than competence. The most common complaint was that doctors did not listen. This mirrors the views expressed by both medical practitioners and patients about where complaints arise and ties in neatly with the following section.<sup>20</sup>

#### **11.13.4      Theme 4: The Importance of Doctor/Patient Communication**

Whilst the importance of communication is not directly linked to the law, sociologically it is essential to the doctor/patient relationship and improving the consent process. The patients recognise the importance of this. It is the foundation upon which all good doctor/patient relationships are built. Clinicians have to be able to communicate information about treatment and risks in a manner which patients can understand. The communication of risks and other information is a highly personalised and sensitive activity and the extent to which patients wish to be kept informed invariably depends on their individual character. Edwards has recommended that risk communications should be simply worded, relevant and responsive to the

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<sup>19</sup> See, for example, Longley, D. "Complaints After Wilson: Another Case of Too Little Too Late?" (1997) 5 Med L Rev 172.

<sup>20</sup> Richards, T. "Chasms in Communication" (1990) 301 BMJ 1407.

needs and values of individual patients. There should be a two-way exchange of opinions and values as well as information seeking to maximise trust and support.<sup>21</sup> It is this two-way exchange which forms the basis for effective communication, Roter and Hall suggesting that 'talk is the fundamental instrument by which the doctor-patient relationship is crafted and by which therapeutic goals are achieved.'<sup>22</sup> However, the problem with this, as we have already seen, is that doctors tend to want to communicate with the primary aim of reaching a diagnosis, whereas as Berry suggests, in the communication process patients need to know and understand and need to *feel* known and be understood.<sup>23</sup> As both parties are operating with different objectives in mind there is an inherent danger here. Thus, it becomes important that medical practitioners do not bombard patients with information or seek to over-control the consultation.<sup>24</sup> They must also allow patients the opportunity to ask questions. The most effective way to achieve this optimum balance is to implement the shared-decision making model. One of the problems with this is that many doctors underestimate patient preferences for more information but overestimate their desire for participation in decision making.<sup>25</sup> The patients in this study welcome the provision of information and are not scared to ask questions.<sup>26</sup> In turn, the findings

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<sup>21</sup> This also highlights how important it is to consider the needs of the individual when it comes to communicating risks. This was highlighted in the medical practitioner's study and is supported by Gutteling, J.M. & Wiegman, O. *Exploring Risk Communication* (Dordrecht: Kluwer Academic Publishers, 1996). This study is cited in the legal reflections: risk disclosure section of the medical practitioner's study.

<sup>22</sup> Roter, D.L. & Hall, J.A. *Doctors Talking with Patients / Patients Talking with Doctors* (Westport, CT: Auburn House, 1992).

<sup>23</sup> Berry, D. *Risk, Communication and Health Psychology* (Berkshire: Open University Press, 2004) at 70.

<sup>24</sup> See, for example, Beckman and Frankel (1984). Here it was found that patients were interrupted on average 18 seconds after beginning their description of the problem, and that only 23 per cent of them went on to complete their statements. Beckman, H.B. and Frankel, R.M. "The Effect of Physician Behaviour on the Collection of Data" (1984) 101 *Annals of Internal Medicine* 692.

<sup>25</sup> See, for example, Strull, W.M. *et al.* "Do Patients Want to Participate in Medical Decision Making?" (1984) 252 *Journal of the American Medical Association* 2990.

<sup>26</sup> These findings are supported by the various empirical studies cited *op cit* n 5. However, there appears to be conflicting evidence relating to patients' willingness to ask questions. Moores and Pace suggest 67 per cent of patients in their study had no unprompted questions to ask at the point of

suggest that the clinicians themselves are prepared to answer these questions honestly.<sup>27</sup> Yet, the extent to which this can be described as a shared-decision making process is open to debate. Various studies suggest that doctors and patients do not actually engage in shared-decision making and the findings here tend to support this.<sup>28</sup> In order to combat this problem, and to achieve effective communication, doctors and patients need to alternate between information giving and seeking. As such, Stewart has suggested that when taking a medical history, doctors should ask a wide range of questions, not only about the physical aspects of a patient's problem, but also about his or her fears and concerns, understanding of the problem, expectations of therapy, and perceptions of how the problem affects function.<sup>29</sup> Similarly, patients should be encouraged to ask questions in order to precipitate a truly reciprocal process.

How then does this relate to the law? In actual fact the law can have little direct effect on communication, but this is perhaps where its symbolic power comes into play. The mere fact that medical practitioners are conscious of the law, despite knowing little of its operation, may lead to them improving their communication methods with a view to keeping the patient more informed. Perhaps more significantly, there is evidence to the effect that patients are more willing to adhere to treatment regimes and follow the doctor's recommendations if they perceive clinicians as good communicators. For example, Squier concluded that there is strong evidence that the affective quality of the doctor/patient relationship is a key determinant of both

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consenting. See Moores, A. & Pace, N. "The Information Requested by Patients Prior to Giving Consent to Anaesthesia" (2003) 58 *Anaesthesia* 684. However, Maclean queries this against the findings of his study that only 3 patients (7 per cent) would rather be told nothing at all. See Maclean, *op cit* n 5 at 15.

<sup>27</sup> This is in accordance with their legal duty enunciated by Lord Bridge in *Sidaway*, *op cit* n 11 at 898. The duty to answer questions honestly was confirmed by Lord Woolf MR in *Pearce* *op cit* n 12 at 120.

<sup>28</sup> Stevenson, F.A. *et al.* "Doctor-Patient Communication About Drugs: The Evidence for Shared Decision Making" (2000) 50 *Social Science and Medicine* 829.

<sup>29</sup> Stewart, M.A. "Effective Physician-Patient Communication and Health Outcomes: A Review" (1995) 152 *Canadian Medical Association Journal* 1423.

patient satisfaction and adherence to treatment.<sup>30</sup> This is of particular interest when viewed in the context of the section below which suggests the patients underlying concern with the provision of information is to alleviate worry and to improve the healing process.

#### **11.13.5 Theme 5: Therapeutic Outcomes**

Teff accurately identified the therapeutic benefits of keeping the patient informed. These include, amongst other things, enhanced communication leading to a more realistic appraisal of the limitations of treatment, alleviating the distress and depression which often results from unfulfilled expectations. Also, the patient is better equipped to cope with subsequent medical needs and throughout the management of chronic illness.<sup>31</sup> This is supported by various other pieces of research that suggest patients recover quicker if they are kept informed about their treatment.<sup>32</sup> The medical practitioners in this study seem to confirm this. More importantly, the patients in this study relate to these issues and acknowledge it is a lot easier to cope with bad news, manage side-effects and arrange aftercare if they are made aware of what to expect.

The underlying purpose of the doctrine of informed consent, from a legal point of view, is firstly to respect the patient's autonomous right to self-determination, and secondly, to redress the imbalance of power within the doctor/patient relationship. This is achieved by providing the patient with the right to be given a certain amount

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<sup>30</sup> Squier, R.W. "A Model of Empathic Understanding & Adherence to Treatment Regimes in Practitioner-Patient Relationships" (1990) 30 *Social Science & Medicine* 829.

<sup>31</sup> Teff, H. "Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance?" (1985) 101 *LQR* 432.

<sup>32</sup> See various studies cited in Teff, *ibid* at 433. For example, Gutheil, *et al.* "Malpractice Prevention Through the Sharing of Uncertainty: Informed Consent and Therapeutic Alliance" (1984) 311 *New Eng J Med* 49; *Making Health Care Decisions*, President's Commission for the Study of Ethical Problems in Medicine (1982) Chap 1. Brazier also highlights these issues in Brazier, M. "Patient Autonomy and Consent to Treatment: The Role of the Law?" (1987) *LS* 169.

of information before treatment.<sup>33</sup> However, it appears patients here are not predominantly concerned with these factors, or at least they do not perceive the above as the most important basis for enhanced disclosure and openness in the consultation process. Very few, if any, related being kept 'informed' specifically to the consent process. Likewise they failed to relate consent to their right of self-determination. Instead the importance they attach to it is bound up in the manner in which it enhances the coping mechanisms and the healing process. There is a sense of irony here that may go some way towards explaining why the law can never be viewed as a proactive mechanism for protecting patients' rights. In effect the law is seeking to protect a right that patients are either unaware of, or do not attach any significance to. Whilst this is happening it can never achieve its purpose. The law, by its very nature, is reactionary. Its focus is on compensating patients once damage has occurred. Thus the emphasis on disclosure in consent will never really change. Thus, an argument can be made out that greater emphasis needs to be placed on making the patient aware that they are being provided with the necessary information in order that they can make an informed choice, and that ultimately the consent process is about their right to decide.

#### **11.13.6 Theme 6: Improving Consent**

Patients in this study suggest a number of ways to improve consent which go beyond merely reforming the legal side of things, perhaps recognising the only way to improve consent procedures is to look beyond the courts. This is best achieved by encouraging patient participation in consultations working towards the consent process and information exchange operating as a truly a reciprocal process. There is evidence that these patients are willing to learn about their treatment and condition

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<sup>33</sup> Jones, *op cit* n 10 at 129.

and are prepared to engage with medical staff. They are also committed towards wider participation in NHS initiatives aimed at giving the patient a voice. It appears this can be achieved through patient focus-groups. The patients involved in this study suggest it is up to those who *are* willing to get involved in these groups to encourage wider participation amongst *other* patients. This is evidence of a change in attitude towards encouraging patient involvement. This is an encouraging sign. Patient support groups that are run by specialist medical practitioners provide an invaluable opportunity for patients to voice their concerns and to get any grievances out in the open. This is the only way in which any system can be improved, by identifying the short-comings in the eyes of those that really count.<sup>34</sup>

Specifically in respect of consent, patient focus-groups provide the opportunity to identify patients' objectives. This is something which is imperative in terms of consent, even though these objectives will undoubtedly vary from patient to patient. This could highlight what the majority of patients want out of the consent process; what they perceive as being important; what they actually want in terms of information; and how they subsequently use this in the decision making process. These groups can be used to educate patients about consent and that it concerns their right to make a decision using the information available. Perhaps more significantly, a suggestion is made that the patients involved in the groups should offer their services in the consent process by visiting waiting patients pre-operatively and discussing their treatment experiences with them. Here they could provide comfort and support, could clarify concerns, and answer any questions. It would also serve to alleviate the distress of existing patients by demonstrating that many people do actually make a full recovery and can cope after treatment. If this system was

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<sup>34</sup> For discussion of the effectiveness of support-groups see Bishop and Yardley, *op cit* n 4.

implemented it has the potential to self-perpetuate as those patients who have been visited may be willing to do the same for others. This is another way of encouraging a change in culture. This will not happen over-night and a system like this will have to evolve over time. Yet, it does appear that if the NHS was prepared to experiment with such schemes, there are actually people who are willing to participate and try out new ideas. It is only hoped that few may then turn into many. As Sir Clive Woodward once quoted 'never doubt that a small group of thoughtful committed people can change the world. Indeed it is the only thing that ever has.'<sup>35</sup>

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<sup>35</sup> See Woodward, C. *Winning* (London: Hodder & Stoughton, 2004) at 168.

## **12 STUDY 3: INFORMED CONSENT IN SECONDARY CARE**

### **PART 3 - OBSERVATIONS OF CONSENT IN PRACTICE**

#### **12.1 INTRODUCTION**

This component of the study observes consent procedures in secondary care. The researcher was invited to attend a number of outpatients' consultations. Also, a number of days were spent shadowing individual consultants and observing their work. The study employs qualitative observational methods to investigate how consent is obtained and explores whether or not the findings in the qualitative interview studies are an accurate portrayal of what happens in practice. It analyses the dynamics of the doctor/patient relationship and assesses what is meaningful to both parties in the consent process. Detailed field notes were kept from the observations. These were transcribed and uploaded into NVIVA for computer-assisted analysis. A thematic analysis was conducted on all the observational notes and the findings are discussed in the context of the identified themes.

The study begins by providing a brief justification for the work and then progresses to discuss the procedure, participants and methods of analysis. It then moves on to provide the substantial discussion of findings and, finally, in keeping with the philosophy which underpins the qualitative methodology, there is a reflexive section which reflects on the findings in a legal context.

#### **12.2 JUSTIFICATION**

In projects of this kind it is not uncommon for researchers to conduct interviews with participants and then to supplement these with observations. In this sense the study is triangulated (please see chapter 4.9.1 for further discussion). It also allows for a comparison of data between the observations and interviews to check for consistency

and reliability. It is a theory into practice issue allowing the researcher to check if what clinicians actually do is an accurate reflection of what they say they do.

### **12.3 RESEARCH QUESTION**

To observe and reflect upon consent procedures in secondary care. Please see chapter 7.3 for a full list of research questions.

### **12.4 SCENARIOS OBSERVED**

The research was carried out one day a week for a period of three months. The researcher was invited to attend a range of outpatients' consultations. Also, a number of days were spent shadowing individual consultants and observing their work. One day was actually spent in theatre. Observations were at the discretion of the individual consultant in charge and the patients were asked whether it was acceptable that their consultation was observed. Permission was sought and consent was obtained prior to the researcher being present at the consultation.

### **12.5 METHODS**

This component of the study employed unstructured observational techniques and shadow studies. Please see chapter 4.9.2 for further discussion.

### **12.6 ANALYSIS**

During the observations a reflexive research journal was kept and this was updated at the end of each session. The field notes were transcribed and uploaded into the software package NVIVA. The findings were then analysed using the computer-assisted software to identify recurring themes. Please see chapter 8 for further discussion. As this is a qualitative study, within the discussion there are no references to numbers of participants or percentages. However, for a summary of figures relating

to the number of themes and the importance attached to each, please see the tables at the end of this study. (See section below for further details). Quotations included in the discussion are taken from the researcher's personal diary and reflective field-notes, examples of which can be found in appendix 4 at the end of this thesis.

## **12.7 ORDER OF THEMES**

As the studies started out with no pre-defined themes, the themes are presented in the order in which they developed from the base upwards within the field notes. Within the findings below, the importance attached to each theme is noted in brackets underneath the relevant heading. The level of importance was assessed by the number of times each theme occurred within the analysed field notes. However, for a complete summary, and to identify the importance attached to each particular theme, refer to the table providing the summary of themes in section 12.10 of this study.

## **12.8 STUDY LIMITATIONS**

Due to the tight time-restrictions, and also the problems associated with access, it was only possible to conduct a limited number of observations. Thus it is impossible to generalise in relation to the findings. It was also difficult because whilst it became possible to develop a rapport with the consultants who were being shadowed, it was very difficult to build up a relationship with the patients who were the subject of the observations. There was the further difficulty, as with any overt observational research of this kind, that the researcher unduly influences the behaviour of participants. However, both these issues were accounted for in a reflective journal so as to make the researcher aware of any prejudices during the data analysis. The research itself was extremely concentrated in the sense that it targeted only one

specialism. Despite this, what the study lacks in representativeness, it makes up for in terms of depth, boasting some very detailed qualitative observational findings.

## **FINDINGS**

### **12.9 THEMES FROM OBSERVATIONS IN SECONDARY CARE**

As this acts as a reflective component to the thesis, based on the researcher's personal interpretations from observational field notes, the discussion will change to the past tense and will be written in the first person.

#### **12.9.1 Theme 1: Good Practice in Consent**

(There were 10 occurrences of this theme in the observational field notes. For further details refer to the table providing the summary of themes in section 12.10 of this study.)

The majority of the consultants demonstrated a commitment towards putting the patient at ease. They seemed to adapt very effectively to meet the requirements of the patient before them. For example, in one of the consultations viewed, the patient was very elderly and the surgeon went to great lengths to make her feel at ease and to explain things carefully. The patient's relatives were present at the consultation and were prevented from taking the decision for the elderly patient. The consultant stressed ultimately the choice was the patients and no-one else's.

*Consultant asked questions, spoke clearly and slowly, engaged with her and spoke to her personally. Got her involved. The family seemed to ask him some quite difficult questions; he answered fully. At one point the daughter interrupted to make the decision for her. Both the husband and the Consultant stopped her and reminded the patient that ultimately it was her choice. Consultant explained in terms of risk / benefit ratio and talked about aftercare / quality of life. Explained it would involve a short stay in hospital.*

Likewise, where the same consultant was dealing with a much younger patient with a potentially embarrassing condition, time was taken to answer questions relating to levels of aftercare and how it would affect her work and social life. It was visible that

the medical practitioners seemed able to pitch their communication at an appropriate level depending on the type of patient they were dealing with.<sup>1</sup> I also saw that both doctors and nurses have a lot of patience when dealing with difficult individuals. In one of the days spent in outpatients, a particularly intoxicated and aggressive patient attended. The consultant dealt with this appropriately and whilst it is a difficult situation, time was still taken to ensure the patient understood what the problem was and that no decision could be made for him. From a reflective point of view, this enhances the notion that there is no such thing as a reasonable patient.

*He listened with interest to the patients concerns and answered his questions in full, even though these questions were very difficult to address as the patient had difficulty in articulating them. It never once seemed like the surgeon too busy to listen to the patient. Not many risks inherent in this procedure as it was local. Benefits explained.*

There were a number of other good practices which I noticed. One of these included the circumstances in which bad news was broken to a patient. Here the doctor was very compassionate, yet provided the patient with all the necessary information explaining the proposed procedure with intricate detail to both the patient and his family. As there was clearly a lot to digest in a short space of time, the doctor made a point of not obtaining consent on that occasion. Instead he suggested the patient ought to take some time to take everything in and that he would return later to go through the procedure and the consent form. Building on this, I witnessed some encouraging practices concerning the effective way in which things were explained to patients via the risk/benefit ratio. These themes are raised in respect of both the patients and the medical practitioner's interviews as the only effective way in which treatment can be conceptualised. It seems they are carried over into practice. In nearly all the consultations observed the doctor or nurse always started off by explaining to the

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<sup>1</sup> For a recent observational study identifying the importance of communicating in reference to the individual see Brooks, *et al.* "Information Required to Provide Informed Consent for Endoscopy: An

patient what is wrong with them, what treatment they propose, why it is necessary and what benefits it will have. Only then did they seek to qualify these benefits by explaining the risks. A sceptical view may be that this is an easier way of obtaining the patients agreement. However, I felt generally this was not intended and should be classed as positive aspect of practice; it is the only way patients can gain some sort of perspective on treatment.

*However, put the patients mind at rest by putting the risks in context and asking him to consider the risk / benefit ratio.*

One final example of good practice that I witnessed concerned the methods in which understanding was enhanced. Time was often spent explaining the treatment to the patients, and even though there is only a limited *assessment* of patients' understanding, attention was paid to ensure they have some idea of what is going to happen. The majority of good practice concerned the use of diagrams to explain the treatment. Diagrams help patients to visualise what is going to happen. In actual fact, in referring to the field notes by way of example, one of the consultants levelled direct criticism at the consent form due to its lack of space and the fact that it fails to account for the use of diagrams in explaining treatment.

*The most impressive part about the surgeon's work was his use of drawings and diagrams to enhance understanding. Surgeon spoke loudly, yet very slowly and used simple language so the patient could understand. Explained in detail the risks, yet played them against the benefits and spelt it out quite categorically that the patient needed the operation or it would catch up with him soon.*

### **12.9.2 Theme 2: Controversial Practice in Consent**

(There were 5 occurrences of this theme in the observational field notes. For further details refer to the table providing the summary of themes in section 12.10 of this study.)

As well as witnessing what I considered to be encouraging medical practice, there were also some other less encouraging routines which I observed. Firstly, it is noted

in the above section that the consultants tended to discuss things in the context of risk/benefit ratios. Thus, the controversial issue is not concerned with the doctors willingness to disclose risks; it became evident they were more than happy to do this. It was the manner in which the risks were portrayed which I considered to be problematic. In the majority of observations the consultants seemed to disclose the risks in a very regimented manner, and even where some of the patients requested not to be told something, they went ahead and did it anyway. Whether or not this was as a result of me being present I am unsure, but it does seem at odds with the idea forwarded in the interviews that risk disclosure ought to be tailored to the individual. Doctors seem to be able to communicate generally and pitch consultations at the appropriate level for patients, but do not seem able (or willing) to use the same discretion in risk disclosure.<sup>2</sup> Likewise, it re-enforces the notion that doctors, in some instances, disclose too much and are ignorant of the right to the waiver.

*Banding / Injecting of Piles Outpatients.*

*Very invasive procedure. Once again, implied consent and verbal consent.*

*Query whether this should be written?*

*Risks and pain explained. Risks were disclosed in a regimented manner with little pause for breath and no discussion as to whether the patient actually wanted to hear them.*

*Surgeon maintained effective communication throughout; few questions were asked. Any that were, the Surgeon answered honestly and fully.*

*Once again I got the feeling the patient wanted this sorted at all costs she would have consented to anything.*

*Nurse present.*

There were also a number of controversial issues in respect of specific treatments for certain illnesses. The first thing that I noticed was that there were a lot of cases dealing with a specific condition referred to as a 'pilonidal sinus' syndrome. This is a condition which involves hairs growing inwards towards the lower part of the back burrowing down towards the anus. These in-growing hairs form a sinus; a small

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<sup>2</sup> Again, for further discussion of how it is essential to base *risk disclosure* on individual patients see

cavity in the back passage which becomes infected and forms an abscess. After initial conversations in the interviews with the medical practitioners it seems that this condition is particularly difficult to treat as there is no one way which guarantees a final cure. Also, each procedure carries with it varying degrees of aftercare and the chances of the condition recurring fluctuate depending on which operation is performed.<sup>3</sup> This was a frequently occurring condition within the observations and is an example of treatment that ought to be based on patient preference.

*Pilonidal Sinus Outpatients.*

*Patient was young and was confident in her attitude towards the consultant. Asked a few questions mainly relating to how the condition would affect her work.*

*Consultant did not talk much about the extensive aftercare involved in this procedure if the wound is left open.*

*Not much offered in the way of alternatives to treatment. I know at least one alternative that was not mentioned.*

*Operation explained and diagram drawn.*

*Risks inherent in procedure not really identified however, risk at recurrence was identified.*

The available operations could include the patient having the sinus excised and the wound left open to heal from the bottom upwards. This procedure carries with it less risk of infection and can be performed in day surgery. However, it takes a much longer time for the wound to heal and the levels of aftercare are potentially disruptive to someone who has an active social life and a demanding job. District nurses are required to dress the wound on a daily basis for up to three months. Yet, another available option is a procedure involving closing the wound with sutures by creating a

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Brooks, *op cit* n 1.

<sup>3</sup> See, for discussion, Cihan, A. *et al.* "Modified Limberg Flap Reconstruction Compares Favourably With Primary Repair for Pilonidal Sinus Surgery" (2004) 74 *Anz J. Surg* 238; Tastini, M. *et al.* "Treatment of Chronic Pilonidal Sinus with Local Anaesthesia: A Randomised Trial of Closed Compared with Open Technique" (2001) 3 *Colorectal Disease* 427; Dylek, O. & Bekereciodlu, M. "Role of Simple V-Y Advancement Flap in the Treatment of Complicated Pilonidal Sinus" (1998) 164 *Eur J Surg* 961.

flap which covers the sinus. This is a much more elaborate and detailed procedure. It means the patient is subject to a longer stay in hospital and will inevitably suffer greater post-operative pain. On the positive side aftercare levels are less extensive as the wound remains closed and thus may be a preferable option for some patients. The statistics relating to failure and recurrence rates are open to debate in respect of both procedures.<sup>4</sup> There is however less chance of recurrence with the latter treatment, but greater risk of infection. Again, one would imagine this is something the patient would want to weigh in the balance after having explored the various options. This proved not to be the case. The only treatment which was offered to the patient was the first option which could be performed in day surgery. It was only when the condition was frequently recurring that the alternative treatment options were discussed with the patient. When quizzed as to why this was the case the consultants seemed to justify it on evidence-based practice. On reflection, this seems somewhat strange, particularly bearing in mind that the procedure offered, the 'Bascombe's Procedure', has a failure rate which is generally accepted as being within the 10 per cent region.<sup>5</sup> This is not the first time this thesis has demonstrated that certain choices are made for patients based on evidence-based practices or consultants' preference for one particular treatment over another. For example, in the interview section themes were drawn out in relation to the selection of colonoscopy over the barium enema as an investigative technique, both carrying with them different levels of risks.<sup>6</sup>

*Reflective Point: The condition 'pilonidal sinus' was a frequent condition in outpatients and surgery. The suggestion from the interviews is that there are a number of treatments available for this. Not many of these were discussed with patients. The procedure offered seems to depend on the consultant's preference.*

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<sup>4</sup> See *ibid* for discussion of failure and success rates of each treatment option.

<sup>5</sup> See, Senapati, N. et al. "Bascombe's Operation in the Day-Surgical Management of Symptomatic Pilonidal Sinus" (2000) 87 *Br J Surg* 1067; see also response letter by Parvaiz, A. & Kennedy, R. in (2001) 88 *Br J Surg* 155.

<sup>6</sup> See, for discussion, Atkin, W.S. & Saunders, B.P. "Surveillance Guidelines After Removal of Colorectal Adenomatous Polyps (2002) 51 *Gut* 6.

*However, the levels of risks and aftercare vary greatly. What is the legal position in respect of this? Build from interviews and relate to decisions in respect of colonoscopies and barium enemas.*

An issue that was brought to my attention by the medical practitioners themselves concerned certain invasive procedures which were being carried out in outpatients. For example, a common condition that is treated in outpatients is the banding of haemorrhoids. This is an invasive procedure which carries risks of haemorrhaging, bruising, and perforation. The consultants themselves indicated that they feel written consent ought to be adopted for these procedures, and even though they have asked for this to happen, the NHS trust under investigation had recently rejected this proposal as unnecessary.

*Reflective Point: The consultants seemed very anxious about the invasive nature of certain treatments in outpatients. In particular the banding of piles. This is invasive and carries with it a number of risks. Consultants suggest to me they want written consent for this. What is the legal position? Would written consent be feasible / beneficial? Would it be too time consuming? There is a suggestion that Sheffield NHS trust bumped this idea contrary to the advice of the Association of Coloproctologists? Why? Follow this up?*

### **12.9.3 Theme 3: Perceptions of Patients' Attitudes to Consent**

(There were 32 occurrences of this theme in the observational field notes. For further details refer to the table providing the summary of themes in section 12.10 of this study.)

In many of the observations the consultants took the time to go through the consent form and explained the risks and benefits. During this process I got the distinct feeling that patients were indifferent to hearing this information. This is not to suggest that they did not want to hear it, but rather it did not affect their decision making. The patients seemed extremely nervous in the face of medical consultations, and even though many of the consultants attempted to put the patients at ease by reassuring them, there was still an air of tension when it came to filling out the consent form.

*Patient seemed a little confused and nervous; this is understandable.  
Asked medical practitioner to make decision for him relating to pain management.*

*Patient seemed nervous yet articulate.*

*Patient seemed very nervous and quiet.  
Admitted that he was scared to death at needles.  
Seemed intimidated and confused by the long / drawn out form.*

It appeared that the patients would have been happy to sign anything, and my personal perception is that they would have signed the form irrespective of whether or not any information was provided.

*Patient did not really realise what he was consenting to this was tagged on to the consultation and was only really paid lip-service to. Patient saw consent as laborious.  
Stated he just wanted to sign the form.*

Some patients did make some general inquires relating to levels of aftercare and how this would effect their social lives and working lives. This only represented the minority and, in actual fact, patients asked very few questions. Any questions that were asked tended to be in the context of discussions about treatment as opposed to at the point where it came to signing the consent form.

*Reflective Point: Patients tend to ask few questions specifically in relation to consent. However, there is some concern about aftercare. In relation to consent they seem to sign the form without really giving much attention to the details contained on it.*

This may be where some of the difficulty lies. Purely from a theoretical point of view, it seems a fair assumption that general discussions about treatment and issues of consent are interchangeable and should flow directly into one another as they are all part and parcel of the same decision-making process. However, the observations provide further empirical evidence that patients do not perceive consent in this manner. As has been previously suggested in this thesis, they see it as a means to an end; a process in isolation from their decision making.

*Not really a process patient was involved in; wanted to get on.  
Patient asked a few questions.*

*Patient given opportunity to ask questions.  
Did not do so.*

*Reflective Point: I get the distinct feeling that patients at this stage of proceedings see consent as something that is necessary. They do not truly understand what it is actually about and whether the information that is provided assists them in their decision making process is questionable at best.*

It is possible to draw two criticisms at this assertion. The first is linked to the stage at which some of the observations took place. These were on the morning of the operation and immediately prior to the commencement of surgery. Patients may understandably perceive themselves as having 'no other choice' at this stage. As a result, with the agreement of both the clinicians and patients, some of observations were switched to outpatients where consent was often sought before the patient was actually admitted to hospital for treatment. In outpatients my perception remained the same. Consent was very much a procedural requirement in the eyes of patients; something that they just had to do. This leads to the second criticism, which concerns the seriousness of the patient's condition. Clearly, the patient's perception of their illness will affect their views on the necessity of the treatment. As has already been suggested, the specialism under investigation mainly concerned cancer treatments and some patients would undoubtedly have thought they had no other choice but to agree to treatment. For this reason a number of other conditions were deliberately targeted ranging from invasive procedures which were non-life threatening to mildly invasive treatments which could be performed in outpatients. Here my impression was that the elective nature of these treatments did not alter the fact that patients do not necessarily understand that consent is about their right to receive certain information.

#### **12.9.4 Theme 4: Perceptions of Medical Practitioners' Attitudes to Consent**

(There were 32 occurrences of this theme in the observational field notes. For further details refer to the table providing the summary of themes in section 12.10 of this study.)

I genuinely felt that the medical practitioners under observation demonstrated an accurate portrayal of what takes place in everyday practice. My initial interpretation was that the clinicians place a tremendous amount of emphasis on risk disclosure; they were more than happy to divulge this information to patients.

*Consent form gone over with patient; written info added.  
Explained all the risks inherent in procedure ranging from the mildly serious to extremely serious risks at impotency.*

*Risk at soiling was not paid a lot of attention. Although surgeon mentioned 5% risk in passing this would have catastrophic effect on patient should it transpire. All these risks noted on consent form by consultant, although only superficially explained. Reflective Point: Merely medico-legal requirement?*

However, I got the feeling that consent was seen as very much a functional part of their job.

*Doctors seem to see consent as a 'functional' part of their job as opposed to the patient's right to decide.*

They perceived it as something that had to be done, and as a process whereby a certain number of formalities have to be adhered to in order that they could progress to the next stage, performing the treatment. In a somewhat ironic sense this almost mirrors those views shared by patients. Some of the consultants under investigation seemed to consider risk disclosure as a regimented process that gave little consideration to the position of the patient.

*The doctors under investigation often disclose risks in a regimented and uniform fashion, and I get the feeling patients sometimes do not want this information.*

In addition, a great deal of time was spent filling out the consent form in considerable detail; whilst this was being done there was no communication between the doctor

and the patient and this seemed to add to the atmosphere within the consultation. This was compounded by the fact that I was also present, as was a nurse, and none of us were saying anything at that time. Awkward silences tend to create feelings of tension; in my eyes the elaborate nature of the form definitely contributed towards this.

*Again, a long time spent filling out the consent form added tension in the room, as there was silence.*

*Reflective Point: In many of the consultations there was a feeling of tension. My perception was that the detailed and elaborate nature of the consent form added to this atmosphere. A great deal of time and effort is afforded to filling out the form. This leads to the communication process breaking down; there is silence from both doctors and patients and this creates tension. My perception is that patients are very nervous and pensive before consultations.*

On the other hand, I witnessed some excellent practices in respect of consent. Many of the consultants communicated effectively with the patients and went into detailed explanations of treatments. Risks were offset against the benefits and encouragingly patients were always invited to ask questions. Some attention was given to facilitating understanding, though little was done to assess this.

*In the observations, whilst there are various methods used to enhance understanding, there is little emphasis afforded to assessing patient understanding, the emphasis is on disclosure of risks.*

All of the above represented patient-enhancing consent practices, though it remains open to conjecture whether I was witness to a working model of 'shared-decision making.' My perception was, at the time of the consultation, both parties had already made their decision.

*Patient clearly trusted the Surgeon and wanted to get the problem sorted. Future operation was discussed and agreed consent for this to be taken at a later date.*

After the initial 'good practice' was carried out, the laborious filling out of the form and regimented disclosure of risks ensued. I felt this was a strong indicator that the

process of filling out the form and obtaining the patients signature was a wholly artificial exercise based on the requirement of adhering to legal formalities. In order to classify consent as a true process, surely the procedural requirements should remain interchangeable with the explaining of the treatment. If this does not happen, the importance of consent has the potential to be overlooked by both parties in the transaction. It is possible to conclude that the consent process plays an important role in the jobs of medical practitioners and is afforded a great deal of significance in contemporary medical practice. However, the extent to which this is driven by ethical obligations over and above legal and procedural requirements remains questionable.

#### **12.9.5 Theme 5: Personal Feelings of the Researcher**

(There were 10 occurrences of this theme in the observational field notes. For further details refer to the table providing the summary of themes in section 12.10 of this study.)

At this point it is perhaps worth noting some of personal feelings I had about this component of the study. In referring to my research diary, it seems I had some initial concerns about the reliability of this method. Thus, I feel it is important to comment on feelings about honesty, openness and validity.

Whilst the qualitative interviews provide depth, they are detached from the realities of consent and are a somewhat artificial scenario where participants are able to remove themselves and articulate answers with greater care. More importantly, in respect of patients, they were all interviewed post-operatively or after any consultations. This was not the case with this component of the study where the observations took place immediately prior to the operations or in outpatients where various procedures and consenting took place. In this sense the study provides a valuable insight into the dynamics of consent in practice.

*Generally speaking the most beneficial observations were the day I spent in outpatients and the day surgery cases where I got to see consent in practice. In some of the outpatients' clinics, consent forms were not dealt with specifically but I got to see the level of information which is imparted to patients. It is very much a continuing process.*

In addition, some of the problems associated with the 'Hawthorne Effect' were flagged up in the methodology section of this thesis. The real question centres on the potential effect that my presence had on the consultations bearing in mind I was operating as an overt researcher. In respect of patients, all the participants welcomed me in viewing and observing the consultations, some did not even mind me being present at the invasive stage of the proceedings. I was even fortunate enough to observe a day in theatre. Many of the patients did actually take an interest in my work and asked a few questions. However, despite the fact I explained my work, I still got the impression patients did not understand what it was about and why it was important to investigate consent. My presence did create greater tension in the room, particularly in the process of filling out the consent form. This was probably by virtue of the fact that there was actually one more person in a room which was compounded by the silence as time was taken to deal with the documentation.

*Reflective Point: From the outside looking in, I get the general feeling that this was an honest appraisal of what happens in the consent process during the day-to-day operation of NHS clinics. There was only one occasion where I felt what I was seeing was not a true reflection on the realities of the consent process. On this occasion the consent process seemed somewhat 'staged.' This was in one trip to outpatients and I got the distinct feeling that the consultant under observation went to great lengths to demonstrate the importance that is attached to consent in practice. Indeed one of the nurses commented as to why the patients were being asked to discuss things in a room independent of where the consultation took place. In addition to this, interestingly enough, I got the distinct impression the patient was slightly more nervous as a result of me being there.*

In relation to the consultants and practice nurses, I genuinely felt they were pleased to have me there and many of them went out of their way to make me feel welcome by showing interest in my research. There was only one occasion where I felt what I was

seeing was 'staged' and did not represent an accurate reflection on what would normally happen; this was accounted for in my notes. Overall I felt my attendance did not change the way in which the medical practitioners obtained consent and the observations provided a fair reflection on the everyday practices in respect of consent procedures.

## **12.10 TRIANGULATION: COMPARISON OF OBSERVATIONAL THEMES WITH INTERVIEW THEMES**

This study acts as a continuation the main body of interview work. It is a method of checking and enhancing the validity of what is suggested in theory, by assessing whether it truly reflects what happens in practice. A number of issues were noticeable. Firstly, within the interviews, the medical practitioners all suggested that they were more than willing to share information about risks with patients. This seems to be an accurate reflection on practice. Additionally, there seems to be truth in what the health care professionals state about portraying information though the spectrum of the risk/benefit ratio. This also appears to be a common occurrence in practice. Clinicians stress the difficulty that patients find in understanding and highlight that patients often do not want to communicate with them and ask questions. They identify ways of putting the patient at ease and comment on ways of enhancing understanding. These methods seem to be implemented in hospital settings, which is encouraging. However, a slight discrepancy becomes evident here. Whilst the patients who were interviewed did suggest that it may vary from individual to individual, they intimated that they themselves would feel happy in questioning doctors. In practice, the conclusion has to be that the views held by medical practitioners are more precise; the majority of patients are unwilling to question doctors, particularly in relation to the consent process. This, amongst other things, re-enforces the initial interpretation from

the patient's interviews that they have difficulty in relating to and understanding consent. The observational findings support the theory that patients see consent as purely a means to an end and something that they just have to do.

There were also some other themes common across both studies. The medical practitioners suggest in the interviews that in some situations they feel the law places an obligation on them to disclose too much information, there is also evidence that they fail to recognise the waiver. These were both issues which became visible during the observations and can therefore be linked to the previous arguments made out in respect of defensive medicine.

The real difference may lie in how medical practitioners actually perceive consent. In the interviews this is portrayed as an ethical requirement as opposed to a legal one. However, as a result of the observations it is possible to conclude that consent is driven by legal formalities and that consultants may see it a functional aspect of their job. This was not the case on every occasion, but was undoubtedly noticeable in some of the observations.

## 12.11 SUMMARY OF OBSERVATIONAL THEMES

<u>Initial Coding Category in NVIVA</u>	<u>Number of Coded Entries Within Each Category</u>
Good Practice in Consent*	10
Controversial Practice in Consent*	5
Perceptions of Patients' Attitudes to Consent	32
Perceptions of Medical Practitioners' Attitudes to Consent	32
Personal Feelings of the Researcher*	10

### IDENTIFICATION OF SUB-THEMES

<u>Initial Theme</u>	<u>Sub-Theme</u>
Good Practice in Consent*	Putting the Patient at Ease
	Benefit v Risk Disclosure
	Enhancing Understanding
Controversial Practice in Consent*	Case Study: Pilonidal Sinus
	Case Study: Banding of Piles in Outpatients
Personal Feelings of the Researcher*	Honesty
	From the Outside Looking In

\*For the purposes of the discussion section, the sub-themes are analysed in accordance with the primary theme.

## 12.12 CONTINUING LEGAL REFLECTIONS: OBERVATIONS

In relation to some treatments, the consultants were often vague about what it was they were actually consenting for. A lot of the time the procedures were described as exploratory procedures to be carried out under anaesthetic. These procedures typify the esoteric nature of medicine and often the consultants admitted they did not know what they were going to do until they had investigated and knew the exact nature of the problem.

*One of the problems was that the Surgeon was undertaking exploratory procedures in order to understand the full nature of the problem so the patient didn't actually know what she was being consented for.*

*He did note that had it transpired to be something major he would have to wake her up as she could not possible consent to that extent of surgery on that day.*

*Little explained in terms of actual risks at failure / alternatives. Reflective Point: White lie told?*

Once the problem was established, the patients were informed that any one of a number of procedures may be carried out whilst they remained under anaesthetic. The varying degrees of risks associated with these different options were not really elaborated on.

*'Consultant stated if he found a fistula when the patient was unconscious he would deal with it there and then. Reflective Point: This is a major procedure and the effects were not really explained to the patient, particularly the aftercare side of opening the wound up.*

Whilst this may be understandable insofar as it is difficult to accurately disclose risks when unsure of the precise nature of the procedure, it does pose problems for patients. They are almost being asked to sign a 'catch all' consent form without being given the necessary information about specific procedures. The only caveat that was added to this was if it transpired the condition was more serious than first envisaged the consultants would wake the patient up and discuss further treatment with the patient before proceeding. This perhaps indicates that for the more serious conditions and

subsequent procedures consent should always be specific as, presumably, the risks are enhanced.

During my time as a researcher, I was invited to spend a day in theatre. It was interesting to see that whilst in theatre, before the operation, the consent form was checked by three independent members of theatre staff to ensure the patient's signature was present. A high degree of importance was attached to this checking procedure. This demonstrates the importance of the legal and procedural side of consent.

*Something I noticed in surgery; the consent form is independently checked by two separate scrub nurses to check it has been signed.*

Another issue which I noted was the difference in consultations where the condition was not treatable with invasive surgery. All the consultants under observation were general surgeons and may understandably have been inclined to recommend surgery. Some of the conditions viewed in outpatients were not treatable in this manner. When this was the case it was encouraging to see the time taken to explain the wide range of non-surgical techniques and alternatives that were available to the patient to help control the condition.

*Irritable Bowel Syndrome Outpatients.*

*Here no consent was given or discussed. What was interesting was the amount of time the Surgeon spent with the patient discussing non-surgical intervention and alternative treatments, which may cure the condition.*

This creates somewhat of a paradox. It has already been demonstrated that there are confused signals as to the willingness to discuss alternatives with patients. In respect of some of surgical procedures it seems some decisions are implicitly made on behalf of the patient. However, here it seems the emphasis changes. It becomes possible to conclude that surgeons seem more prone to discuss alternatives with patients where surgery is not an option, but are less willing to do this when, in their opinion, there is

an appropriate surgical technique available. This is perhaps because they view surgery within the direct remit of their professional expertise and therefore there is less room for negotiation about what is the most 'appropriate' treatment. It would be interesting to see whether this operated the other way round and if physicians shared the same sentiments as surgeons.

Perhaps my most significant reflection was the recurrence of the phrase 'we are obliged to tell you this.' This was a common statement made by both nurses and consultants during the consent process and was often used as a precursor to introducing and explaining the risks. It was relied upon as justification for disclosing risks where patients had suggested they did not want to hear them. In referring to my research journal, there are two points which I flag up. First, does the expression suggest that if they were not legally obliged to disclose this information they would not do? Second, how does this relate to what has been previously suggested about the importance of consent not being bound up in the law? Secondly, could the use of this qualifier potentially serve to de-emphasise the importance of what medical practitioners say about risks? Indeed, upon hearing this, patients may view the information which follows as something that doctors just *have* to say and, as such, may not give it the attention it deserves.

*Reflect Point: What is the significance of this interesting phrase which is used so often in medical consultations 'we are obliged to have to tell you this.' Sometimes it was clear patients did not want the information and simply wanted to get on with the procedure, even more so when the medical practitioner suggested they were 'obliged to disclose this information' it seemed the patient just switched off. Reflect on this: Firstly, does it suggest that the medical practitioners would not provide the patients with the information if they were not legally required to do so? Secondly, does the phrase 'we are obliged to tell you this' de-emphasise the importance of the information as to patients it may seem as something doctors 'just have to do.' They may then not pay as much attention and listen in the manner that perhaps they should.*

## **13 STUDY 4: SOLICITORS' PERCEPTIONS OF INFORMED CONSENT**

### **13.1 INTRODUCTION**

This section of the study explores informed consent from solicitors' perspectives. It employs qualitative interview methods to investigate how the law of consent and information disclosure operates in practice. Whilst the study is extremely concentrated in the sense that it only approaches two participants, it provides depth and clarity in relation to a number of issues. It looks at the dynamics of consent litigation and identifies the frequency and success of claims in addition to analysing the divide between the law of battery and negligence. The study further explores views on compensation cultures, the various standards of care in relation to information disclosure and the difficulties that are faced by both claimants and defendants in relation to the practicalities of litigation. The research concludes by providing a number of suggested reforms aimed at improving consent in both a legal and non-legal sense.

Two solicitors were interviewed; one acting for the claimant and one acting for the defendant. Interviews with just two solicitors cannot be used to justify statements about what happens generally in legal practice. Accordingly, the participants were not interviewed up to the point of saturation; rather they were allowed to develop their answers until they had exhausted all their opinions on any particular issue. Therefore, what the study lacks in representativeness, it makes up for in terms of depth, boasting some very detailed qualitative findings. The interviews were transcribed and uploaded into NVIVA for computer-assisted analysis. A thematic analysis was conducted on all the interview transcripts and the findings are discussed in the context of the identified themes.

The study begins by providing a brief justification for the work and then progresses to discuss the procedure, participants and methods of analysis. It then moves on to provide the substantial discussion of findings and, finally, in keeping with the philosophy which underpins the qualitative methodology, there is a reflexive section which reflects on the findings in a legal context.

## **13.2 JUSTIFICATION**

There is a huge difference between the law in theory and the law in practice. This component of the thesis explores some of these differences. The statistics in the literature review (see 2.1.12) demonstrate that information disclosure cases are rare, and any that are pursued are likely to be unsuccessful. The study discovers why this is the case by eliciting the views of solicitors who represent doctors and patients. It identifies the problems with the law of battery and negligence in practice and discovers the difficulties faced by both parties in the litigation process. It also investigates what is meaningful to solicitors when dealing with different types of clients and how, if indeed at all, the law can be improved in this area.

## **13.3 RESEARCH QUESTION**

To investigate and develop a clearer understanding of how the law operates in relation to consent and information disclosure in practice. Please see chapter 7.3 for a full list of research questions.

## **13.4 SUMMARY OF PARTICIPANTS**

The number of participants in this study was:

Solicitors (N=2) – One defendant solicitor, one claimant solicitor.

Both participants worked for reputable firms and had been practising law for a number of years. They had been involved in a number of high-profile clinical negligence cases.

### **13.5 METHODS**

This component of the study employed semi-structured qualitative interviews. Please see chapter 4.8 for further discussion.

### **13.6 ANALYSIS**

Due to the small number of participants in this part of the study, rather than conduct the interviews up to a point of saturation (see 7.5.3.1), the interviews continued until each participant finished giving their opinions on the topic under investigation. The interviews were transcribed and uploaded into the software package NVIVA. The transcripts were then analysed using the computer-assisted software to identify recurring themes. Please see chapter 8 for further discussion. As this is a qualitative study there are no references to numbers of participants or percentages. However, for a summary of figures relating to the number of themes and the importance attached to each, please see the tables at the end of this study. (See section below for further details).

### **13.7 ORDER OF THEMES**

As the studies started out with no pre-defined themes, the themes are presented in the order in which they developed from the base upwards within each particular study. Within the findings below, the importance attached to each theme is noted in brackets underneath the relevant heading. The level of importance was assessed by the number of times each theme occurred within the transcripts. However, for a complete

summary, and to identify the importance attached to each particular theme, refer to the table providing the summary of themes in section 13.14 of this study.

## **13.8 STUDY LIMITATIONS**

Due to tight time-constraints, only two solicitors were interviewed for this study. This included one solicitor who acted for claimants and one who acted for defendants. Thus it is impossible to generalise in relation to the findings. Interviews with just two solicitors cannot be used to justify statements about what happens generally in legal practice. The research itself was extremely concentrated in the sense that it targeted only two participants. Despite this, what the study lacks in representativeness, it makes up for in terms of depth, boasting some very detailed qualitative findings.

## **FINDINGS**

### **13.9 THEMES FROM BOTH SOLICITORS**

#### ***13.9.1 Researcher's Note***

As noted in the previous qualitative studies, due to the nature of the semi-structured interview format not all the answers provided by the participants were directly related to the initial question posed by the researcher. Often a topic was introduced and then the participant would elaborate on this in great detail. Thus, a number of themes overlapped and this was drawn out in the analysis. Accordingly, within the discussion section, the extracts provided as evidence sometimes do not marry up with the precise nature of the question asked and, in some instances, the initial question posed by the researcher is not displayed. Also, in the findings which concern the common themes across both solicitors, extracts are provided from each participant.

### **13.9.2 Theme 1: General Perceptions of Informed Consent**

\* (There were 7 occurrences of this theme in the defendant solicitor's interview and 4 occurrences in the claimant solicitor's interview. A total of 11 occurrences combined across both solicitors. For further details refer to the table providing the summary of themes in section 13.14 of this study).

The findings suggest that true consent cases are only those which involve claims framed in battery, and that the focus of the negligence action switches to an examination of what constitutes accepted medical practice. Informed consent is divisible into two component parts. There is the consent element. This typically involves an examination of the presence or absence of consent and these cases fall under the battery heading. Then there is the informed part of the definition which focuses on how much information a patient is given prior to treatment, this is concerned with negligence.

**Researcher:** As a legal practitioner what is your view of informed consent and how would you define it?

**Defendant Solicitor:** I think that I mean there are two elements to that. There is the informed nature of the consent and there is the consent itself. For me the idea that consent is informed implies that the patient fully understands the nature of the procedure that is going to be performed and the possible implications of that procedure and also understands any alternatives there may be to that procedure...

The findings indicate that information disclosure cases do not work as the frequency and success of claims is so minimal to be insignificant.

**Claimant Solicitor:** ...Well I don't think enough is made of that in analysing this case because for the most part cases without consent are so few and far between. Unless you are talking about a case like *Appleton v Garret* because for the most part it is irrelevant, what is the remedy worth?

Both parties seem to recognise that the law is paternalistic in nature and this has developed as a result of the outside influence of the medical profession. Nevertheless, there is an indication of a slight movement away from this standard based on recent developments in case law, the introduction of human rights and the development of professional guidelines.

### 13.9.3 ***Theme 2: Views on the Standard of Care***

\* (There were 7 occurrences of this theme in the defendant solicitor's interview and 4 occurrences in the claimant solicitor's interview. A total of 11 occurrences combined across both solicitors. For further details refer to the table providing the summary of themes in section 13.14 of this study).

Both participants acknowledge the problems with the current standard of care. The findings demonstrate that although there has been some refinement to the standard of care based on the judgment in *Bolitho*, the change has not been that significant insofar as the roots of the *Bolam* test still provide the basis for judging professional negligence. They highlight the source of the problem as residing in the fact that it is a standard dictated by the medical profession. The feeling seems to be that this allows both the medical and nursing professions too much discretion. Whilst the participants concede there are some safeguards against this, the profession is still ultimately allowed to dictate its own standard of care. For example, one of the participants draws a contrast with the way in which solicitors themselves are judged in negligence actions. Here it would be for the courts to decide what constitutes negligent conduct and it is unnecessary to defer this judgment to a reasonable body of professional opinion. Thus, there seems to be recognition that the courts are more sympathetic and grant more leeway to the medical profession.

**Researcher:** What do you think about the professional standard of disclosure? The *Bolam/Sidaway* test in relation to this disclosure? Do you think that is the appropriate standard to apply?

**Defendant Solicitor:** I think, of course we have had the slight amendment to *Bolam* with *Bolitho* haven't we? Which has slightly changed the picture although not hugely. The problem that is perceived is that still places an awful lot of discretion in the hands of the medical and nursing professions albeit there you are not looking at the view of one practitioner you are looking at the view of a responsible body of practitioners. But it still means that they are setting their own standard. I read a paper last week I think it was Mr Justice Brook or Lord Justice Brook as he now is, and he was saying that we give medical practitioners a great deal more leeway than we give legal practitioners. Because in legal practice the courts say "we will decide what is negligent and what is not" and generally speaking if there is a complaint of negligence against the solicitor we don't need external evidence. And you can't use a *Bolam* like test.

The courts will decide whereas in medical cases they are prepared to defer to this responsible body of medical opinion.

A further problem concerns the way in which the *Bolam* test operates. The *Bolam* test seems to be viewed as a poor basis for determining what should constitute 'good' medical practice. The test is an examination of what practice is acceptable to clinicians, and often what is acceptable to clinicians is based on the lowest common denominator.

**Researcher:** As a legal practitioner what is your view of the doctrine of informed consent?

**Claimant Solicitor:** Well I think probably it is a misnomer because the doctor ought to disclose all of the known risks. I think the real difficulty with it is that the only really worthwhile analysis that any of us has come to in any of the proven cases is that of Lord Scarman's dissenting judgment in *Sidaway*. And it was proposing a reasonable patient or reasonable body of opinion ...it is hardly surprising that it is ignored. But I think that most of the judgments that have come even down to consent issues really are insufficiently coherent because they are based on the *Bolam* model and the *Bolam* model is a poor basis to determining what should be good practice. Because it is the study of what is acceptable to clinicians what is the lowest common denominator that is acceptable to clinicians rather than whether or not they are rated objectively as good practice in relation to patients.

Thus, it sets a typically low descriptive model instead of a prescriptive standard grounded in what is objectively good practice in respect of patient care.<sup>1</sup> The suggestion seems to be that in respect of information disclosure, an objective standard of care should apply whereby the courts determine what ought to have been disclosed in reference to the expectations of the reasonable patient in the circumstances.

### **13.9.4 Theme 3: Frequency and Success of Claims**

\* (There were 5 occurrences of this theme in the defendant solicitor's interview and 3 occurrences in the claimant solicitor's interview. A total of 8 occurrences combined across both solicitors. For further details refer to the table providing the summary of themes in section 13.14 of this study).

Information disclosure cases are rare. The indication is that often claims are brought under a general medical negligence heading and that questions relating to the

adequacy of information disclosure are often added as ancillary considerations. In this sense the claimant attempts to pursue every possible avenue available to them. Yet it appears, as noted in the opening theme, that cases concerning the battery action are uncommon.

**Defendant Solicitor:** ...I think you very rarely see a case which is purely about the lack of informed consent. I think the patient has another complaint so perhaps a surgery has been imperfectly performed and then they bolt on the complaint that there has been a lack of informed consent. You do in mental health because the procedures are so much more strictly set out so you do have patients complaining solely about that in mental health but it is comparatively rare in medical cases.

**Researcher:** Why do you think judges are really reluctant to categorise claims in battery?

**Defendant Solicitor:** Yes...it would be interesting to see what would happen, because of course at the root of it, it is not for the Judges to decide is it? It is up to the claimant to decide how they frame their case. I think the reason that we don't see those problems is, because as we have said before, in most cases where there are allegations of a lack of informed consent that is simply shackled to an allegation of clinical negligence. So the claim has to go through as clinical negligence and the damages are less.

The findings also suggest that information disclosure cases are rare as it remains very difficult for claimants to be successful in negligence actions. This seems to be related to two factors. Firstly, as has been demonstrated above, the standard of care operates in such a way so as to restrict patients' opportunity for success by being sympathetic towards the medical profession. Secondly, although a major obstacle to overcome is the standard of care, this is not the true determining factor. The most difficult issue, and the most restrictive barrier when bringing an action for negligent information disclosure, is still one of causation. Both participants illustrate this is very difficult to establish and the majority of claims fail as a result. The suggestion from one of the participants is that the restrictive nature of both the standard of care and causation is underpinned by a judicial reluctance to adopt a patient-centred approach to information disclosure and consent cases.

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<sup>1</sup> For further discussion see Montrose, J.L. "Is Negligence an Ethical or Sociological Concept" (1958)

**Researcher:** Do you think the courts synthesised the *Sidaway/Bolitho* judgment and then out of that came the *Pearce* judgment? Do you think that is going to enhance the law at all?

**Claimant Solicitor:** No well Ian Kennedy used to offer a £5 prize for anyone who could understand the judgement in *Sidaway*. I think the truth is that what he describes judgment and with his wonderful phraseology he sort of says "and if you accept this there is a complete disjunction between what has gone before this judgment and what comes afterwards, which is rather more *Bolithoish*. But I don't think it is as complicated as that. The fact is that judges are paranoid about creating an environment in which there is, in their perception, a more patient orientated test, because they perceive that it will open the floodgates. The fact of the matter is that they are quite wrong in that because the real issue is that of causation. To establish and making the liability test different doesn't necessarily solve the problem, it doesn't solve our problem.

#### **13.9.5 Theme 4: Problems with Damages and Settling Claims**

\* (There were 3 occurrences of this theme in the defendant solicitor's interview and 2 occurrences in the claimant solicitor's interview. A total of 5 occurrences combined across both solicitors. For further details refer to the table providing the summary of themes in section 13.14 of this study).

The notion that resultant harm must eventuate from the breach of duty is the very notion upon which the tort of negligence is predicated. However, there are problems with this in the context of consent. For example, a patient may not give a proper consent, yet if no risks eventuate no harm will transpire. In this sense an invalid consent may not always lead to 'damage.' Patients are highly unlikely to complain unless something goes wrong. However, the findings suggest that a common question asked by patients is "have I got a valid claim by virtue of the fact that I have not 'consented' properly?" In return, it seems the question often posed to clients by solicitors is "what have you lost by virtue of the failed consent?"

**Claimant Solicitor:** If you come to me and say "I have got a case and it is about consent" I am going to say "what have you lost by virtue of failed consent?" You have lost an opportunity to undertake something at the time and on terms of your choosing and that is it. There is no damages remedy that is worth more than 2p about it. The fact that you haven't had a proper consent doesn't lead to the consequence of the unanticipated but eventuating risk in the procedure.

The majority of claims settle outside court. This is a problem concerning all claims. Doctrine develops only through the chance accident of litigation. Nonetheless this has potentially far-reaching implications for the development of the law insofar as its capacity to progress in this area is thereby restricted. The medical profession will inevitably settle the cases which they fear may create dangerous precedents and open the flood-gates in the future. In turn patients will often accept what they perceive to be a lucrative offer.

**Researcher:** It is informed consent I suppose the reason why not many cases go to court is this because if they have got a certain claim do they tend to settle outside the court. Is that why?

**Defendant Solicitor:** Yes that is certainly true I mean claims are settled. I think there is a general unwillingness on the part both of claimants and defendants not to run case that may set uncomfortable precedents. So if you have a case, if you are a claimant and you have a case that you think you are likely to lose and you are given an economic offer you are very likely to say "well we will take that." Likewise for the defendants. They think well "we have got a chance of winning this but if we lose it may well be that we will attract a whole raft of claims." So possibly makes them keen to settle.

**Researcher:** So that is a problem because in a sense it is reducing the laws capacity for development?

**Defendant Solicitor:** Yes it is this is always the problem isn't it? Because the development of the law rests on individual litigants in most cases bringing the cases to the court and yes you are right and they won't unless we have a system that allows cases to be brought simply on public interest grounds. You know while we are still wedded to this idea of the damages and individual settlements there will be that problem.

Settling claims is problematic for the morale of the medical profession as doctors do not like it when cases are settled as they think it reflects badly on them. The defendant solicitor suggests they do not realise these cases are settled because they are often incontestable or because the cost of pursuing them is disproportionate.

**Researcher:** Do doctors tend to think that when cases get settled do they see it as a bad reflection on themselves?

**Defendant Solicitor:** They don't necessarily see that its a cause for blaming for themselves. What they are concerned about is what other people will think and other professionals and other patients will think that the reason the case has been settled because it was indefensible and they felt that that was often not true. It was simply just not economic to...these cases are settled for lots of

reasons sometimes because they are unwinnable, sometimes because the cost of pursuing them can be wholly disproportionate.

The participants indicate medical practitioners may feel aggrieved as their perception is that cases are settled because it is convenient to do so, or for economic reasons when, in their eyes, they have done nothing wrong and have not been afforded the opportunity to clear their name.

### **13.9.6 Theme 5: Reforming Consent**

\* (There were 12 occurrences of this theme in the defendant solicitor's interview and 4 occurrences in the claimant solicitor's interview. A total of 16 occurrences combined across both solicitors. For further details refer to the table providing the summary of themes in section 13.14 of this study).

Both participants consider a number of broad themes which relate to reforming consent. First, that consent should be based on a model not dissimilar from contract law. For example, the consent process should consist of a number of terms and conditions laid out before the commencement of treatment, thereby enshrining a number of clear expectations from both parties before an agreement is reached whether or not to proceed. This was also indicated as desirable by the medical consultants where the suggestion was made that a system ought to be implemented whereby the clinician can 'opt in' to an operation when a certain number of conditions are satisfied by patients.

**Claimant Solicitor:** ...My only view as somebody in clinical cases you have to start with a model that actually has a lot in common with the law of contract. Because there ought to be a model, which at the end of the consultation relates to the beginning and getting the consent in that both parties have a certainty as to terms. I am not suggesting that they should be conclusive but I suppose they are not bad questions to ask but if you are looking in the commercial sense to say is there an agreement to go ahead in business in the case, is there in place a contract. It is not a bad starting point to say are there certain terms and conditions as to what procedure are you going to carry out? What you are going to tell me are the risks, what my expectations are this and that...

Second, consent ought to be considered as a continuing process which should be obtained at different stages within the medical encounter. This again demonstrates a

point of convergence with a number of themes identified by both patients and medical practitioners.

**Defendant Solicitor:** ...but I think it is important that each step of a particular procedure gains informed consent, and I think it is important, and it is something that I try to stress is that practitioners shouldn't just imagine that it is necessary to take consent once. It is a continuing process really. Each time that you are undertaking a significantly different intervention you have to ask "do I have consent for this and is it truly informed consent."

Both participants also discuss a number of legal improvements that ought to be considered. These are aimed at refining the standard of care. They suggest that the current standard is too paternalistic in nature and is incompatible with patient rights. However, there is some disagreement as to how this should be reformed and the extent to which, if indeed at all, the test for judging the information provided can detach itself from medical input. The solicitors suggest that the judgment in *Bolitho* has certainly modified the standard of care to some extent, yet both concede that to all intents and purposes the new test has not had any great practical effect. Firstly, because it remains a test that is based on accepted professional practice.

**Researcher:** Do you think that *Bolitho* has advanced the law from beyond *Bolam* and *Sidaway* in practice?

**Defendant Solicitor:** It has, it has altered the law a little bit. It has changed it in some fairly small way. There have been cases in my own field of mental health that have almost shadowed *Bolitho* but I don't think it has changed the overall features of the area. I think still *Bolam* is the test of professional standards and if you could see *Bolam* type tests being used in other areas eg social work negligence or educational negligence again the test that is used there is very much derived from the *Bolam* test.

Secondly, the opinion of both the solicitors seems to be that whilst *Bolitho* does pave the way for the courts to scrutinise medical practice in greater detail, what it fails to do is provide any criteria or guidelines to equip judges to do this. In addition, where there is a *risk* or *riskier* scenario balanced against a *less risky* scenario, the courts ought to look to the option which subjects the patient to the *least risk* when determining whether or not a course of action is indeed negligent.

**Claimant Solicitor:** ...I also acted in *Bolitho* so I have a very clear view of *Bolitho*. Here is a missing element in the test and I think...well firstly I think a reasonable patient test would be better anyway. But even on the analysis that we have the missing bit from the judgment in or the speech of Lord Browne-Wilkinson...we put in as a proposal to him that there should be in order to determine the scrutiny that you ask the Court to undertake a criteria to typify the way in which the scrutiny is exercised. And we suggested that in any case where you were evaluating 2 scenarios, one of which was a risk scenario or the riskier scenario, as it was in this case, as against a less riskier scenario suggested by experts, that the criteria should be least risk to the patient. And it is...so they say that you can scrutinise what is said by experts, but it doesn't equip the judges with any means to do so, or the criteria to do so.

There seem to be a number of indirect ways of refining the legal standard of care.

One of these ideas centres on the implementation of professional guidelines in respect of consent. It is stated that these are generally commendable. However, in order that they work they must be pragmatic in what they expect to achieve. If they prescribe a typically low standard which can be met with ease, this will have little effect on improving standards of care and will invariably dictate the legal standard under the *Bolam* test. If they are adhered to it will make it extremely difficult to mount a successful legal challenge, therefore they must presuppose a satisfactory yet not excessive standard of consent that is extensive but not unrealistic. The boundaries set by the guidelines must be sufficiently flexible so they can be kept under review and adapt to meet the changes in contemporary medical practice.

**Researcher:** If the protocols are adhered to do you think that that makes it basically impossible to mount a successful legal challenge?

**Defendant Solicitor:** 'Pretty much of course when you look at the question of negligence and test it against the practice acceptance proffered by a reasonable body of medical people i.e. the *Bolam* Test. The question is what is the practice accepted as proper and generally speaking it is whatever is in the guidelines. You know so that is your *Bolam* Test isn't it? Essentially, that is the test to apply in practice and so if the guidelines, as we have said, have been drawn in accordance with the law they should represent the *Bolam* Test. But that means of course that they need to be constantly updated as the view of practitioners changes, as practice changes, the guidelines must be kept up to date but if you stick by the current guidelines you should be OK.'

The findings highlight the desirability of introducing a Charter of 'Good Medical Care' in respect of consent. This would have the advantage of providing a base-line assessment against which consent procedures can be judged.

**Defendant Solicitor:** ...I am not quite sure what the alternative to that would be. I suppose the alternative would be some sort of charter of correct behaviour and appropriate and clinical behaviour. But again I don't know how you could produce such a charter without significant input from medical clinicians.

There remains an acknowledgement that any professional guidelines and Charters cannot be designed without medical input. This renders the idea subject to the common dangers previously identified with the paternalistic nature of the standard of care. In allowing the profession too much discretion in setting their own standards, the temptation is to work from the lowest common denominator. This in turn can have the reverse effect of lowering standards if, in practice, what is being asked is nothing more than the bare minimum which is easily achievable.

## **13.10 THEMES IDENTIFIED BY THE DEFENDANT SOLICITOR**

### **13.10.1 Theme1: Clients Perceptions of the Law**

\* (There were 3 occurrences of this theme in the defendant solicitor's interview. For further details refer to the table providing the summary of themes in section 13.15 of this study).

The solicitor who acted for defendants raised a number of specific issues. The findings suggest that medical practitioners, as clients, find some difficulty in relating to and understanding the law. The solicitor intimates that to be more effective the law ought to be disseminated more comprehensively amongst medical practitioners.

**Researcher:** How do you think the law could be improved?

**Defendant Solicitor:** I think, I mean I am acutely aware of the fact that the law is extremely paternalistic in the sense that it still gives an awful lot of power to individual doctors. And I think that is something that is susceptible to be eroded. I think as patients' rights and notions of human rights begin to get ground. I think that is one area where we could be looking at change you know the idea of advanced refusals of medical treatment and the introduction of the Capacity Act I think that is going to have a big effect. So that is one area where I think the law should be changed. I think it will be changed but my other

feeling is not so much the contents of the law it is what the law requires is more, is better disseminated amongst practitioners, they need to understand it more. They need to understand what the law requires, but also what it doesn't require. They need to understand the limits of the law because you can be rather like a rabbit in a spotlight. You can be slightly disabled, paralysed, terrified of taking a particular action because you know it is going to be unlawful whatever you do which is probably not the case, there is probably one solution at least that is lawful.

Making doctors and nurses aware of not only what the law requires, but also what it does not require, may help health care professionals feeling threatened in their jobs and may ultimately serve to benefit patients by allaying any perceived fears that could potentially lead to defensive practices.<sup>2</sup> The participant suggests greater training should take place and within the firm where he works there are already a number of moves afoot to increase the number of training days they offer for medical practitioners as an aspect of continuing professional development.

### **13.10.2      Theme 2: No-Fault Compensation**

\* (There were 2 occurrences of this theme in the defendant solicitor's interview. For further details refer to the table providing the summary of themes in section 13.15 of this study).

A further issue was raised in connection with adopting a no-fault compensation scheme. The perception seems to be that this would be a drastic change that will probably never happen. This is because of the potential knock-on effect in other areas. If it becomes possible to claim compensation without attributing fault for medical accidents, there is no reason why this should not be the case in other general personal injury cases; this of course casts the net much wider. The defendant solicitor suggests that medical practitioners may not welcome the move, for reasons that are

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<sup>2</sup> There may of course be some professional resistance to this. For an interesting discussion of how professional institutions may perceive legal values as 'unwelcome intruders' and how large organisations often have strong internal cultures which resist interference from legal values see Sunkin, M "Review Article: *Judicial Review and Compliance with Administrative Law* " (2006) 26 LS 120 at 124. See further Halliday, S. *Judicial Review and Compliance with Administrative Law* (Oxford: Hart Publishing, 2004) at 59. However, this appears not to be the case in relation to the junior doctors interviewed in the earlier in the thesis who suggest they would welcome further legal training. See section 10.10.2 for further discussion.

comparable with the present system where so many claims are settled outside court. This reflects badly upon their practice as, in their eyes, they never have the opportunity to clear their names.

**Researcher:** What is your view, I know you mentioned earlier about no fault compensation scheme for medical accidents. What is your view about that?

**Defendant Solicitor:** I mean it would transform that landscape there is no doubt about that it. I think it would have a knock on effect because then the argument would be well if you can gain compensation without proving fault in medical accidents why not do it everywhere else as well. You know and I think it could have a knock on effect. I very much doubt that it will come in. I think doctors will be, well doctors are opposed to it, because they don't like the current system because they feel that too many cases get settled for economic reasons and that cuts them out of it, and it makes them look bad. I can't see how this will improve even though I am sure they would be given reassurances that the compensation that was being paid was no reflection on their practice.

Although under a no-fault scheme the compensation paid out should not reflect the personal standards of individual clinicians, it has the potential to compound the above problem as suggested by the participant.

### **13.10.3      Theme 3: Development of Consent Through Human Rights**

\* (There were 9 occurrences of this theme in the defendant solicitor's interview. For further details refer to the table providing the summary of themes in section 13.15 of this study).

Some comments were made in relation to the effect of the Human Rights Act. As a result of its introduction it is suggested medical practitioners are more aware of the law operating in the background. However, the effect on consent cases is minimal and the indication seems to be that the significance of the Act was massively overplayed in the build up to its implementation. In practice it has not really had the effect originally envisaged.

**Researcher:** Do you think the Human Rights Act is going to have a major effect on consent cases perhaps?

**Defendant Solicitor:** I am not sure that it is. I think its significance was hugely overplayed in the months and years before it came into effect. I think, in most areas, the general consensus is that it hasn't had the effect that it was expected to have...

**Researcher:** Do you think that it may place a greater effect on the issue of patient rights?

**Defendant Solicitor:** It will certainly place attention on the question of patient rights. Whether it significantly alters those rights I am not sure because it seems to me that this may be something to do with innate conservatism in the courts. But generally speaking when the courts reach a decision that has an impact on health care rights they are at pains to say that this is a decision that was produced by the common law anyway. You know there is a very great tendency to say this...they are very reluctant to admit the European convention at all.

Whilst the solicitor concedes that the introduction of the Human Rights Act has had very little effect on medical care and consent provisions generally, its true power is to be found in its symbolic nature. It pays greater attention to patient rights yet, as the solicitor suggests, 'whether it significantly alters those rights' remains to be seen.

### **13.11 THEMES IDENTIFIED BY THE CLAIMANT SOLICITOR**

#### **13.11.1 Theme 1: Documentation and Consent**

\* (There were 3 occurrences of this theme in the claimant solicitor's interview. For further details refer to the table providing the summary of themes in section 13.15 of this study).

The claimant solicitor also draws attention to some of the perceived problems with consent in practice. His perception seems to be that not enough attention is paid to the needs of the patient when it comes to obtaining consent. Whilst diagnosis and treatment are undoubtedly the pressing issues with which clinicians are primarily concerned, the findings indicate that consent is seen merely as an administrative procedure and medical practitioners do not take the time to note it down properly. For example, they do not sit down and explain all the risks and benefits to the patients. What they may tend to do is document consent in order to ward off litigation as opposed to reflecting the discussions which have taken place.

**Claimant Solicitor:** ...Yes I mean diagnosis and treatment are big issues. I mean consent as with this case of xxxx is sometimes. But often it is an administrative issue. I think one of the problems we have got is that a lot of clinicians don't take time to note the consent properly. They see the patient and instead of sitting there and explaining the problems and answering questions it is half a days work, it is not a big deal and yet even now.

**Researcher:** Do you think in practice that a lot of the decisions are based on documentation, the medical notes, dental notes, things like that?

**Claimant Solicitor:** I think that they tend to note to ward off litigation in consent rather than noting it to reflect the discussion that they have had. The good doctors that you see and the good practice that is very much around to be observed I think are much more patient orientated with regard to consent. I have had a lot to do with over the last few years with neurosurgeons and spinal surgeons and it is much more typical in neuro/spinal surgery to write very full narrative patient orientated notes. Probably because the surgeons have more time to write the notes. I think that the answer to that is that people need more time. I think that consent is more of an issue with the doctors in their management of the patients that it is for doctors and the lawyers. Because I think the remedy of a breach of consent is not that great.

If the above rings true, the needs of the patient may become lost in the administration side of consent; in order for consent to become truly effective it has to become much more patient orientated with full and narrative notes. The suggested answer seems to be give doctors and patients more time in the consultation stage, and better training in consent issues.

### **13.11.2 Compensation Cultures**

\* (There was 1 occurrence of this theme in the claimant solicitor's interview. For further details refer to the table providing the summary of themes in section 13.15 of this study).

The claimant solicitor also identified some interesting points about what has been described as the 'compensation culture.' His view is this is a myth. Patients are reluctant to sue their doctor and to accuse them of any wrong doing.

**Researcher:** These new professional guidelines with regard to informed consent are sort of watertight. Do you think that will have an effect?

**Claimant Solicitor:** I don't know. It depends on what spirit they are drawn in the answer. And anything that is drawn in spirit to reduce clients rather than enhancing practice would be a waste of time and I suspect that in the Royal Colleges you have got guidelines designed to make practice clearer, more coherent, more patient friendly and they will be a success. The real problem that most people never acknowledge is that actually that very few people sue. The talk of the compensation culture is a laugh. The truth is that fewer than 1:6 people may have a claim and would go and see a lawyer, which is true in the USA, but the vast majority of people never want to accuse their doctor of any wrong doing. And my feeling is that people only ever go and see a lawyer when not only have they not been properly treated, but there has been a kind of a breach of trust...that the relationship with the doctor has broken down to the

point where they no longer trust them. We are strongly in favour of good practice and enhancement.

In accordance with what some of the medical practitioners and patients suggest, the only circumstances in which patients may consider recourse to the law is where there has been a breakdown in the relationship of trust.

### **13.12 COMPARING AND CONTRASTING DEFENDANT AND CLAIMANT THEMES**

The research illustrates a number of similarities between both participants' beliefs in respect of consent and the law in practice. A majority of issues overlap. For example, the paternalistic nature of the law, the difficulties associated with placing too heavy reliance on accepted medical practice, and the problems encountered when attempting to move away from this dependence. There are also comments highlighting clinicians' lack of understanding of certain aspects the law, the difficulties faced by claimants leading to infrequent claims, and the problems with damages. Both parties discuss issues relating to the standard of care and how best to resolve these problems. It is possible to conclude that this is where the only real disagreement presents itself. One suggests a move to an objective standard of care, whereas the other would like to see a movement away from the traditional legal approach towards the development of Patient Charters in respect of consent that can be used to assist in developing a more coherent standard of care.

### **13.13 COMPARISON OF INTERVIEW THEMES BETWEEN HEALTH CARE PROFESSIONALS, PATIENTS AND SOLICITORS**

Given the nature and role of practising solicitors within the consent debate, the lines of inquiry here differed from the issues explored with both clinicians and patients. Whereas the focus of the study in terms of clinicians and patients was to develop a deeper understanding of consent issues in medical practice, the focus of the solicitors' study was to develop a clearer understanding of how the law operates in relation to consent claims. Thus, understandably different questions were posed. Despite this, there are some similarities.

The first theme which is recurrent across all the studies and amongst all participants, is that consent should not be viewed as a one-off event and a process in isolation. It should be a continuing and reciprocal process which starts at the beginning of the patient's medical encounter, and carries on through each stage of treatment, ending only when the patient is finally discharged. The second issue is that it is rare for patients to resort to the law and it is unlikely that patients will ever complain about doctors. This relates to what the patients say about their personal reluctance to pursue legal actions against medical practitioners and their diastase for those who seek to make money out of the medical profession. The perception of the solicitors is that patients only ever complain when the relationship of trust breaks down and where there has been a lack of honesty. This is a view echoed by a majority of medical practitioners. Patients again seem to agree with this notion stressing the importance of honesty and openness, yet at the same time stressing that medical practitioners should not be penalised for mere mistakes that happen in the course of their jobs.

### **13.14 COMPARING THE OBSERVATIONAL FINDINGS WITH THE SOLICITORS' THEMES**

There are some differences between the views held by medical practitioners and those views held by practising solicitors, connected to the importance medical practitioners attach to consent and their perceptions of the rationale which underpins the concept. It seems the solicitors think that some doctors and nurses may pay too much attention to the documentation side of consent and that this carries with it the potential danger of overlooking the needs of patients in an attempt to ward off litigation. Thus, the bureaucracy of the process overtakes the interests of the patient. This is a view which is in contrast with what the clinicians themselves say about the importance of consent. They stress its significance is bound with in the needs of the patient and suggest that the unnecessary bureaucratic nature of trust consent forms hinders this. However, at this point, in pausing to reflect on the findings in the observational study, it seems there is some truth in what the solicitors suggest about the attention clinicians pay to the administrative side of consent. Whilst many of the clinicians attempt to deny it, it is apparent that sometimes, whether consciously or not, they do focus too much on documentation.

### 13.15 SUMMARY OF THEMES FROM BOTH SOLICITORS

<u>Initial Coding Category in NVIVA</u>	<u>Type of Solicitor</u>	<u>Number of Coded Entries Within Each Category</u>
General Perceptions of Informed Consent*	Defendant Solicitor	7
	Claimant Solicitor	4
Views on the Standard of Care	Defendant Solicitor	7
	Claimant Solicitor	4
Frequency and Success of Claims*	Defendant Solicitor	5
	Claimant Solicitor	3
Problems with Damages and Settling Claims	Defendant Solicitor	3
	Claimant Solicitor	2
Reforming Consent*	Defendant Solicitor	12
	Claimant Solicitor	4

#### IDENTIFICATION OF SUB-THEMES

<u>Initial Theme</u>	<u>Sub-Theme</u>
*General Perceptions of Informed Consent	Paternalistic Nature of the Law
	Developments in the Law
*Frequency and Success of Claims	Consent Tagged On
	Causation
*Reforming Consent	Origins of Consent in Contract
	Consent as a Continuing Process
	Developing the Standard of Care: Difficulties with Reliance on Medical Input

\* For the purposes of the discussion section, the sub-themes are analysed in accordance with the primary theme. In addition to facilitate an effective discussion, the findings are commented on in present tense.

## 13.16 SUMMARY OF THEMES RELEVANT TO CLIENT REPRESENTED

### 13.16.1 *Defendant Solicitor*

<u>Initial Coding Category in NVIVA</u>	<u>Number of Coded Entries Within Each Category</u>
Clients' Perceptions of the Law	3
No Fault Compensation	2
Developing Consent Through Human Rights	9

### 13.16.2 *Claimant Solicitor*

<u>Initial Coding Category in NVIVA</u>	<u>Number of Coded Entries Within Each Category</u>
Documentation and Consent	3
Compensation Cultures	1

## 13.17 CONTINUING LEGAL REFLECTIONS: SOLICITORS

### 13.17.1 *Theme 1: The Mythical Compensation Culture*

The phrases 'compensation culture' and 'litigation crisis' are terms which are often used interchangeably by those who assume there is an increased willingness to resort to legal action when something untoward happens. Williams has suggested that 'the growth of a "compensation culture" implies an increased and unreasonable willingness to seek legal redress when things wrong, whilst "litigation crisis" implies that this shift in social attitudes has been translated into unbearable levels of formal disputing.<sup>3</sup> Both terms are used frequently in a medico-legal context and are often used to level criticism at patients, the law and the way that it operates, and at lawyers themselves.<sup>4</sup> The negative connotations associated with the two phrases are often used to highlight the harmful effect they have on medical practice, being relied upon

<sup>3</sup> Williams, K. "State of Fear: Britain's 'Compensation Culture' Reviewed" (2005) 25 LS 1 499 at 500.

<sup>4</sup> See, for example, Tribe, D. and Korgaonkar, G. "The Impact of Litigation on Patient Care: An Enquiry into Defensive Medical Practices" (1991) PN 2; Jones, M.A. and Morris, A.E. "Defensive Medicine: Myths and Facts" (1989) 2 *Journal of the Medical Defence Union* 40.

by some to substantiate claims of defensive medicine.<sup>5</sup> However, whether or not the problem actually exists is open to conjecture. Despite a sharp increase in claims (from a relatively base) since the 1970's<sup>6</sup>, recent figures suggest clinical negligence claims are falling.<sup>7</sup> Any statistics themselves have to be approached with caution as they are not an accurate reflection of what happens in practice.<sup>8</sup> Yet, something that can be said with a higher degree of certainty is that the numbers of adverse incidents that take place in the NHS far outweigh the number of patients who complain.<sup>9</sup> At this point, let us pause to reflect the findings of this study.

Based on the patients' and solicitors' studies there is further evidence that we are not living in a compensation culture. The patients in this thesis suggest that they are reluctant to turn to the law and would only ever do so as a last resort, indicating even then that they would be unlikely to pursue this course of action.<sup>10</sup> The only time when complaints seem likely to arise is when there has been a communication breakdown or a feeling that health practitioners have acted dishonestly.<sup>11</sup> In actual fact the patients seemed hostile to those who actually seek legal redress with a view to obtaining compensation, implying that the compensation culture is not welcomed; if anything the reverse is true. Secondly, the solicitors in this study confirm that the

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<sup>5</sup> For discussion see Ennis, M. and Vincent, C. "The Effects of Medical Accidents and Litigation on Doctors and Patients" (1994) 16 *Law and Policy* 97. For empirical evidence see Summerton, N. "Positive and Negative Factors in Defensive Medicine: A Questionnaire Study of General Practitioners"(1995) 310 *BMJ* 27.

<sup>6</sup> The total expenditure on clinical negligence claims is estimated to have risen from £200 million in 1995/6 to 1.5 billion in 1999/2000. National Audit Office *Handling Clinical Negligence Claims in England* (London: National Audit Office, 2001). For further discussion see Pleasence, P. *et al* "The Experience of Clinical Negligence within the General Population" (2003) 9 *Clinical Risk* 211 at 211.

<sup>7</sup> According to statistics from the NHS Litigation Authority claims are falling. Between the years of 2002-03 the number of claims was estimated at 7,798 claims. Between the years of 2003-04 the figures decreased to 6,251 claims (*NHSLA Fact Sheet No 3*, August 2004). During 2004-05 the number of claims was estimated at 5,609 (*NHSLA Fact Sheet No 3*, July 2005).

<sup>8</sup> It is extremely difficult to locate accurate statistics. The NHSLA is probably the most reliable source. However, the statistics provided do not account for the number of claims settled outside court and they do not show the number of claims in which the claimant loses.

<sup>9</sup> See Jones, M. Evidence Submitted in the Report of the House of Commons Constitutional Affairs Committee on the Compensation Culture (Third Report of Session 2005-06) at 189. See also Pleasence, *op cit* n 6 at 211.

notion of a compensation culture is something of a myth, particularly in relation to information disclosure cases. There is evidence that the majority of cases brought by claimants concern negligent treatment and diagnosis, and that any claims for negligent disclosure are added on as ancillary components to the original claim. These findings reflect Professor Robertson's empirical study in 1991 where he found that in only 13 out of the 117 cases (i.e. about 11%) did the plaintiff rely *solely* upon an alleged failure to disclose information.<sup>12</sup> They also mirror the findings provided by Jones mentioned in the literature review of this study which demonstrate that inadequate disclosure claims are rarely the principal basis for medical malpractice claims.<sup>13</sup>

Recently, a report of a select committee of the House of Commons has firmly denied we are living in a compensation culture.<sup>14</sup> The evidence presented also suggests there is no problem in the context of clinical negligence. Jones, commentating specifically on medical negligence litigation, suggests there is 'no evidence of a compensation culture in clinical negligence litigation.'<sup>15</sup> This is supported by the fact that the number of claims as proportion of the likely number of medical accidents is small (probably under ten per cent).<sup>16</sup> This is something that the current author agrees with and the findings in this thesis support the existing evidence. What is slightly more contentious, and what does not sit as easily with the researcher, are assertions about defensive medicine. True it is extremely difficult to define defensive medicine and many contentious claims are made about the effect of the law on medical practice in the absence of empirical evidence. It is important to remember

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<sup>10</sup> See section 11.8.5 for discussion.

<sup>11</sup> Fentiman, I. "Litigation and Doctor-Patient Communication" (2003) 9 *Clinical Risk* 180.

<sup>12</sup> Robertson, G. "Informed Consent Ten Years Later: The Impact of *Reibl v Hughes*" (1991) 70 *Canadian Bar Review* 423.

<sup>13</sup> Jones, M. "Informed Consent and Other Fairy Stories" (1999) 7 *Med L Rev* 103 at 122.

<sup>14</sup> The Report of the House of Commons Constitutional Affairs Committee on the Compensation Culture (Third Report of Session 2005-06 Vol .1).

<sup>15</sup> Jones, *op cit* n 9 at 190.

<sup>16</sup> Jones, *op cit* 9 at 189.

that this argument works both ways. If the lack of empirical evidence is the key, it is impossible to confirm *or* deny categorically that defensive medicine is a problem. Claims made denying its existence are also based on lack of evidence. It seems then that the problem does not reside in the existence of *evidence*, but is more concerned with a question of *interpretation*.<sup>17</sup> When it is impossible to define or identify an ambiguous concept such as defensive medicine, evidence ought not to be confused with proof. Thus, on one interpretation, the findings in this thesis which suggest that health care professionals engage in excessive risk disclosure could, by some, be described as defensive medical practice.<sup>18</sup> This is not to say that the study provides stalwart proof there is a problem. For example, one may prefer Jones's interpretation that it is a good thing if doctors treat patients more carefully and are more cautious in their assessment of risks.<sup>19</sup> No matter what, any arguments relating to the laws effect on medical practice derive from a *perceived* rather than a *real* threat amongst health care professionals.<sup>20</sup> This perceived threat is arguably a good thing if it promotes careful practice, but it can also be dangerous. This is particularly the case if it is seen as eroding clinical judgement in medical decision making. (See sections 10.9.13 and 10.17.3 in the Health Care Professionals in Secondary Care Study for further discussion). Essentially what is needed in the context of information disclosure is a balance. A culture of openness and more extensive disclosure is desirable in medical practice; it seems this is recognised by the participants in this study, the medical

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<sup>17</sup> Interestingly enough, this is the concept which underpins the qualitative methodology used in this thesis. It is submitted that the positivist approach of thinking things are as they are simply because statistics and empirical evidence tells us is inappropriate when dealing with issues relating to defensive medicine. The importance one attaches to any assertions made about defensive medicine depends on the interpretation one gives to the concept itself.

<sup>18</sup> See sections 10.8.13 and 10.16.3 in the Health Care Professionals in Secondary Care Study earlier in this thesis. See also Heywood, R. "Excessive Risk Disclosure: The Effects of the Law on Medical Practice" (2005) 7 *Med L Int* 93.

<sup>19</sup> Jones, *op cit* n 9 at 190.

<sup>20</sup> For discussion see Symon, A. "Reactions to Perceived Risk: Defensiveness in Clinical Practice" (2003) 9 *Clinical Risk* 182.

practitioners' study and the patients' study. However, on the other hand, healthcare professionals need to remain aware that the law does allow some clinical discretion in respect of information disclosure. This discretion needs to be exercised by considering carefully the circumstances of the individual patient and whether, in the opinion of the healthcare professionals, too much information would be detrimental to the patient's mental or physical health. If this is the case, disclosure in this context ought to be tailored accordingly.

### **Theme 2: Difficulties for Claimants**

The solicitors confirm that the law has generally developed in an extremely paternalistic manner. The standard of care in *Bolam*<sup>21</sup> has inevitably made it very difficult for claimants to succeed in medical negligence cases. In particular this has rendered it virtually impossible to win information disclosure cases. This, in addition to the difficulties in establishing causation, supports Jones's assertion that 'the law of informed consent does not work, at least as a remedy for breach of the rules on information disclosure cases. Very few claimants succeed in their cases.'<sup>22</sup> The practical effect of this is articulated neatly by Brazier. She suggests that in the majority of cases legal aid is no longer available so claimants are forced to find solicitors who will act on a conditional fee basis. It follows there must be strong evidence that the doctor or hospital was negligent in order for solicitors to accept the case; they are unlikely to do so unless there is reasonable chance of success.<sup>23</sup> Add to this the fact that any cases providing strong proof of negligence will undoubtedly be settled by the medical profession for fear of setting a dangerous precedent, it becomes evident that the capacity of the common law for incremental development is

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<sup>21</sup> *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

<sup>22</sup> Jones, *op cit* n 13 at 107.

<sup>23</sup> Brazier, M. *Medicine, Patients and the Law* (London: Penguin Books, 2003) at 221.

restricted. There is however evidence of late suggesting a delicate movement away from this paternalistic stance with a greater emphasis now being placed on patient rights. Cases such as *Bolitho*,<sup>24</sup> *Pearce*<sup>25</sup> and *Wyatt*<sup>26</sup> have gone some way towards refining the standard of care and steering it towards a more patient-orientated approach. Sceptics may argue that these decisions have only advanced the law in theory, and the practical difficulties still remain for most claimants.<sup>27</sup> Thus, it is with interest one should view the recent decision emanating from the House of Lords. In *Chester v Afshar*<sup>28</sup> the court, as a matter of policy, moderated the stringent rules of causation in order to give better effect to the patient's right of autonomy. This indicates an increased willingness from the courts to recognise this right and demonstrates that law does have the capacity to evolve.<sup>29</sup> *Chester* represents a decision where the court was willing to look beyond the straightjacket application of the law to consider the rationale behind imposing a duty of care and to look at the very right it seeks to protect. In the present climate of patient rights, and in light of the fact that the legal rules pertaining to causation have been manipulated, is it possible to articulate an argument that the standard of care ought to be moderated too?

### **13.17.2      Theme 3: Reflections on the Standard of Care: Considering Disclosure with Reference to the Individual Patient**

Most of the debate over informed consent in a legal sense has centred on how best to judge the adequacy of clinicians' disclosure. Scrutiny has focussed on the appropriateness of the 'two' most commonly accepted standards of care; the professional and prudent patient standards of disclosure. These tests operate at

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<sup>24</sup> *Bolitho v City and Hackney Health Authority* [1998] AC 232.

<sup>25</sup> *Pearce v United Bristol Healthcare NHS Trust* (1998) 38 BMLR 118.

<sup>26</sup> *Wyatt v Curtis* [2003] EWCA Civ 1779; [2003] WL 22827037.

<sup>27</sup> Heywood, R. "Re-Thinking the Decision in *Pearce*" (2005) 7 CIL 264 at 278.

<sup>28</sup> [2004] UKHL 41; [2005] 1 AC 134.

different ends of the spectrum; the former protecting medical decision making, and the latter purporting to recognise the importance of patient autonomy.

In the present study, the solicitor who acted for claimants put forward a strong argument for adopting an objective approach to judge the adequacy of disclosure based on the reasonable patient standard. This is in line with a move away from paternalism within the law. Amidst the on-going debate over the 'two' standards, there is a major problem. This is highlighted by Maclean, and is confirmed at various points in the empirical findings of this study.<sup>30</sup> The significance that patients attach to risks and the extent to which they wish to be informed is inherently subjective. The concept of informed consent is relative to the patient and thus if the law approaches this issue using the reasonable patient standard, it attempts to answer a subjective question objectively. Kennedy and Grubb confirm the dangers with this suggesting that the courts may often become embroiled in an objective examination of reasonableness and miss the bigger picture concerning the patient as an individual.<sup>31</sup> Whilst there has been a recent proposition that empirical research can be used to 'give the reasonable patient a voice', any kind of methodology which attempts to reach a consensus on what information the reasonable patient requires is simply inconsistent with what it presupposes.<sup>32</sup> It will never provide an answer to what will always remain a subjective question.

Most of the legal analysis in England has concentrated on which test; *either/or*. Too little consideration has been given to the implementation of a third standard. This is a test which contains a subjective element allowing for some

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<sup>29</sup> See 2.1.9 in the Literature Review for discussion of how the courts are perhaps developing a hierarchy of 'rights' where the right to be informed is taking precedent over the right to correct treatment and diagnosis.

<sup>30</sup> Maclean, A. "Giving the Reasonable Patient A Voice: Information Disclosure and the Relevance of Empirical Evidence" (2005) 7 *Med L Int* 1 at 12.

<sup>31</sup> Kennedy, I. & Grubb, A. *Medical Law* Third Edition (London: Butterworths, 2000) at 680.

consideration of the individual circumstances of patients.<sup>33</sup> If operating in isolation this is problematic and considerations such as self-serving testimony and hindsight reasoning have, in all probability, led to this option receiving little attention.<sup>34</sup> The researcher submits that the third standard need not operate as a purely subjective test. It just has to have *scope* for a subjective element. This is not a completely new idea. For example, this standard seems to have been applied in the Australian case of *Rogers v Whitaker*.<sup>35</sup> Here it was suggested in the joint judgment that:

'A risk is material if in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it *or* if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.'<sup>36</sup>

There appears to be some academic disagreement as to whether this approach actually provides a 'specific' subjective element. For example, Chalmers and Schwartz suggest the test is merely an amalgam. The rule remains predominantly objective but allows room to consider certain subjective elements.<sup>37</sup> This is slightly different from saying that the rule provides a *specific* subjective component. Yet, some academics argue this does actually exist. Kennedy and Grubb, approaching the issue from a different perspective, suggest it depends on the reading of the word '*or*' in the above quotation as to whether or not the *Rogers* test can be interpreted as incorporating a subjective element. For example, an alternative interpretation could be that the court merely

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<sup>32</sup> See Maclean, *op cit* n 30.

<sup>33</sup> Kennedy and Grubb, *op cit* n 31 at 680.

<sup>34</sup> See discussion by Lord Scarman in *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 at 888. Here he clearly rejects the particular patient test for these very reasons.

<sup>35</sup> *Rogers v Whitaker* (1992) 109 ALR 625 (High Court of Australia).

<sup>36</sup> *ibid* at 630-631.

<sup>37</sup> See, for example, Chalmers, D. & Schwartz, R. "Rogers v Whitaker and Informed Consent in Australia: A Fair Dinkum Duty of Disclosure" (1993) 1 Med L Rev 139 at 150 fn 43. In this sense the blending of an objective/subjective approach would not be dissimilar to test used for establishing causation. See, for example, the first instance decision in *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med LR 285 at 289. However, the test here works the opposite way round. Whilst, in relation to causation, the subjective position of the patient is considered first and then measured against an objective criterion. Here, the objective element is considered first and is then weighed against the subjective position of the patient.

stated the reasonable patient test in an alternative form.<sup>38</sup> Manning indicates otherwise though in suggesting 'it is by virtue of the second limb of the *Rogers* test that the individual claimants in both *Rogers* and *Chappel v Hart*<sup>39</sup> were ultimately successful.<sup>40</sup> On this interpretation, which is one the current author agrees with, the test is clearly divisible into two parts and does provide a *specific* subjective component thereby reinforcing the true right of autonomy. Given that academic opinion suggests the English decision in *Pearce* is similar to *Rogers*, before going on to argue why it is so important that English law incorporates a subjective element into its standard of care, it is first essential to analyse whether *Pearce* itself allows for any consideration of this.

There is also academic disagreement over the precise nature of the decision in *Pearce*. Kennedy and Grubb suggest 'the formulation in *Pearce* is indistinguishable in substance' from the decision of the Australian High Court.'<sup>41</sup> Lord Woolf MR in *Pearce* did not explicitly refer to *Rogers*.<sup>42</sup> Yet, this endorsement of *Pearce* seems to have gained support from other academics.<sup>43</sup> Kennedy and Grubb further intimate that in looking to set the standard of disclosure, the courts will look to the needs of the reasonable patient in the setting of the actual patient.<sup>44</sup> On this formulation it appears *Pearce* is similar to Chalmers and Schwartz's amalgam theory used to describe the approach in *Rogers*.<sup>45</sup> With this in mind, a fair degree of creative interpretation is needed before one can say there is *specific* scope to consider the needs of the

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<sup>38</sup> Kennedy and Grubb, *op cit* n 31 at 700.

<sup>39</sup> [1998] HCA 55.

<sup>40</sup> Manning, J. "Informed Consent to Medical Treatment: The Common Law and New Zealand's Code of Patients' Rights" (2004) 12 Med L Rev 181 at 193.

<sup>41</sup> Kennedy and Grubb, *op cit* n 31 at 709.

<sup>42</sup> Lord Woolf MR (in *Pearce*, *op cit* n 25) attempted to fuse *Bolam* with the two House of Lord's decisions of *Sidaway* and *Bolitho* (at 122-125). *Rogers* was not specifically relied upon in *Pearce*, but may have had some indirect influence on the decision. For discussion see Heywood, *op cit* n 27 at 266.

<sup>43</sup> See, for example, Brazier, M. & Miola, J. "Bye Bye *Bolam*: A Medical Litigation Revolution" (2000) 8 Med L Rev 85 at 110.

<sup>44</sup> Kennedy and Grubb, *op cit* n 31 at 709.

particular patient. It appears Kennedy and Grubb recognise this in light of their later assertion that the Australian High Court appeared to go one step further than the English Court of Appeal in introducing the terminology of the 'particular patient.'<sup>46</sup> This is supported by Skegg who notes the omission of the subjective limb of the test may not affect the outcome of many cases as:

'Some instances which would fall within the 'particular patient' limb can be brought within the reasonable patient/consumer' category, once emphasis is placed on the reasonable person, in the circumstances in question.'<sup>47</sup>

Thus, it seems there is a difference between the *Rogers* and *Pearce*. As it stands, the latter does not directly allow for any consideration of the needs of the actual patient. However, based on Skegg's assertion, there does seem to be some consensus that over time, and with a degree of judicial pragmatism, this difference could be slowly eroded. Whilst undoubtedly it would be encouraging if the courts showed signs of doing this, one criticism can be made of this approach. Whenever arguments are advanced for modifying the standard of care to give true effect to the right the law is trying to protect, the courts (and seemingly some commentators<sup>48</sup>) often hide behind the justification that the standard remains one of negligence in the *circumstances*. The *circumstances* component provides the mechanism by which the courts can look to the surrounding context and, to some extent, the individual circumstances of each case.<sup>49</sup> This can become a worthless and undermined component if, in reality, the

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<sup>45</sup> See Chalmers & Schwartz, *op cit* n 37.

<sup>46</sup> Kennedy and Grubb, *op cit* n 31 at 709.

<sup>47</sup> Skegg, P. "Informed Consent" 3rd Annual BIIA Medical Law Conference. December 2001 in Manning *op cit* n 40 at 193.

<sup>48</sup> See Skegg, *ibid*. In addition there is an on-going debate as to whether negligence in the *circumstances* is the appropriate standard of care for negligently inflicted sporting injuries. For discussion see McArdle, D. "The Enduring Legacy of Reckless Disregard" 34 CLWR 316. He argues in favour of negligence in the circumstances. However, Charlish suggests this is an inappropriate standard as the courts pay little attention to the *circumstances* component. See Charlish, P. "A Reckless Approach to Negligence" (2004) 4 JPIL 291.

<sup>49</sup> Particularly in the context of how Lord Woolf MR in *Pearce* (*op cit* n 25 at 125) suggests a doctor ought to determine a significant risk. 'the doctor...has to take into account all the relevant considerations, which include the ability of the patient to comprehend what he has to say to him or her

courts give it little attention. Unfortunately this seems to be particularly true in relation to information disclosure cases. To give a classic example, Maclean, commenting on the decision in *Pearce*, suggests that there may well have been a different outcome if the courts had asked the question 'would the reasonable person, pregnant, post term and concerned to deliver a healthy baby, find the risk significant.'<sup>50</sup> Since *Pearce* there has been a mixed reaction from the courts in respect of cases where the standard of care has been an active issue.<sup>51</sup> Thus, it is with interest one should view the recent decision emanating from the Court of Appeal where there is evidence that the courts seem more inclined to consider the position of the particular patient. In *Wyatt v Curtis*<sup>52</sup> Sedley L.J. seemed prepared to place emphasis on the individual patient's perception of the risk in holding it was grave and substantial and thus ought to have been disclosed. However, whilst *Pearce* is on the way, it falls one step short and has not quite got us where we need to be. The law needs to introduce a standard of care which provides specific scope for taking into account the wants and needs of the particular patient. As has been noted, this argument is not proposing a completely new standard of care. The law could operate in much the same way as *Rogers*, remaining predominantly objective. The empirical findings in both the health care professionals in secondary care and the patients' study do provide evidence and justifications as to why a specific subjective element ought

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and the state of the patient at the particular time, both from a physical point of view and an emotional point of view.'

<sup>50</sup> Maclean, A. "The Doctrine of Informed Consent: Does it Exist and has it Crossed the Atlantic?" (2004) LS 386 at 409. However, Maclean points out that one of the anonymous reviewers of his article suggested that judgment is required as to what to disclose. This is supported by the current author. See Heywood, *op cit* n 18. In response, Maclean suggests the central issue is how that judgment is exercised and by whom. If it is left mainly to the doctors, the legal standard becomes 'a doctor must disclose those risks that the *reasonable doctor* believes the *reasonable patient* ought to find significant to a decision.' See Maclean, *infra* n 63 at 214. This is perhaps why Maclean (*op cit* n 30) asserts *Pearce* lies somewhere between *Bolam* and the prudent patient standard.

<sup>51</sup> In the case of *Burke v Leeds Health Authority* [2001] EWCA CIV 51; (Unreported elsewhere) it was suggested that *Bolam* is far from dead and buried. Lord Justice Schiemann stated (at para. 32), 'Clearly what a doctor must tell his patient or his parents at what point and with what force are matters of clinical judgment for the doctor.'

to be incorporated into the standard of care when dealing with information disclosure.<sup>53</sup> It is contended that it does not go beyond the requirement of reasonableness in negligence to expect doctors to take reasonable steps to investigate any special circumstances which may be of concern to individual patients that may cause risks to become significant when ordinarily they would not be.

Critics of this approach will immediately point to the fact that the law of negligence is based around an objective assessment of what is reasonable in the circumstances. Thus, why should the standard of care be modified when similar proposals have been rejected in other fields?<sup>54</sup> This is a strong argument. It is submitted that it is the nature of the right of autonomy and patient self-determination that provides the justification for moderating the standard of care. The competent patient's right to decide what is done with their own body is afforded a great deal of protection in contemporary society, both legally and medically.<sup>55</sup>

Perhaps the real reason why the subjective approach has received little support may be floodgate arguments.<sup>56</sup> Theoretically it would make it easier for claimants to win and thus litigation levels may increase. In response to this, firstly, this study provides evidence that we are not living in a compensation culture; patients seem

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<sup>52</sup> *op cit* n 26.

<sup>53</sup> See 10.8.9 where the health care professionals in secondary care stress how important it is to consider the subjective position of the patient in terms of information disclosure.

<sup>54</sup> For example, it has been argued that when considering negligently inflicted sporting injuries the ordinary standard of care ought to be modified to a more stringent test for establishing a breach of duty based around a standard of 'reckless disregard.' See *Wooldridge v Sumner* [1963] 2 QB 43. However, this submission has been rejected as it was said negligence is an objective standard in the circumstances. See *Condon v Basi* [1985] 1 WLR 866 and *Caldwell v Maguire and Fitzgerald* [2001] EWCA Civ 1054; [2002] PIQR P6. The difference here is of course the argument is in reverse. Reckless disregard is a *lower* standard of care with a *higher* threshold for liability; introducing a subjective element into the duty of disclosure imposes a *higher* standard of care with a *lower* threshold for establishing liability.

<sup>55</sup> It appears the courts are now, whether intentionally or otherwise, affording greater significance to the right of patient autonomy. As a result of the decision in *Chester* (*op cit* n28) are we now seeing a hierarchy or rights developing whereby autonomy is at the top of the list? See 2.1.9 in the Literature Review for discussion.

<sup>56</sup> See discussion by Lord Scarman in *Sidaway*, *op cit* n 34 at 887 pertaining to defensive medicine and the potential litigation crisis. As a result, see further rejection of the particular patient test at 888.

willing only to sue as a last resort.<sup>57</sup> Secondly, there is evidence the implementation of the proposed test would not have this effect; the law would probably operate in much the same way.<sup>58</sup> The subjective component would only function under the rarest of circumstances; nonetheless, for the reasons offered above, it remains desirable.

Amidst this criticism, the faultfinders and the worried clinicians should not ignore one important fact. If a subjective element were to be introduced within the standard of care, it would not only allow the courts to consider what would be significant to the individual patient, but also what was not significant to that particular patient and thus what they might not have wanted to hear. This would allow scope for maintaining and recognising that discretion still plays a part in disclosure without having to rely specifically on the therapeutic privilege as a justification for withholding certain information from patients. (See section 3.1.8 in the Literature Review 2 for discussion). Finally, and to conclude the argument, if the stringent rules of causation can be manipulated in order to give effect to the patient's right to decide, arguably there is no cogent reason why the standard of care cannot be alerted in the same way.<sup>59</sup>

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<sup>57</sup> See 11.8.5 for further discussion.

<sup>58</sup> This is supported by various other pieces of empirical evidence which suggest litigation levels do not alter dramatically upon altering a 'different' standard of care. See, for example, Robertson, *op cit* n 12. In the following ten years since the decision in *Reibl* there were only 117 cases involved informed consent and over half of these were unreported. Moreover, the claimant failed in his or her action in 82 per cent of cases where breach of duty was relied upon. See also figures by Addison demonstrating the effect of the reasonable patient standard in Australia. Addison, T. "Negligent Failure to Inform: Developments in the Law Since *Rogers v Whitaker* (2003) 11 *Torts LJ* 165.

<sup>59</sup> See *Chester v Afshar*, *op cit* n 28. It is possible that the modified test for causation, combined with a subjective element to the standard of care, would increase the number of successful claims. However,

### 13.17.3 **Theme 4: Moving Away from Paternalism: Closer Scrutiny of Bolitho**

The decision in *Bolitho*<sup>60</sup> has received acclaim from legal scholars as the missing link in clinical negligence actions which has served to restore *Bolam* to its original limits.<sup>61</sup> Whether or not this is a true movement away from the judicial acceptance of medical paternalism is disputed.<sup>62</sup> Theoretically speaking, the decision should make it easier for claimants to succeed in actions against the medical profession. Practically speaking, there is evidence it has had little effect because the practical barriers to successful litigation continue to exist.<sup>63</sup> The judicial reasoning in the case itself is not without fault. The judgment sets forth a condition that before medical practice can be accepted, the courts must be satisfied that it is supported by 'responsible body' of medical opinion. If the body in question does not live up to this standard the courts are entitled to reject that opinion. The problem with this is neatly identified by one of the solicitors in this study. The courts talk about subjecting medical decision making to logical scrutiny. Yet, they have been vague in defining the criteria against which this scrutiny can be exercised. In support of this, the solicitor in question, who actually represented Patrick Bolitho, provided documentary evidence of a submission made by his firm to Lord Browne-Wilkinson outlining what they felt the test ought to include. This is contained in the appendices of this thesis.<sup>64</sup> The suggestion is that in order for the test in *Bolitho* to retain any meaningful content, the courts must be allowed to engage in an independent evaluation of the medical decision making. This would typically take place where there is some concern as to whether the reasons put

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there is no conclusive evidence either way that this would happen, and even less proof that it would cause a litigation crisis.

<sup>60</sup> *op cit* n 24.

<sup>61</sup> See, for example, Feenan, D. "Beyond Bolam: Responding to the Patient" (1994) 1 Med L Int 177; Brazier and Miola, *op cit* n 43.

<sup>62</sup> The decision is criticised by Glover, N. "*Bolam* in the House of Lords" (1999) 15 PN 42.

<sup>63</sup> See Maclean, A. "Beyond *Bolam* and *Bolitho*" (2002) 5 Med L Int 205.

<sup>64</sup> See appendix [6].

forward for exposing the patient to a given risk are sufficient to justify that risk in the circumstances. This in isolation is fine, *Bolitho* as it stands allows the courts scope to do this. Lord Browne-Wilkinson in *Bolitho* touched on the risk/benefit analysis, but not to any great extent.<sup>65</sup> However, what he did not do, and what the solicitor's submission goes on to argue, is that there ought to be specific criteria provided against which the courts can measure the acceptability of medical practice. The most important of these criteria provides that where there is evidence of what would otherwise be two accepted practices, the courts should be entitled to prefer the view which exposes the patient to the least risk in the circumstances.<sup>66</sup> Initially this seems like an attractive proposition. However, on closer inspection it becomes problematic. This is due to the delicate nature of medical decision making. In a recent address to the Medico-Legal society, Badenoch suggest he would re-write Lord Scarman's dictum in *Maynard*<sup>67</sup> as follows:

'In the realm of diagnosis and treatment, negligence may be established by preferring one respectable body of opinion to another...because, while the body of medical men may be responsible and respectable, it is possible that their practices or their opinions, judged objectively, are not. For there will be occasions, which the judge must be ready to identify, when two opposing contentions cannot both be right.'<sup>68</sup>

It is submitted that this is perhaps going too far. The hazards associated with this are illustrated later in the same paper where it is highlighted that on some occasions there is a division of opinion. The example cited is in relation to the treatment of a subarachnoid bleed in the head. Some hospitals may move in and try to clip the bleed immediately, whereas others may delay invasive surgery for a number of days as they believe the risk of a second bleed is less than the dangers of invasive surgery for this

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<sup>65</sup> *Bolitho*, *op cit* n 24 at 243. Lord Browne-Wilkinson suggested that the relative risks and benefits ought reasonably to have been weighed by the experts in forming their opinions.

<sup>66</sup> See appendix [6].

<sup>67</sup> *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634 at 639.

particular condition.<sup>69</sup> Two points are evident here. First, there is an inherent danger in asking a judge to resolve an argument that has defeated neurosurgeons for almost thirty years. Badenoch himself acknowledges that it is inappropriate to ask judges to arbitrate between insoluble medical problems which great experts on each side say with equal force should be dealt with in different ways.<sup>70</sup> Second, is it fair to say that just because one course of action poses a greater risk than the other that the doctor is automatically negligent as per the suggestion by the participant in this study? It is very difficult to sustain this argument, particularly if the potential benefit conferred by the riskier option is far greater than the 'less risky' option. This standard of care would be unworkable in practice.

It is not a matter of preferring one body of respectable opinion to another, it is a matter of careful judicial scrutiny in order to assess whether or not the medical opinion in question passes the threshold for being 'responsible.' This can only be achieved by undertaking a thorough analysis of the risk/benefit ratio. In actual fact it seems Sachs L.J. may have got this right as early as 1968. In *Hucks v Cole* he said:

'Where the evidence shows that a lacuna in professional practice exists by which risks of grave danger are knowingly taken, then however small the risk the courts must anxiously examine that lacuna, particularly if the risk can be easily and inexpensively avoided. If the court finds on an analysis of the reasons given for not taking those precautions that in the light of current professional knowledge there is no proper basis for the lacuna, and that it is definitely not reasonable that those risks should have been taken, its [that is the court's] function is to state that fact, and where necessary to state that it constitutes negligence.'<sup>71</sup>

Perhaps a good working example of this is again taken from Badenoch's address to the Medico-Legal Society. He cites an example of the difference in medical opinion concerning how to protect the lower part of the body when clamping the aorta. Some

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<sup>68</sup> Badenoch, J. "Brushes With Bolam. Where Will it Lead?" (2004) 72 *Medico-Legal Journal* 127 at 136.

<sup>69</sup> *ibid* at 137.

<sup>70</sup> *ibid*.

techniques involve grafting and cooling, others rely simply on the speed of their hands. Both options carry with them comparable risks and benefits. Despite this, the 'safer' option would be to take precautions and cool the patient. Badenoch explains how, if the surgeon relies purely on hand speed and something untoward happens, the courts ought to be entitled to reject the body of opinion which supports this. Despite the fact that any number of eminent, distinguished and experienced men may be prepared to approve and endorse doing nothing when you clamp the biggest blood vessel in the body, it is not logical to say that you do not need to take any adjuvant measures to protect the patient when the aorta is being clamped for an unknown period of time, and the precautionary measures are cheap and relatively simple to take.<sup>72</sup>

Thus, where the courts are faced with two contrasting medical opinions, and one of these opinions exposes the patient to risks which are disproportionate to the benefits conferred, or where there are relatively few benefits at all, then the courts should be entitled to reject this evidence by saying 'this particular practice is not what we consider responsible in the circumstances.' Clearly had this test been applied in *Bolitho* the outcome would have been different.

Does this go against the traditional common law principle that the courts are not allowed to prefer one body of medical opinion to another?<sup>73</sup> It does not. The argument can be maintained as long as it is recognised that the courts do not prefer one 'responsible' body of opinion over another. The body of medical opinion which subjects the patient to any practice which has a clear disproportionate risk/benefit ratio would fail to withstand the logical scrutiny of the courts, thereby rendering it

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<sup>71</sup> *Hucks v Cole* (1968) [1993] 4 Med LR 393 at 397.

<sup>72</sup> Badenoch, *op cit* n 68 at 141.

<sup>73</sup> *Maynard*, *op cit* n 67.

incapable as being accepted as a 'responsible' body of medical opinion.<sup>74</sup> This approach would represent a definite movement away from paternalism by opening up new avenues for claimants by allowing the courts greater scrutiny of medical decision making. On the facts *Bolitho* was decided wrongly. Nevertheless, the judicial reasoning in the case is perhaps more accurate than one initially envisages, but it only works if the courts *are* prepared to scrutinise medical opinion rather than just saying they will. It is time for action instead of just words.

#### **13.17.4 Theme 5: Reform: Consent Beyond the Courts**

##### **Enhancing Awareness of the Law**

Perhaps the best way to improve the consent process, as suggested by the solicitors, is to enhance medical practitioners' awareness of the law. There are, of course, two sides to this argument. Enhancing medical practitioners' knowledge of the law may negate its intended purpose if it becomes evident, as it would do to most, that the law is very much on their side. For instance, if one were to educate clinicians about the Human Rights Act 1998 and how it operates, they will soon realise its threat is more theoretical than it is real, thereby reducing its symbolic effect. Add to this the common argument that medical practitioners do not have enough time to engage in legal training, there is likely to be resistance to enhancing clinicians' awareness of the law.<sup>75</sup> The findings in this study indicate otherwise. The clinicians intimate a desire for more extensive legal training seemingly recognising that even though the law is not their discipline, knowledge of the enduring issues is essential to maintaining the effective discharge of their duties. The main bone of contention seems to be exactly when this training should take place. Ideally speaking this training ought to be

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<sup>74</sup> Teff touches on this point relating to identifying a 'responsible' body of medical opinion and testing credibility. See Teff, H. "The Standard of Care in Medical Negligence - Moving on from *Bolam*?" (1998) 18 OJLS 473 at 476-477.

ongoing. Yet, the quantitative section of this thesis illustrates the difficulties with trying to fit any type of legal training into an already detailed and crowded undergraduate syllabus.<sup>76</sup> Perhaps the most appropriate way to deal with this is to adopt what the defendant solicitor in this study suggests. Training could take place as a part of the continuing professional development of Senior House Officers and Registrars; it was indicated by the clinicians that this is the stage when consent issues begin to feature in their daily practice. Solicitors' firms ought to be encouraged to offer their services to the NHS, and in turn both the primary and secondary care trusts should work in partnership with these firms to encourage the provision of legal training for clinicians. This way the two professions need no longer be viewed as being diametrically opposed with the legal profession being perceived as protectors of autonomy and the medical profession being viewed as staunch supporters of paternalism. Developing knowledge and awareness of the law amongst medical practitioners is a method of enhancing consent which allows both the law and medicine to exist in harmony.<sup>77</sup> The advantage is that medical practitioners need no longer fear the law; not only will they become aware of what they *have* to do, but will also realise what they do *not have to*. This is important as it allows scope for the development and maintenance of clinical discretion, something which this thesis considers important.

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<sup>75</sup> For discussion see Halliday, *op cit* n 2 at 59.

<sup>76</sup> See section 6.10.5.2.

<sup>77</sup> However, it is extremely important to ensure any legal training does not become lost in the large organisational structures of the NHS. This could be prevented by aiming the training directly at practising health care professionals and by ensuring CPD training is delivered by 'outside' firms. For discussion of how legal knowledge can be impaired by large organisational structures and the problems of how to feed this knowledge into decision-making processes see Halliday, *op cit* n 2 at 48-49.

## The Symbolic Effect of the Human Rights Act

The effect of the Human Rights Act on consent and information disclosure is symbolic. The Act has no direct impact and is unable to explicitly influence the development of domestic law.<sup>78</sup> Whilst it is impossible to say with any certainty that its implementation has brought about a change in attitude from both the domestic courts and the medical profession, the *perception* of the Act itself may have provided some indirect influence towards encouraging greater respect for patients' rights. There is a great deal of social stigma attached to Human Rights. Arguably this has led to a greater awareness amongst the medical profession, and the emphasis has switched towards recognising the importance of 'patient rights', one of these of course being patient autonomy. A classic example of this is to be found in the guidelines produced by the medical profession. These are in advance of what the law requires and may have been constructed with patient rights in mind.<sup>79</sup>

Thus, as the defendant solicitor in this study suggests, educating health care professionals about Human Rights would be beneficial, as would disseminating further information about the legislation. Increasing the publicity surrounding the Act may serve to play up the importance of respecting the patient's right to be involved in their health care decisions and their right to receive information prior to treatment.

Likewise, awareness of the Human Rights Act amongst the judiciary may also have led to an increased willingness to respect patient rights. For example, it appears the courts have demonstrated a new found respect for autonomy based on the decision

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<sup>78</sup> See discussion in section 2.1.10 in the Literature Review of this thesis. See also, Plomer, A. "Medical Research, Consent and the European Convention on Human Rights and Biomedicine" in Garwood-Gowers, A., Tingle, J., Lewis, T. *Healthcare Law: The Impact of the Human Rights Act 1998* (London: Cavendish, 2001) at 314.

in *Chester*.<sup>80</sup> It is possible this recognition may well have been influenced by the Human Rights Act. This may, in turn, provide evidence that the courts are now more willing to depart from the paternalistic acceptance of medical-decision making which has been a historical trait of the law.

### Departing from the Law: Professional Guidelines and Charters of Medical Care

The debate over no fault compensation is on-going.<sup>81</sup> It would undoubtedly have its advantages and would operate more favourably for aggrieved patients. However, it also has drawbacks which, it is submitted, outweigh the benefits. In all probability this will prevent the system from ever being implemented in England.<sup>82</sup>

There needs to be some consideration given to other non-legal ways to improve and enforce patient rights. Firstly, there is the recent development of professional guidelines in respect of consent. These can assist the courts and can be used to indirectly set new standards amongst clinicians in terms of enhanced disclosure. Secondly, a way to develop consent would be to look beyond the courts in implementing a 'Patient's Charter of Good Medical Care.' This could be accomplished with input from clinicians, lawyers and patients. Here emphasis could be placed on informed consent and information disclosure. The benefit of a Charter of Good Medical Care in respect of consent is that, despite input from all parties, it would be predominantly aimed at patients as opposed to clinicians. This would spell out the importance of consent by providing a number of clear expectations that patients should anticipate in respect of consent and information disclosure. This

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<sup>79</sup> See, "Seeking Patient's Consent: The Ethical Considerations" (London: GMC, 1998); "Good Practice in Consent Implementation Guide: Consent to Examination or Treatment" (London: DoH Circular, 2001).

<sup>80</sup> *op cit* n 28.

<sup>81</sup> See, for example, Ham, C., Fenn, P. & Harris, D. *Medical Negligence: Compensation and Accountability* (1998) in Kennedy & Grubb, *op cit* n 31. In particular see the cost/benefit analysis provided at 548 and 549.

would go some way towards finding a solution to the problems identified in the patients' findings, that they simply do not fully understand what the consent process is all about. In addition, it could explain the law so they can recognise where they may have a valid legal claim and where they would simply be wasting their time.

These schemes will probably never fully replace the law of tort as a method of compensating patients. However, they can operate alongside it, being used to assist in determining whether or not a breach has in fact taken place and gradually, over time, these could be used to effect a culture change by stressing the importance of informed consent to all the parties involved in the process.

### The NHS Redress Bill

It is beyond the scope of this thesis to provide a detailed discussion of the proposed NHS Redress Bill. However, a brief summary is necessary in order to highlight its potential benefits and drawbacks in relation to information disclosure cases.

The Bill seems to be a knee-jerk reaction to the Department of Health's consultation report *Making Amends* in 2003.<sup>82</sup> The Bill proposes a scheme of redress for patients harmed as a result of 'seriously substandard' NHS hospital care. Whilst it does not mention specific figures, it seems any measures introduced would be limited to low-value claims capped within the region of £20,000. The scheme provides for the awarding of compensation and giving explanations of what went wrong. If the patient settles under the scheme they must waive their right to future legal action and the limitation period would be suspended until the NHS redress is complete.

NHS redress will undoubtedly provide an easier means of obtaining compensation for patients whose claim does not exceed £20,000. This, coupled with

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<sup>82</sup> *ibid.*

<sup>83</sup> Chief Medical Officer. *Making Amends: Proposals for Reforming the Approach to Clinical Negligence in the NHS* (London: Department of Health, 2003).

the other advantages of reduction in delays and legal costs, makes the redress scheme *prima facie* a desirable prospect. Perhaps the most notable benefit is the obligation to provide the patient with information about what went wrong. This may encourage a culture of honesty and openness in the NHS which it would seem patients welcome.<sup>84</sup> Thus, the overall number of complaints within the NHS may well be reduced, although it has already been suggested that this problem is perhaps exaggerated. Yet, as Jones points out, 'an explanation or apology does not constitute an admission of liability.'<sup>85</sup> As long as NHS redress is underpinned by a finding of clinical negligence, an explanation and apology will not guarantee compensation and may end up as nothing more than a symbolic gesture. Likewise, any notion that the proposed scheme will move us away from a 'blame culture' is deeply contentious given that someone will still need to be held to account for the negligence that has taken place.

In all probability, the NHS redress scheme will have little effect on information disclosure cases. Whilst it may make it easier for claimants to succeed in obtaining compensation, it has been demonstrated that complaints and actual litigation in this field are minimal. The downside to the Bill is that any scheme of redress such as the one proposed does not carry the same symbolic and prescriptive force of the courts. Thus, it may reduce the overall perceived threat of the law and do little to contribute towards improving consent procedures in clinical practice via its powers of deterrent.

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<sup>84</sup> See sections 11.8.5 and 11.8.7 for further discussion.

<sup>85</sup> Jones, *op cit* n 9 at 188.

## **14 REFLEXIVITY: CONCLUDING THOUGHTS OF THE THESIS**

### **14.1 Researcher's Note**

In keeping with the hermeneutical reflective philosophy underpinning this thesis, as opposed to writing a traditional conclusion, I felt it was more appropriate to construct a reflective chapter to close this study. This attempts to consider all the views and opinions provided by the participants and reconcile these with my own thoughts as a researcher. In this way, I can chart how my views have changed and how, if indeed at all, a renewed understanding of informed consent has been developed. As such, this chapter will be written in the first person.

### **14.2 The Study: Providing the Answers?**

When writing the concluding thoughts of this thesis, it was important to reflect upon whether the study accomplished what I initially set out to achieve. To answer this I gave my mind to three questions:

1. Does this study provide valuable knowledge about informed consent beyond the courts? Does it answer the initial question posed by Professor Jones<sup>1</sup> which provided the inspiration upon which this research was based?
2. Does this work provide a clear understanding of the difficulties faced by those who are actively involved in the consent process and does it provide any solutions to these problems?
3. What do the findings demonstrate about the views, opinions and feelings of the different parties involved in the consent process and how have these views shaped my initial understanding as a researcher? What conclusions could be drawn about the law of consent based on my reflections?

The first two questions were answered with relative ease. This research offered an examination of consent beyond the courts. It presented empirical findings that analysed the operation of consent in practice from the points of view of those individuals who were actively involved in the process. The study identified the problems faced by the different participants and made a number of suggestions as to how these could be remedied.<sup>2</sup> However, it was the third question which was perhaps a little more difficult to address. This provides the focus for the remainder of this chapter.

### **14.3 Informed Consent: An Unreachable Consensus of Opinion**

There was no general consensus of opinion relating to informed consent. Indeed, any attempt to reach this would be inconsistent with what is presupposes. There was some agreement between the different sets of participants. Yet, ultimately, the opinion one holds about informed consent depends very much on the angle that you approach it from. From my point of view, I initially saw consent from a purely legalistic standpoint, as an issue that was shrouded with academic uncertainty, providing the forum for intellectual debate. This was different from the views held by the practising solicitors who were interviewed in this study. They demonstrated the practical problems faced by themselves as practitioners, and also highlighted the difficulties faced by their clients as a result of the law and the way it operates in practice.

In addition, there were the many views expressed by health care professionals. These were a combination of opinions from individuals operating at different levels and within different areas of practice with the NHS. The feelings tended to highlight the difficulties they face in practice and their focus was often on the dynamics of the

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<sup>1</sup> Jones, M. "Informed Consent and Other Fairy Stories" (1999) 7 Med L Rev 103 at 123.

consent process in clinical settings. Whilst there was some agreement between the various health care professionals, there was also some difference of opinion as and between different grades of clinicians. A classic example of this is the way in which nurses saw the importance of their role in consent as being different from that of consultants.

In contrast, there were the opinions expressed by medical students in the questionnaire study whose views on consent were understandably different from those medical practitioners who had experience of dealing with consent issues in practice. Finally, there were the beliefs held by the patients. These again illustrated the differences between what they saw as important in consent compared to what the law seeks to protect. These were very different from the initial views held by myself and they uncovered a number of points that were quite distinct from the law. These included such things as the importance of communication and honesty and a general unwillingness to complain. It is now necessary to discuss how I saw my own views change over the course of the research as a result of my ongoing reflections, and ultimately what conclusions can be drawn from the study.

#### **14.4 Myself as Situated in the Research**

One of the most interesting aspects of this work was the logical progression of the study. Theoretical questions were constructed in the literature review, from here the project developed into an investigation of the feelings and opinions of those involved in practice, into an actual examination of practice. Thus, in my eyes, the study almost went full-circle. As this progressed my own views changed as my knowledge increased. A common question I asked myself is how did I see myself operating as part of this research and what effect, if any, did my presence have on the work?

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<sup>2</sup> See the following chapter for future recommendations and protocols.

From the outset it is worth noting that I did perceive myself as having an active role in the investigation. I never considered myself as a 'disinterested observer.' As such, there were elements of this work that were subjective; I openly acknowledge this.

My overall impression is that I was party to an honest appraisal of consent in practice in terms of both the feelings and views expressed in the interviews, and also the observations. I felt the majority of the participants were genuine in terms of their opinions and did not try to hide anything or mislead me; they also tried their best to open up. In turn, I was honest with them and when they asked me questions, or for my opinion, I gave it. This was conducive to a more productive set of qualitative studies. Inevitably, there were times where I might have used leading questions where interviews dried up, likewise there were probably occasions when the participants put their spin on things to an extent where they may have not been totally honest and perhaps told me what they thought I wanted to hear. I felt this was the case in relation to some of the views expressed in the primary care study. These occurrences were usually identified and, on reflection, they were appropriately accounted for thus preventing them having any detrimental effect on the research findings.

What was more interesting was the way in which my views changed as my knowledge accumulated and how this allowed me to modify some of the initial lines of inquiry. There were often times when participants would say to me 'have you thought about this?' or 'you might want to follow that up with other participants?' This I often did and, as a result, it was interesting to see how the interview schedules changed. Participants often raised issues that I would reflect on from a legal point of view. A classic example of this was found early in the study. I thought I would be able to ask the participants about their understanding of the law and how it operates. I quickly realised that this was inappropriate as neither patients nor clinicians had any

real understanding of the law. I came away from these early interviews realising that I would need to focus on issues that the participants could actually relate to, yet that were still capable of being reflected on in a legal context. This allowed me to chart a number of clear legal reflections within each component of the study.

### 14.5 Legal Reflections

The law itself has little direct effect on improving consent procedures in practice. If we are to say the intention of the law in this area is to promote patient empowerment and afford recognition to the importance of self-determination, it becomes clear that the law is failing to achieve its purpose. It can never be viewed as a proactive mechanism for protecting patients' rights. Firstly, it fails in its quest to compensate victims of medical misfortune; very few patients succeed in information disclosure cases and the numbers of claims are minimal. On one view this turns the law into almost an empty threat. Secondly, the legal rules are reactionary, springing into action only when something untoward happens. Nonetheless the law arguably does have some influence on consent in clinical practice insofar as it is prescriptive in nature and thus ought to provide some deterrent against poor consent procedures.

A further difficulty resides in the inappropriateness of the negligence action itself. Under existing tortious liability it may be relatively straightforward for a medical practitioner to escape liability if all that is required is a regimented disclosure of all risks, followed by a subsequent signature on a form. This may be a legally valid consent; it is not informed consent, and for all intents and purposes never will be.

One of the problems here may be linked to the way in which health care professionals *perceive* the law. There appears to be circumstances where the emphasis on obtaining informed consent via the medium of excessive risk disclosure exhausts the therapeutic benefits of the doctrine. Thus, it is essential that medical practitioners

should not interpret the law as eroding their clinical discretion to an extent where they feel backed into a corner with regard to what they tell a patient in terms of risk factors. The law recognises that discretion still plays a key role in modern medical practice and can (and should) be relied upon in some circumstances in order to protect the patient from unnecessary over-exposure.

Essentially what is needed in the context of information disclosure is a balance. A culture of openness and more extensive disclosure is desirable in medical practice; it seems this is recognised by a majority of the different participants in this thesis. However, on the other hand, health care professionals need to remain aware that the law does allow some clinical discretion in respect of information disclosure. This discretion needs to be exercised by considering carefully the circumstances of the individual patient and whether, in the opinion of the health care professionals, too much information would be detrimental to the patient's mental or physical health. If this is the case, disclosure in this context ought to be tailored accordingly. In actual fact, some of the health care professionals in this study imply that they still rely on clinical discretion in some circumstances, but it is becoming increasingly difficult to do so. Doctors need to be aware of situations where it is appropriate to invoke their discretion as to what to tell the patient and do so accordingly; likewise the law should not seek, nor be used as an excuse, to encourage defensive medical practice.

Finally, the common law's capacity for incremental development is restricted. Only very rarely do patients actually resort to legal action and any cases that are controversial or have a chance of success will inevitably be settled by the Medical Defence Unions for fear of creating a dangerous precedent. Recent developments in the common law have made some leeway into patient rights. In my opinion, there is only one more development needed in order for the law to have reached its limits in terms

of the protection it can afford via the prism of the negligence action. If the courts were to establish a subjective component to the current test for establishing a breach of duty then, combined with the liberal approach to causation, the law can do no more. Even if it were to adopt this measure it would still fall short of an effective mechanism for protecting the patient's right to self-determination. The strength of the law is bound up in its symbolic and prescriptive nature and its actual powers to improve consent in clinical settings are limited to this extent.

### **14.6 Informed Consent: A New Understanding Negotiated?**

What does the study tell us and how does this relate to a renewed understanding of informed consent? It appears that the patients in this study perceive the importance of receiving information prior to operations as being intrinsically linked to therapeutic benefits post-operatively. They see the information as a prerequisite for improving their coping mechanisms and healing time after surgical procedures. Often they failed to make the link between the consent process *per se* and the provision of information. Drawing on one of the points made above, it is evident the law is failing to achieve its purpose. The law seeks to protect self-determination, yet it seems patients focus less on this right and more on the therapeutic benefits of enhanced disclosure. The law is protecting a right that patients here are either unaware of, or are not concerned with. Many of the patients indicated that the consent process was a necessary part of their treatment, something they had to do in order to get better. In a similar fashion, whilst many of the clinicians talked about consent as being important as an ethical requirement grounded in the rights of the patient, I gained the distinct impression that they perceived the consent process as somewhat of an ancillary and functional component of their job. That is, a requirement that needs to be performed, the function of which is to get to the operative stage of treatment. On one interpretation,

and somewhat ironically, the patients and medical practitioners in this study view consent in almost the same way; as necessary. Hence the problem goes full circle and is self-perpetuating.

This led me to ponder a question that I had perhaps not originally given my mind to. The findings in this study, on the whole, suggest that both patients and health care professionals are happy with consent procedures. Patients seem happy with the information they receive and are glad to have the operation to get them better. In turn, medical practitioners feel they give an appropriate amount of information that allows them to get to where they want to be, in a position where the patient can give an adequate consent and they can then perform the operation. Thus, as food for thought, in the eyes of the people that actually count, the consent process may actually 'work.' Notwithstanding this, some general concluding thoughts are necessary to complete the thesis.

### **14.7 Concluding Thoughts of the Thesis**

This study does not provide all the answers to the problems surrounding the law and practice of informed consent. The methodology that underpins this work does have its limitations as highlighted at various points throughout this study. The most evident of these being that the study is extremely concentrated and relativistic. Yet, what it lacks in objectivity and representativeness, it makes up for in detail, depth and clarity. The study does tell us something, something that we would not have known had it not been carried out. It provides valuable knowledge about the different views and opinions held by the various parties, and goes some way towards suggesting a few *possible* solutions to these problems. More importantly, it confirms two things. Firstly, informed consent, as a concept, means different things to different people. The importance one attaches to the concept is affected as a result of this. It is

virtually impossible to achieve a 'fully informed consent' because, as a notion, consent is relative, both to the person obtaining it and the individual expressing it. The second point is implicitly linked to the first. An objective consensus of opinion will never be reached about informed consent and, as such, there is no *definite* solution to the problems identified in this study. What is certain is the law concerning information disclosure does not work insofar as compensating victims of medical misfortunes. In my opinion, if one thing is to be taken from this study it is this. The reality of the consent process is a far cry from the theoretical ideal of keeping the patient 'fully informed.' No matter which side of the line one falls in the information disclosure debate one thing is certain, in an ideal world the consent process should not be a one way transaction. It should be reciprocal in nature with dialogue ensuing from both physician and patient in order to negotiate a clearer understanding of both parties' intentions and objectives. This does not happen at present as both parties, for the most part, seem satisfied with the consent process. For this to alter, a change in culture and attitude is required, not only from medical practitioners, but also from patients. In my opinion, this demands that both parties take a step back to realise that consent is neither just a professional obligation nor a necessary step undertaken in order to reach the next stage.

Rob Heywood  
September 2005.

# 15 FUTURE RECOMMENDATIONS & PROTOCOLS

## 15.1 THE LAW

### 15.1.1 *The Standard of Care*

1. The specific standard of care in relation to information disclosure ought to be modified to include a subjective component. This is to allow for the nature of risk disclosure and the provision of information. Clearly this can only be considered in the context of patients as individuals. The current English approach should be modified to match the Australian approach in *Rogers*. [See p 385, section 13.17.2 for discussion - Solicitors' Study].
2. Within the general standard of care in medical negligence, judges ought to ensure, as per the ruling in *Bolitho*, that they do actually engage in a risk/benefit assessment of medical decision making. The practice has to follow the rhetoric and emphasis should be placed on the weighing of risks against benefits in order to decide what constitutes a 'responsible body of medical opinion.' [See p 393, section 13.17.3 for discussion - Solicitors' Study].
3. The professional guidelines emanating from the DoH and GMC should be used to assist the courts in developing a more coherent and certain standard of care providing a base-line criteria against which the adequacy of disclosure can be judged. [See p 291, section 10.17.7 for discussion - Health Care Professionals in Secondary Care Study].

### 15.1.2 *Causation*

1. The general rule for causation should operate in the same manner as it does already. The courts should ask the subjective question, "What would this patient have done in the circumstances?" However, this is measured against an objective criterion that allows the courts some freedom to balance the subjective component with what the reasonable person may have done in the circumstances. [See p 31 - 40, sections 2.1.8 and 2.1.9 for discussion - Literature Review 1].
2. The stringent test for causation should continue to be interpreted in a more liberal manner as in *Chester*. This makes it easier for claimants to establish and is more 'patient friendly' in practice. [See p 31 - 40, sections 2.1.8 and 2.1.9 for discussion - Literature Review 1].

### 15.1.3 *Articulating a Duty to Enhance Understanding*

1. The courts ought to pay more attention to the understanding component of informed consent. They need to make clearer the scope of the duty that is placed upon clinicians to 'take reasonable steps' to facilitate at least some level of understanding. Consideration needs to be given to the patient's ability to comprehend the information portrayed. This will include looking at the timing

and context in which the information is imparted, and the surrounding environment and personal circumstances of the patient. [See p 69, section 3.1.10 for discussion - Literature Review 2].

2. In considering the reasonable steps that can be taken to facilitate patient understanding, the courts should have regard for some of the examples of good practice discovered in this study. For example, attention ought to be given to doctors' methods of explaining treatment, the use of analogies, diagrams and the dissemination of effective written information about procedures. [See p 244 - 246, section 10.9.10 for discussion - Health Care Professionals in Secondary Care Study].

### ***15.1.4 Dissemination of the Law***

1. The law needs to provide more clarity in terms of consent and information disclosure. This is for all parties involved including medical practitioners, patients and practicing solicitors. This can be achieved by disseminating information leaflets charting recent develops in the law to hospitals, patient help groups and solicitors' practices. These leaflets should be written in non-technical language, should be concise, yet still provide a clear and accurate picture of the law. [See p 397, section 13.17.4 for discussion - Solicitors' Study].

## **15.2 CONSENT IN PRACTICE**

### ***15.2.1 Encouraging Patient Participation***

1. Medical practitioners need to encourage patient participation in the consent process. More time should be taken to explain fully the nature of the consent process and what it is truly about. That is, the patient's right to decide on a course of action in command of the necessary information. Consent should no longer be viewed as a 'functional' aspect of the clinician's job or a 'necessary' component of a patient's treatment. [See p 324 - 327; 332-335, sections 11.13.1, 11.13.2, 11.13.5 and 11.13.6 for discussion - Patients' Study].
2. Medical Practitioners should encourage open communication, should take the time to encourage patients to question them and should not frown on this. More time should be taken to encourage patients to familiarise themselves with their conditions and proposed treatments, by guiding them to useful and appropriate sources of information. [See p 288, section 10.17.5 for discussion - Health Care Professionals in Secondary Care Study].

### **15.2.2 Provision of Information**

1. Clinicians ought to provide patients with adequate, but not excessive information that is relevant to their treatment and condition. Whilst undoubtedly this should include information about risks, it should also include other information about benefits and alternatives. [See p 279 - 287, sections 10.17.2, 10.17.3 and 10.17.4 for discussion - Health Care Professionals in Secondary Care Study].
2. Clinicians ought to disclose alternatives to patients. They ought to be wary of making treatment decisions for patients justified on evidence-based practice and on the assumption of best interests. Particularly where there are different levels of risks for each available option. [See p 286 - 287, section 10.17.4 for discussion - Health Care Professionals in Secondary Care Study].
3. Clinicians ought to tailor the information provided to the needs of the individual patient. They should not allow the law to fetter the professional discretion and judgment and should not 'bombard' patients with risks. [See p 242, section 10.9.9 for discussion - Health Care Professionals in Secondary Care Study].
4. Medical practitioners should recognise that the patient can waive their right to informed consent. This is as much a part of their right to self-determination as the very provision of information itself. Legally speaking the waiver ought to be recognised. [See p 285, section 10.17.3 for discussion - Health Care Professionals in Secondary Care Study].

### **15.2.3 Consent as a Continuing Process**

1. Consent should not be viewed as on a one off process and in isolation. The procedure of information giving, explaining, and facilitating patient understanding should begin on the opening day of the patient's referral to outpatients and should continue right up to the point they are discharged. Effective communication should be maintained and encouraged throughout by the clinician. Consent should no longer be viewed as the mere signing of a form. [See p 290-291, section 10.17.6 for discussion - Health Care Professionals in Secondary Care Study].
2. Delegation in consent to junior doctors should be encouraged as long as they are appropriately supervised and have enough knowledge of the procedure in question. This is an invaluable teaching method as junior doctors do not have much opportunity in the training to practice and improve their consent skills. [See p 291, section 10.17.7 for discussion - Health Care Professionals in Secondary Care Study].

#### ***15.2.4 Methods of Enhancing Understanding***

1. Clinicians ought to be encouraged to facilitate patient understanding. This can be achieved by using analogies to explain treatment, using diagrams and visual aids, disseminating appropriate written information, directing patients to suitable websites on the Internet and perhaps using audio tapes in consultations. [See p 288, section 10.17.5 for discussion - **Health Care Professionals in Secondary Care Study**].

#### ***15.2.5 Implementing a New Consent Form***

1. A component ought to be added to the standard consent form to account for the acquiescent and apathetic patient, or the patient that wishes to waive their right to informed consent. [See p 293, section 10.17.8 for discussion - **Health Care Professionals in Secondary Care Study**].

#### ***15.2.6 Written Consent in Outpatients***

1. Written consent ought to be implemented for certain invasive procedures that take place in outpatients. These would include procedures, which are both invasive and carry with them certain risks such as the banding of haemorrhoids. [See p 345, section 12.9.2 for discussion - **Observational Study**].

#### ***15.2.7 Dissemination of Professional Guidelines & Protocols***

1. The guidelines ought to be updated to reflect the realities of consent in practice and allowances should be made for clinical discretion in some circumstances. [See p 398, section 13.17.4 for discussion - **Solicitors' Study**; p 257, 291, sections 10.9.15 and 10.17.7 for discussion - **Health Care Professionals in Secondary Care Study**].

#### ***15.2.8 Provision of Legal Training as CPD***

1. Solicitors' firms and universities should be encouraged to work in collaboration with the NHS to provide training on the legal issues concerning consent and information disclosure. This training could be provided as part of the continuing professional development of clinicians. It may be most appropriate to provide this training for clinicians when they are at the stage of senior house officers or above. [See p 397, section 13.17.4 for discussion - **Solicitors' Study**; p 266-267, section 10.11.2 for discussion - **Health Care Professionals in Secondary Care Study**].

## **15.3 CONSENT BEYOND THE COURTS**

### **15.3.1 Patient Support Groups**

1. Patients should be encouraged to join support groups as a means of improving their knowledge of consent. Patients should be invited to join these groups from the time of their first appointment to well after the treatment finishes. [See p 333-335, section 11.13.6 for discussion - Patients' Study]
2. Patients from these support groups should be encouraged to actively recruit members and, on a voluntary basis, should be asked to attend hospitals to discuss treatment, risks and aftercare with patients awaiting operations. Here they can clarify any concerns and suggest which questions ought to be asked of clinicians. [See p 317-319, section 11.9.10 for discussion - Patients' Study]

### **15.3.2 Construction of Patient Charters**

1. Consideration ought to be given to designing and implementing a Patient's Charter specifically in respect of consent. Here emphasis should be placed on explaining the consent process to patients and what information they can typically expect in the consultation process. It should also provide information as to the legal mechanisms available to patients should something untoward happen. [See p 400, section 13.17.4 for discussion - Solicitors' Study].
2. Whilst this Charter ought to be predominantly aimed at patients, it must be designed with input from clinicians, solicitors and academics. [See p 400, section 13.17.4 for discussion - Solicitors' Study].
3. The Patient's Charter should work alongside the existing professional guidelines to assist the law in determining whether or not there has been a breach of the duty of disclosure. [See p 401, section 13.17.4 for discussion - Solicitors' Study].

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## **WEBSITES**

*British National Formulary* [www.bnf.org](http://www.bnf.org)

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*MIMS* [www.mims.com.au](http://www.mims.com.au)

## 17 APPENDICES

**Appendix One:** Ethics Letter of Approval  
Letter Overruling Decision Re. Medical Students' Questionnaire  
An Example of the Participant Information Sheet  
An Example of the Participant Consent Form

**Appendix Two:** Medical Students' Questionnaire

**Appendix Three:** An Example of the Interview Schedules

**Appendix Four:** A Worked Example of the Analysis of the Interviews  
Extracts from the Research Diary  
Extracts from the Observational Field Notes

**Appendix Five:** Copy of Standard NHS Consent Form

**Appendix Six:** Correspondence Re. 'Missing Element of *Bolitho*'

Chair, Professor  
Acting Administrator

03/348 - Please quote this number on all correspondence

Principal Lecturer  
Law Division  
Collegiate Crescent Campus  
1 - 53 Broomgrove Road  
Sheffield  
S10 2BP

11/02/04

Dear

**SSREC Ref.: 03/348 - The law and practice of consent to medical intervention - Part I**  
**&D Ref.: 13638**

The Chair of the Research Ethics Committee has considered the amendments submitted in response to the Committee's earlier review of your application on 08/01/04 as set out in our letter dated 01/01/04. The documents considered were as follows:

- the current application form (fully signed and all sections completed), dated 10/12/03***
- participant information sheet, patients, SSREC version 1, received 16/12/03***
- participant information sheet, medical practitioners, SSREC version 1, received 16/12/03***
- participant information sheet, Clinic, SSREC version 1, received 16/12/03***
- consent form, SSREC version 1, received 16/12/03***
- interview schedule, patients, SSREC version 1, received 16/12/03***
- interview schedule, medical practitioners, SSREC version 1, received 16/12/03***
- protocol, SSREC version 1, received 16/12/03***
- peer review, dated 04/12/03***
- Sheffield Hallam University Indemnity***

- letter from dated 20/11/03***
- letter from dated 09/06/03***

**Additional/New Documents**

- participant information sheet, version 2, dated 22/01/04***
- participant information sheet – patient observations, version 1, dated 20/01/04***
- participant information sheet – medical students, SSREC version 1, received 23/01/04***
- medical student questionnaire, SSREC version 1, received 23/01/04***

The Chair, acting under delegated authority, is satisfied that these accord with the decision of the committee and has agreed that there is no objection on ethical grounds to the proposed study. I am, therefore, happy to give you the favourable opinion of the committee on the understanding that you will observe the conditions set out below. Approval is only for Phase I and DOES NOT extend to the planned recruitment of medical students.



**Central Office for Research Ethics Committees  
(COREC)**

Rob Heywood  
Law Division  
51/53 Broomgrove Road  
Collegiate Crescent Campus  
Sheffield Hallam University  
Sheffield

14<sup>th</sup> February 2004

Dear Mr Heywood

Re: SSREC no: 03/348 - The law and practice of consent - Dr R Heywood

I am writing in response to your recent complaint about my understanding of your study is that it is composed of two parts. The first part consists of members of NHS staff and you have received ethical approval for this part of the study. The second part of the study is a postal survey of undergraduate medical students. Apparently LREC have turned down this part of the study on the grounds that they think that this part is too much work for you, not for any ethical or scientific reason. Although burden of work could be a reason for rejection under site specific assessment, one might expect the committee to reach this conclusion after having talked to you and established the level of work which you are undertaking currently. Since you were not invited to attend the meeting when your study was discussed, they have not had an opportunity to do this.

Rather than entering into a long and drawn out appeal procedure, I think we can resolve your difficulty very easily. GfREC quite clearly states what type of research is required to go before a REC for an ethical opinion; essentially we are talking about any research involving patients, their tissue or data, clinical interventions on healthy volunteers and NHS staff when they are the subjects of research. Since the subjects of your proposed postal survey are undergraduate medical students, they cannot be defined as NHS staff. You will not be using the NHS to provide you with a sampling frame as the University of Sheffield is providing you with this. The medical students are therefore outside the remit of any NHS research ethics committee, assuming that you are not carrying out a clinical intervention on them and you are not conducting your research on NHS premises or using NHS resources. There may be ethical issues arising as a result of the questions you ask but these are internal matters for the two universities to resolve and they lie outside the remit of an NHS research ethics committee.

You should therefore cease applying for an ethical approval for part of the study as it is not required. As long as both universities are happy with the research governance aspects of your study, data protection etc you should be free to start your postal survey any time you please.

I hope this is helpful.

Best wishes

Hi Department

No

02 March 2004

Mr Robert Heywood  
18 Stainton Road  
Sheffield  
S11 7AX

Dear Mr Heywood

**LETTER OF AUTHORITY**

I am pleased to advise you that approval is hereby given for you to undertake duties in the Colorectal Surgery Department at the Royal Hallamshire Hospital under the supervision of Roger Ackroyd.

The period of your attachment is from March 2004 to 31 August 2004.

Authority is given only on the proviso that you make yourself familiar with the relevant policies and procedures of the Trust and specifically in relation to Health and Safety and Fire.

This letter of Authority is not a contract of employment and confers no employment rights or entitlements. It is subject to your maintaining the strictest confidentiality of information with which you may come into contact during the course of your time in the Trust, and maintaining acceptable standards of conduct.

The Trust the Sheffield Teaching Hospitals NHS Trust will not accept responsibility for damage to, or loss of, any personal property. You are recommended, therefore, to take out suitable insurance cover.

Finally, I should like to take this opportunity of welcoming you to the Royal Hallamshire Hospital and hope that your attachment proves both interesting and rewarding.

If you agree to accept this Letter of Authority on the terms specified above, please sign the form of acceptance at the foot of this page and return it to the Human Resources Department, 2<sup>nd</sup> Floor Clock Tower Building, as soon as possible. The second signed copy of this letter is to be retained for your future reference.

## PARTICIPANT INFORMATION SHEET - Patients

### ***'The Law and Practice of Consent to Medical Intervention'***

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

#### **PURPOSE OF THE STUDY**

The main aim of this study is to gain a better understanding of the doctor/patient relationship in relation to issues of consent to medical treatment. This will be achieved by interviewing doctors, nurses, students in training, solicitors and patients to elicit their views on consent. The research will examine how consent is seen from a medic's point of view as well as how it is seen from a patient's point of view. For example, a number of issues may be of importance to health professionals which are not to patients and vice versa.

The number of patients involved in this study will be up to six patients.

This is one specific element of a larger scale PhD project that is aimed at exploring informed consent issues in practice. It will be comprised of further empirical interviews with consultants, registrars, SHO's, GP's, nurses, doctors in training and a number of solicitors.

Your identity as an interviewee will remain completely anonymous. The only information that will be used will be extracts from conversations that are of relevance to the research question. No information about you will be recorded or used in the research project itself. Furthermore, the interview data will be kept secure, suitably anonymised, and confidential.

\*If you are unable to give express consent for whatever reason you will be excluded from this study as you will fall outside the 'informed consent' model.

#### **TAKING PART**

*It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.*

## **BENEFITS OF THE RESEARCH**

This project is that it is aimed at improving communication between the doctor and patient.

## **WHAT HAPPENS WHEN THE STUDY STOPS & WHAT HAPPENS TO THE RESULTS?**

The data from the interviews will be analysed and used for the purposes of a PhD degree thesis.

## **WILL MY TAKING PART BE KEPT CONFIDENTIAL?**

All the information gathered in this study will be kept confidential; the interview data will be suitably anonymised and your identity will not be disclosed. The information gathered will be kept securely locked in a filing cabinet and access will be confined to the researcher alone. Any data placed in a computer will be password protected.

## **WHO IS FUNDING THE PROJECT?**

The project is self-funded.

## **WHO HAS REVIEWED THE PROJECT?**

The relevant NHS research ethics committee has approved this project. Furthermore, this project has been subject to the scrutiny of the Ethics Committee for the School of Social Science and Law, Sheffield Hallam University.

## **WHAT IF SOMETHING GOES WRONG**

*If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.*

## **CONTACT FOR FURTHER INFORMATION**

Mr. Rob Heywood,  
Associate Lecturer & Researcher,  
Sheffield Hallam University,  
Law Division,  
51/53 Broomgrove Rd,  
Collegiate Crescent Campus,  
Sheffield,  
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Tel: 0114 225 2541

E-Mail: [Rob.Heywood@shu.ac.uk](mailto:Rob.Heywood@shu.ac.uk)

# **PARTICIPANT CONSENT FORM**

## *'The Law and Practice of Consent to Medical Intervention'*

*Please answer the following questions by circling your responses*

Have you read the information sheet about this study? YES NO

Have you been able to ask questions about this study? YES NO

Have you received answers to all your questions? YES NO

Have you received enough information about this study? YES NO

Who have you spoken to about this study? .....

Do you understand that your participation is voluntary and that you are free to withdraw from this study at any time and without giving a reason?

YES NO

Do you agree to take part in this study? YES NO

Your signature will certify that you have voluntarily decided to take part in this research study having read and understood the information in the sheet for participants. It will also certify that you have had adequate opportunity to discuss the study with the researcher and that all questions have been answered to your satisfaction

Signature of participant: ..... Date:.....

Name (block letters):.....

Signature of researcher:..... Date:.....

Signature of person taking consent:..... Date:.....  
(if different from researcher)

For further details please contact:

Mr. Rob Heywood,  
Associate Lecturer & Researcher,  
Sheffield Hallam University,  
Law Division,  
51/53 Broomgrove Rd,  
Collegiate Crescent Campus,  
Sheffield,  
S10 2BP.

Tel: ~~0114 2767000~~

E-Mail: [Rob.Heywood@SheffieldHallam.ac.uk](mailto:Rob.Heywood@SheffieldHallam.ac.uk)

# APPENDIX 2

## MEDICAL STUDENTS' QUESTIONNAIRE

This questionnaire is aimed at investigating how you perceive the doctrine of informed consent. It is designed to elicit information about the following areas:

- What you think is the function of informed consent.
- The importance you attach to it.
- How effectively you feel you have been prepared to deal with consent issues.
- How difficult you feel it will be to obtain informed consent in practice.
- How you would define the term 'informed consent.'

Please circle the desired answer or tick the desired box where applicable.

- i. What do you think is the most important basis of the doctrine of informed consent?  
(Please circle one box)

**Ethical Obligation**

**Legal Obligation**

**Professional Obligation**

- ii. Please could you rate the level of importance you would attach to the basis of the doctrine of informed consent from the three choices below.

	<b>Very Important</b>	<b>Important</b>	<b>Unimportant</b>	<b>Very Unimportant</b>
<b>Ethical Obligation</b>				
<b>Legal Doctrine</b>				
<b>Professional Obligation</b>				

P.T.O.

iii. How important do you feel informed consent is in relation to medical treatment?  
(Please circle one box)

**Very Important**

**Important**

**Unimportant**

**Very Unimportant**

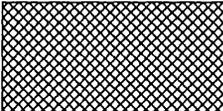
iv. Where do you feel informed consent is most important?  
(Please circle one box)

**Surgery**

**Non-Surgical Intervention**

**Drug Therapies**

v. Please could you rate the level of importance you would attach to informed consent in the three treatment options below.

	<b>Very Important</b>	<b>Important</b>	<b>Unimportant</b>	<b>Very Unimportant</b>
<b>Surgery</b>				
<b>Non-Surgical Intervention</b>				
<b>Drug Therapies</b>				

vi. How effectively do you feel you are prepared to deal with informed consent?  
(Please circle one box)

**Very Effectively**

**Effectively**

**Ineffectively**

**Very Ineffectively**

P.T.O.

- vii. How important do you feel it is to be trained effectively in informed consent in the three treatment options below.

	Very Important	Important	Unimportant	Very Unimportant
<b>Surgery</b>				
<b>Non-Surgical Intervention</b>				
<b>Drug Therapies</b>				

- viii. How confident do you feel about dealing with informed consent issues in practice?  
(Please circle one box)

**Very Confident**

**Confident**

**Unconfident**

**Very Unconfident**

- ix. How important do you feel it is to be confident in dealing with informed consent issues in the three treatment options below?

	Very Important	Important	Unimportant	Very Unimportant
<b>Surgery</b>				
<b>Non-Surgical Intervention</b>				
<b>Drug Therapies</b>				

P.T.O.

- x. How difficult do you feel it will be to obtain informed consent in practice?  
(Please circle one box)

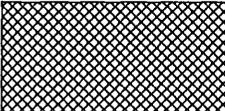
**Very Easy**

**Easy**

**Difficult**

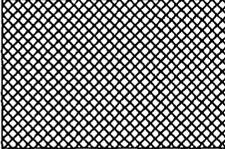
**Very Difficult**

- xi. How difficult do you feel it will be in practice to obtain informed consent in the three treatment options below

	<b>Very Easy</b>	<b>Easy</b>	<b>Difficult</b>	<b>Very Difficult</b>
<b>Surgery</b>				
<b>Non-Surgical Intervention</b>				
<b>Drug Therapies</b>				

P.T.O.

- xii. Please indicate which of the issues below you feel will be most difficult for you when dealing with informed consent in practice.

	<b>Very Easy</b>	<b>Easy</b>	<b>Difficult</b>	<b>Very Difficult</b>
<b>Patient Understanding</b>				
<b>Patient's Lack of Communication</b>				
<b>Patient's Misconceptions About Illness</b>				
<b>Patient's Unwillingness to Ask Questions</b>				
<b>Identifying Patient's Objectives</b>				
<b>Ability to Explain the Treatment</b>				

xiii. Finally, how would you define the term informed consent?

.....

.....

.....

.....

.....

.....

.....

.....

.....

**MANY THANKS FOR TAKING THE TIME TO FILL OUT THIS QUESTIONNAIRE**

For further information regarding this research project please contact:

Rob Heywood (Associate Lecturer & Researcher)  
Law Division,  
51 / 53 Broomgrove Road,  
Collegiate Crescent Campus,  
Sheffield Hallam University,  
Sheffield,  
S10 2BP.  
Telephone: 07855573838  
E-Mail: [Robert.J.Heywood@Student.Shu.Ac.Uk](mailto:Robert.J.Heywood@Student.Shu.Ac.Uk)

FINISH.

# APPENDIX 3

*Interview Schedule:*

**Medical Practitioners - Royal Hallamshire**

The interview will operate by introducing a number of themes as suggested in bold, there will then be an opportunity for the interviewee to expand on these issues addressing the suggested topics as introduced by the interviewer. The following is merely a guide as to how the interview will be structured. The suggested headings are flexible, and serve merely as a suggested order of themes that will be used by the researcher to guide and develop the progress of the interview.

**1. Your View of Informed Consent**

- As a medical practitioner how would you define and how do you view informed consent?

**2. Medical Practitioner's understanding of the law**

- Perception of the law in relation to consent.
- What is its purpose?
- How effective?
- Knowledge of actual law in relation to informed consent - knowledge and extent of duty of disclosure.
- Standard by which the law judges disclosure - knowledge of case law?
- Effect of the law on day to day practice - professional disclosure issues.
- Do medical practitioners know enough about the law? Would they like to know more?

**3. Consent Procedures in Practice**

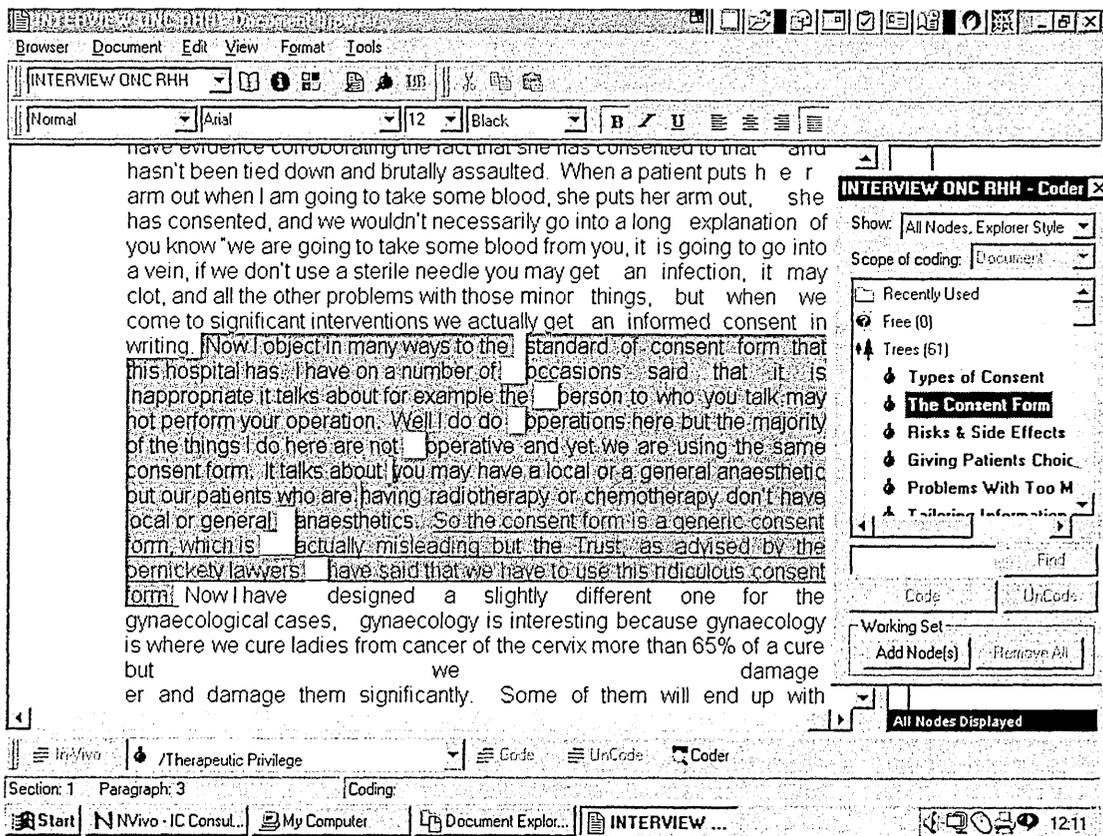
- Consent procedures that are in place within the department.
- Who has the responsibility for gaining a patient's consent - does this change? For example if a patient requested a more senior practitioner to discuss things with, would this be acceptable?
- How long do they spend with the patient?
- What do they see as important in their role as a consent gainer?
- How much information would they give to a patient as standard? Does this change? What type of information? General risks? Special risks? Benefits? Alternatives? Non-interventionist alternatives?
- Does the medical practitioner wait to be asked before offering some information? If so, what kind of information?
- Time constraints on consent procedures in practice.
- Practically, Do consent procedures protect them from legal challenge?

**4. Diversity in practice**

- Is there such a thing as a professional standard in relation to consent procedures? Is this generalised, or in your particular area?
- Does the process change depending on the circumstances of the patient?
- Do practices change depending on which area of medical specialism you are dealing with?

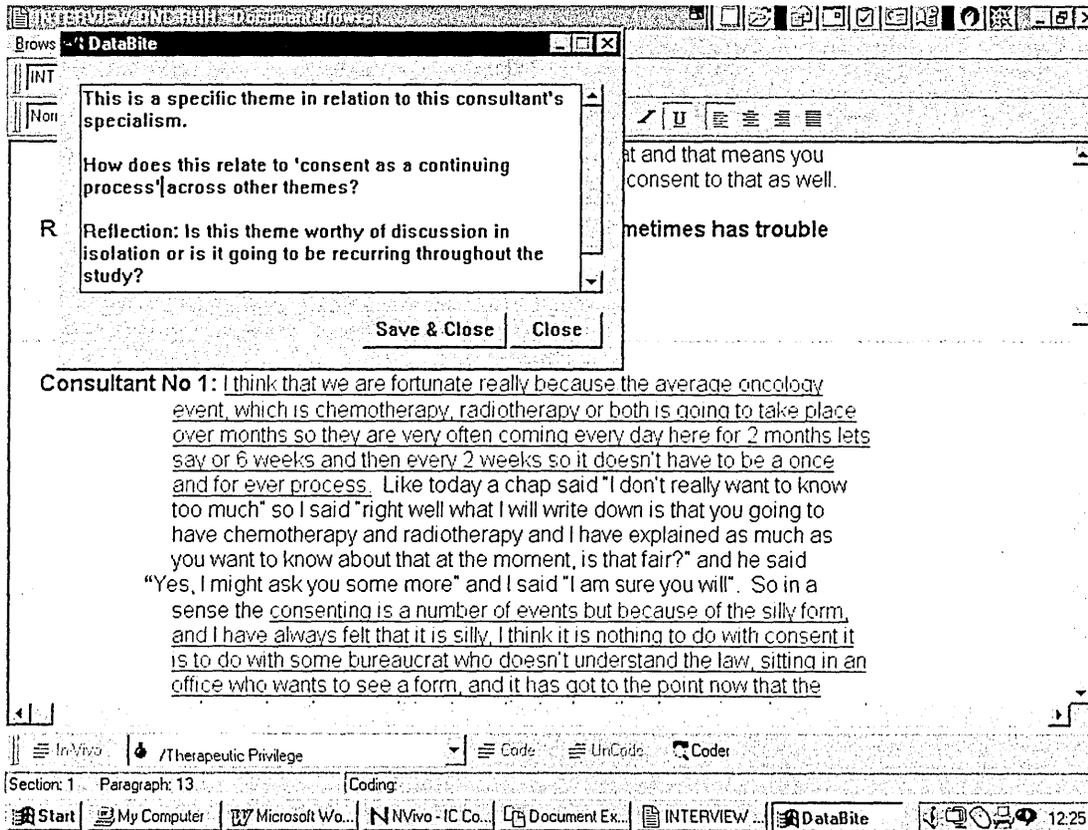
# APPENDIX 4

# DEMONSTRATING THE CODING AND ANALYSIS PROCESS (NVIVA)



The screen shot above shows how the coding system works in NVIVA. The text from the interview is highlighted and the coding categories are demonstrated in the 'Coder' screen on the right hand side. So, in the example above, the section of the text is coded in the general category entitled 'the consent form.' This process of coding remains the same for all interviews and observation notes. As the analysis progresses a number of further coding categories develop in the coding box on the right hand side.

# DEMONSTRATING THE USE OF DATA-BYTES TO ILLUSTRATE SPECIFIC THEMES OF INTEREST (NVIVA)



The above screen shot demonstrates the use of data-bytes to highlight specific points of interest within the interview transcripts and to facilitate the reflective process. The sections of the text underlined in green indicate a data-byte is attached to it. The user can then click on this text to display a data-byte, which allows you to type in your reflective comment. (See data-byte box at the top right hand of the screen).

# DEMONSTRATING THE USE OF THE NODE SCREEN TO IDENTIFY RECURRING THEMES WITHIN GROUPS OF PARTICIPANTS (NVIVA)

The screenshot shows the NVivo Node Explorer window for a project named 'IC Consultants SC'. The interface includes a menu bar (Node, Tools, View), a toolbar with icons for Browse, Properties, Attributes, DocLinks, and NodeLinks, and a main area divided into 'Nodes' and 'All Trees'.

The 'Nodes' pane on the left shows a tree structure with 'Trees (51)' selected. The 'All Trees' pane on the right displays a table of nodes with the following data:

Title	No.	Passages	Created	Modified
Types of Consent	1	1	16/02/05 ...	06/09/05 ...
The Consent Form	2	24	16/02/05 ...	06/09/05 ...
Risks & Side Effects	3	14	16/02/05 ...	06/09/05 ...
Giving Patients Choices	4	14	16/02/05 ...	06/09/05 ...
Problems With Too M...	5	18	16/02/05 ...	06/09/05 ...
Tailoring Information	6	3	16/02/05 ...	06/09/05 ...
Understanding	7	10	16/02/05 ...	06/09/05 ...
Cultures Within the N...	8	2	16/02/05 ...	06/09/05 ...
Standardising Consent	9	7	16/02/05 ...	06/09/05 ...
Information Disclosure	10	10	16/02/05 ...	06/09/05 ...
Patient's Refusing Tr...	11	6	16/02/05 ...	06/09/05 ...
Consent as a continui...	12	8	16/02/05 ...	06/09/05 ...
Risk v Benefit Ratio	13	11	16/02/05 ...	06/09/05 ...
Problems with Just Si...	14	14	16/02/05 ...	06/09/05 ...
Ways to Encourage	15	6	16/02/05 ...	06/09/05 ...

The Windows taskbar at the bottom shows the Start button, 'My Computer', and several open applications including 'Microsoft Word - EXPLA...', 'NVivo - IC Consultants SC', and 'Node Explorer - IC ...'. The system clock shows 13:00.

The above screen shots demonstrates how the recurring themes within the study are identified. As can be seen in the worked example of the interview transcript overleaf, there are initially lots of different coding categories. However, as the study progresses, these are condensed to pick out the recurring themes from all the transcripts. The node screen displays all the categories and the number of passages within each. This allows the user to identify the categories which are most used throughout the research. So we can see above that 'problems with the consent form' has 24 entries amongst consultants, and 'problems with too much information' has 18.

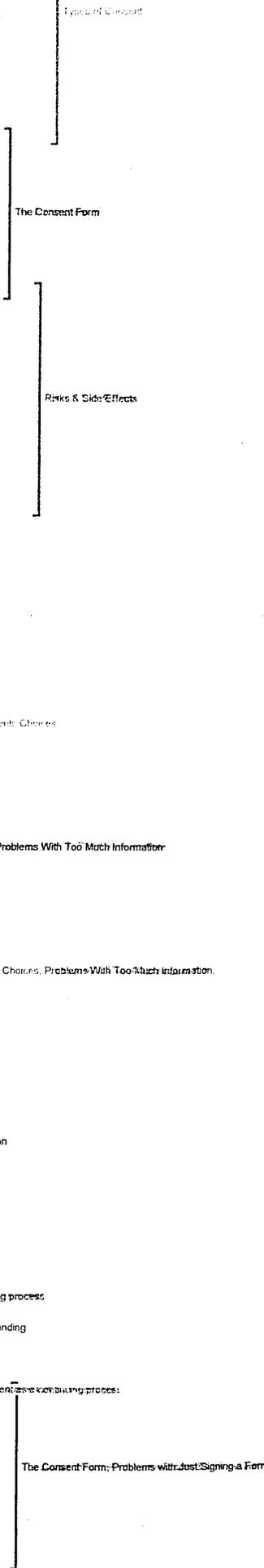
most for what we do is implied so when I say "do you mind if I lie down" and she lies down on the couch and pulls down her knickers, assuming that she is consenting to me examining her. I have a nurse with me when I ask her and I have a nurse with me when I do it so that there is evidence corroborating the fact that she has consented to that hasn't been tied down and brutally assaulted. When a patient puts their arm out when I am going to take some blood, she puts her arm out, has consented, and we wouldn't necessarily go into a long explanation of you know "we are going to take some blood from you, it is going to go into a vein, if we don't use a sterile needle you may get an infection, it may clot, and all the other problems with those minor things, but when we come to significant interventions we actually get an informed consent form in writing. Now I object in many ways to the standard consent form that this hospital has. I have on a number of occasions that it is inappropriate it talks about for example the person to whom you talk may not perform your operation. Well I do do operations but the majority of the things I do here are not operations and yet I am using the same consent form. It talks about "you may have a local general anaesthetic but our patients who are having radiotherapy or chemotherapy don't have local or general anaesthetics. So the consent form is a generic consent form, which is actually misleading but the lawyers, as advised by the pernicky lawyers have said that we have to use a standard ridiculous consent form. Now I have designed a slightly different consent form for the gynaecological cases, gynaecology is interesting because gynaecology is where we cure ladies from cancer of the cervix more than for a cure but we damage her and damage them significantly. Some of them will end up with colostomies due to radiation damage; some of them find that they can't use their bladder properly so these are some of the very very significant side effects of the treatment, but if we don't tell them up to that level we will not cure them. So if we back off from the nasty things that we do they will die of cancer so it is an area where you are saying to somebody "if you want to be cured you are going to accept that your bowels and waterworks are never going to be the same again". So we have over-printed the standard consent form to say "if you have chemotherapy the side effects are damage to your bowels, damage to your waterworks, damage to your central function, risk of infection etc so that is very specific. If you look at medico-legal action in cancer, in oncology the cervix stands out as by far the most common number of cases. I mean the others are common breast, lung and colon but very rarely people sue in lung because most people die. If they sue for damage, some ladies who have suffered damage after radiotherapy to the breast and will sue on that because we cure them. So the diseases we cure people with malignancy are more likely to be the subject of litigation than in situations where people die ironically. So I have a particular attitude, probably more pernicky, myself and my colleague who does the gynaecological malignancy have much more of an awareness of consent, but we do have a standard consent form. If I see a patient with liver cancer with liver deposits so I say to him "look I would suggest", to this very bright chap who is quite young, "if we are going to get to grips with your cancer we are going to have to give you chemotherapy and chemotherapy which will help to get rid of the cancer and side effects will be x,y,z. Now if you like we can use a lower intensity chemotherapy which will be half the effectiveness of what I have described and the side effects will be less, and you have to choose between you want to go on this", and I also ask them at the beginning how do you want to know because it is a difficulty when you are dealing with a life threatening disease, on the one hand we want to get proper informed consent, on the other hand we don't want to overburden the patient with information that they do not want to hear. So I always start at the beginning, and I have taught my juniors to do this, when you sit down with the patient and say "how much do you want to know?" and the patient will very often say "I know that I have got lung cancer, but I don't want to know how long I have got to live or what the chances are, I want you to do whatever you think is appropriate". Now the problem on the other side it becomes more difficult to say to a patient "if we don't treat you you have only got 6 months to live, if we treat you with these drugs, which could really do you a lot of damage and increase the risk of the drug killing you, then we might buy you a 3 in 2000 risk of the drug killing you, then we might buy you a 10% year and we might even buy a 10% chance that you will die of old age if the patient says "I don't want to know how long I have got to live have set a frame of reference around that consenting process.

cher: Do you find that happens a lot?

tant No 1: Yes a lot. I think it is particular to management of rheumatoid arthritis. I mean if you are talking about rheumatoid arthritis you don't have that sort of "what is wrong with me?" but I think that when you are dealing with a life threatening illness you have to be aware of how much information that patient wants to know and you have to tailor the information to that means you have to tailor the information when obtaining the consent to that as well.

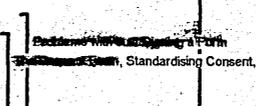
cher: Do you think sometimes that the patient sometimes has trouble understanding?

tant No 1: I think that we are fortunate really because the average life expectancy event, which is chemotherapy, radiotherapy or both is going to last over months so they are very often coming every day here for 2 weeks or 6 weeks and then every 2 weeks so it doesn't have to be a long and for ever process. Like today a chap said "I don't really want to know too much" so I said "right well what I will write down is that you have to have chemotherapy and radiotherapy and I have explained as much as I want to know about that at the moment, is that fair?" and he said "I might ask you some more" and I said "I am sure you will". So in the end the consenting is a number of events but because of the silly nature of it and I have always felt that it is silly, I think it is nothing to do with consent it is to do with some bureaucrat who doesn't understand the situation in an office who wants to see a form, and it has got to be the fact now that the radiographers here won't treat a patient unless they have signed a consent form. Now that signing of the consent form might be telling the patient "sign this consent form" the radiographers will be very happy if there is a signature on the form even if I haven't gone through the proper process of consenting, but the bureaucracy here is as you have a signed consent form and whatever is around that they are a bugger.



high horse now... You have got 2 conflicting cultures in the health  
 ice, you have got the risk takers who are the doctors and to some  
 nt the nurses we have to take risks we would never cure anyone unless  
 ake the risk, we have to risk-maiming people, killing them,  
 icularly in my business, and then you have the hospital managers who  
 risk averse they never get promoted for taking a risk, they are not  
 entrepreneurs, as long as no shit lands on their doorstep they are happy  
 their bosses are happy so you have 2 different cultures but the  
 gers are the ones who have the power to say "if you don't get a signed  
 ent form then this is not going to happen" so you now have this  
 ous business of the standard national consent form which is a  
 ense really, it is too generic to apply to any individual case.

Cultures Within the NHS



archer: So each area is different?

ultant No 1: Yes I suppose if you are doing in-growing toe nails I  
 ose it is adequate consent but what we do here is a consenting process  
 goes over the first meeting to a number of steps so the patient will  
 iven access to diagnosis, the first options of treatment, all of the  
 logy notes are typed and they are continuous and we will record what  
 patients says. We actually have a section which says insight and all  
 patient information is recorded eg she knows she has got cancer, she  
 s that this is very curable, she understands that we are going to give  
 radiotherapy to increase her chance of a cure and that the side  
 cts are x,y,z, and so that is evidence of the consenting process which  
 ctually in the notes, but also when the patient comes, for let us say,  
 herapy the chemotherapy oncology nurses will say "do you know why  
 are having this treatment, do you understand what the side effects  
 , they will go through it again. We give them leaflets, we have a  
 ine for our patients who are about to undergo chemotherapy one of the  
 es will phone them to ask if they have any problems. We have an open  
 for all the new patients having radiotherapy every week. They can  
 along to the Department, walk around, talk to the staff about what is  
 y to happen to them, what the side effects are, what is the likely  
 our of their disease. So it is not one isolated event it is  
 nual communication and because it is an on-going process the patient  
 the opportunity of backing out of it. It doesn't happen very often  
 someone for eg say a little old lady comes for chemotherapy and I say  
 there is an option there is a range of chemotherapy there are 5  
 erent regimes that would suit your cancer, this is pretty nasty, this  
 ry nasty, this has some benefits and this is kind but is not very  
 tive which do you want to go for?" "so shall I go for the kind one  
 ee how we go" and after a couple of that she says "well perhaps I  
 be better off going for the nastier one" so we will swop her over or  
 versa someone may decide that they are not prepared to have anymore  
 is. On the other hand there is a very interesting dilemma. I had a  
 nt who was a royal marine commando, a big boy, tough boy, with  
 in's Disease which gave him big lumps in his neck, a very curative  
 tion, had a wife and a baby and he was pretty ill when he first came  
 e gave him a course of chemotherapy and I spoke to him before his  
 d course and said "how was that" and he said "well it was not too  
 I felt a bit queasy, lost a bit of hair, but fine, after the next  
 e I said "how was that" and he said "not too bad I felt a bit iller.  
 ave lost all my hair but all the lumps have almost gone" after the  
 lot "how was it" "fucking not having anymore of that" really bolshie  
 s disease had disappeared but all he could then think of was the  
 effects because he could see only the side effects he couldn't see  
 efits at all because as far as he was concerned his disease had  
 nd we produced his wife and his baby and persuaded him to go through  
 courses and told him that if he didn't do it for this it would just  
 ack again. If you go through this it will be a bad memory in a few  
 a horrible memory you know, you lost your hair, you felt sick, you  
 uth ulcers, you felt crap but in 6 months time that is it, it has  
 ne and it will gradually fade and you know the strict letter of the  
 rhaps, he could have said he doesn't want his treatment fine, call  
 lay, goodbye, die.

Understanding, Information Disclosure,

~~Consent~~

Understanding, Information Disclosure, Understanding,

Patient's Refusing Treatment, Giving Patients Choices,

Patient's Refusing Treatment

~~Understanding, Information Disclosure, Giving Patients Choices,~~

cher: Do you find that patients communicate, or do they tend not to  
 estions?

tant No 1: Oh they do but I think that is due to the final reference  
 ou set. If you sit down, not opposite to them behind a desk, not in  
 e coat, kneel at the bedside not be intimidatory or authoritarian  
 y "is there anything you want to know about this?" most people will  
 tart to share their concerns and worries with you. It may not come  
 the first visit but maybe the second. It may be on the first visit  
 hey just don't want to know "you just do it" second time "well I  
 ctually made a list at home and my daughter has come with me and can  
 through it again".

Ways to Encourage Communication

~~Consent~~

her: Does it tend to be the senior consultants who take the  
 ?

ant No 1: I think that the rules have changed. It used to be that  
 the most junior person in the building, the Houseman who took the  
 , although not with oncology it was always the person who saw the  
 . The rules now generally throughout seem to have changed in that  
 is going to be responsible for that procedure is going to take the  
 and many surgeons have grumbled enormously saying "this is  
 vely; the time it is going to take them to do the consent they  
 ave been doing 3 more operations or something but I think it is now  
 mmoner to see that who is going to be doing whatever it is whether  
 urgery if it is an operation. With me it is a number of things it  
 cles of chemotherapy, plus radiotherapy, plus an operation and I  
 l be responsible for all of that but parts of it I may not do. You  
 ay perhaps the Radiographers should get consent and then sometimes

Delegating Consent

~~Consent~~

her: As a medical practitioner what is your perception of the law  
 tion to consent?

ant No 1: I think that in relation to consent I think it is OK. I  
 e boundaries, where I get confused is the boundary between  
 ce and consent and I think there are some terrible elements of the  
 and at the moment. has been to me a disgrace I know it is

Understanding of the Law

researcher: Do you think it is designed to enhance autonomy and protect autonomy?

consultant No 1: No if you were really going to advance autonomy you should be looking at the same sort of mechanisms like the Americans, the Canadians, other people who serve proxy consents, a lay assessor and that delays treatments as well, may delay treatment, and there is a danger, it's a bit like diplomats they come and work for the other side. If you've a lay assessor if they are going to be really knowledgeable about the treatment then they have almost become part of the medical team. That is the only way I think you could really improve it is to have a third party standing outside at the time of the consent and not just relying on litigation. Not the third party turning up when it has all gone bad. I know you are doing your project on consent, but from a pure oncology point of view, consent is not what we really worry about, what we worry about is negligence.

Understanding of the Law

researcher: Do you think that the new professional guidelines in terms of consent are starting to harmonise the procedures?

consultant No 1: No the consent forms have now got some guidelines printed on the back so you might actually get people to read that. I happen to have downloaded all this stuff from the Department of Health website all the latest stuff on guidelines and I think there has been some sort of summary sent out by the Trust as well.

Professional Guidelines

researcher: Are you aware that the law in creating what is known as a therapeutic privilege defence that you can withhold information from the patient if you feel that it would be detrimental. Do you think that is relied upon a lot?

consultant No 1: No I don't think.... Well it might be in psychiatry but I don't think it is relied upon in what you might call general medicine like oncology. I suppose this goes back to what I said we do allow the patient to set the frame of reference for the information that they are giving but it is not therapeutic privilege that is their clear defined choice. I'll say, "how much do you want to know? Do you want to know how long you've got to live? Do you want to know what the benefits are if you have this treatment let us say that if you have this treatment for lung cancer, the moment if you don't have any treatment you are going to die within weeks. If you have quite a nasty treatment then you will almost certainly get to survive a year and 4% will survive for 2 years, so it'll buy you a year but it probably won't buy you very much more. I suppose a really horrible treatment then you have got a 20% chance of surviving for 2 years". Now they are pretty hard figures for anyone to understand and mostly when you ask people they will say "I don't want to know much about this, I am aware that I have a life threatening condition that I may die but I really don't know want to know when and if you can make it longer and better then that is about as much as I want to know". Now is that therapeutic privilege the fact that I am saying "right" would like to have chemotherapy" "yes" "yes" so we go ahead and give them what we think they want.

Therapeutic Privilege

Therapeutic Privilege, Risk to Health, Information Disclosure

researcher: So you think that doctors feel a little bit threatened by the law?

consultant No 1: Yes I think junior doctors do. I have been an examiner for the Royal College, Faculty of Oncology and the Royal College of Physicians in Ireland over a number of years and seen the juniors come up to their final exams and realise that they are influenced by how much damage they are prepared to do, paid to patent and I think, this is sort of anecdotal, but I think over the years there has been a backing off of allowing themselves to cause damage even if we are going to drop the cure rate. With many cancers there is a survival curve so if you give a particular dose of treatment you will start to improve the cure rate, so that is the cure rate and that is the dose, like with drugs and then you give too much and then you start to kill people but if this is damage this is what is called therapeutic ration so as you increase the dose you increase the damage so it is this boundary so how much cure are you prepared to accept for how much damage and that isn't clearly defined that is why you have Bolam and all the other stuff you know and Bolitho and ever. I feel comfortable knowing that when I treat a lady with cancer of the cervix I am going to produce about 20% of those patients are going to have significant damage I will produce a cure in those patients of about 35-40% so 20% damage 30% cure I feel reasonably comfortable with that. One of my colleagues from the Centre a bit to the North of London goes for a much higher dose and pushes the cure rate up to 34% his cure rate is also about 34% so more of his patients will have real problems but he will cure a few more percent of them. Now who is right who is wrong?

Defensive Medicine

researcher: Where is the boundary that is the problem isn't it?

Defensive Medicine

consultant No 1: Yes and I don't know who is right and who is wrong and I suppose where Bolam and Bolitho comes in.

Notes: As can be seen, initially there are many coding categories. However, NVIVA allows the researcher to capture and identify the 'strong exemplars' and 'paradigm cases' and separate them from the more 'general' coding categories. The strong recurring themes in this interview are highlighted in green. They are summed up opposite.

- Strong Recurring Themes:
- Consent form (problems)
  - Consent as a continuing process
  - Risks + Side effects
  - Problems with too much info

These themes are then further analysed to break them up into 'sub-categories'

process are much greater than I first anticipated. Consent is a very subjective process, attempting to harmonize it as a result of medico-legal work is impossible.

Final Categories and Sub-Categories	
Types of consent	Law
consent form	prof. Guidelines
Risks + S/E	Defensive medicine.
patient choices	
Too much info.	
Tailoring info.	
Understanding	
Cultures	
Standardising consent	
Info. disclosure	
Patients refusing	
Continuing process	
Risk v. Arbitrariness	
Signing	
Communication	
Delegating	

Emerging Themes from Re-Reading the Constituent Parts

Consent is a very subjective process. It has to be tailored to each individual patient in order to have any meaningful effect. The law does not account for the problems faced by medical practitioners. Sometimes patients request not to be told things and need gentle persuasion. Strong ethical commitment towards understanding.

- Initial Coding Categories in NVIVA
- Types of consent
  - The consent form
  - patient choices
  - Too much information
  - Standardising consent
  - problems with 'just signing a form'.
  - consent as a continuing process
  - Risks + Side-effects

- Initial Horizon of Researcher  
(Legal Understanding & Knowledge Acquired From Other Interviews / Studies)
- Consultants may not perceive consent as important as other aspects of their job.
  - More emphasis on risk disclosure in secondary care.
  - consent as the signing of a form.
  - Little knowledge of law
  - may delegate.

Initial Interpretations / Impressions from Reading Transcript as a Whole

The consultant is involved in some very serious treatments that have significant side-effects for patients. Consent is an on-going process where it is up to the patient to set the frame of reference. The consent form is unnecessarily bureaucratic and seeks to harmonize the unworkable.

- Initial Themes Emerging
- Types of consent
  - patient choices
  - consent forms
  - Standardising consent
  - Continuing process
  - Too much information

Interview Code: Int. Onc. RHH 19/3/04  
Participant / Study: IC Secondary care.  
Date Analysed: April 04.

CONSULTANT RATCH

key: [dots] = Recurring themes with transcript

1<sup>st</sup> Interview: Consultant Oncologist (19/3/04).

## Reflections at Interview

This participant was clearly a medical practitioner who was aware of the bureaucracy within the NHS. This came across within the interview.

He clearly viewed consent as a contentious issue. Consent and the consent process may be markedly different within this specialised field of oncology.

Treatment in oncology entails very significant risks and side-effects. Nevertheless, the risk vs benefit ratio changes as often we are dealing with life threatening situations.

The consent process should not be made unnecessarily formalised. This does nothing for patient or doctor.

Sometimes information has to be tailored to each individual patient → The consent process itself is very subjective.

Sometimes patients can be over-burdened with too much information. The key is to ask the patient how much they wish to know.

The consent process is a continuing process and should be done over a number of consultations. Q. is this the same for different fields?

Strong distaste for standardising consent via the medium of one particular form → Consent is about much more than a signature on a form. The process should change from patient to patient.

Give patients options → Share decisions → allow them to set the frame of reference! Less + deliberative practice? explore in greater detail.

## Commencement of Interviews

- Initial pre-understanding of informed consent from a legal background
  - The law views medical practitioners as agents of disclosure. However how do medical practitioners perceive themselves? I.C. should be at more than mere disclosure of risks.
  - Medical practitioners may be expected to know little about the law
  - The significant cases may have very little effect on the obtaining of consent in practice.
  - Patients may be ignorant as to their legal rights pertaining to informed consent and may not know how to pursue a legal action against their doctor.
  - Due to ever-increasing litigious society patients may be more willing to sue.
  - Law is reactionary - can it ever really be used to improve consent in practice?
  - What is the effect of law? Threatened / Defensive Medicine.
  - Risk disclosure should not be confined to statistical precision.
  - Law sees self-determination in functional terms - negligence/battery divide.
  - Doctors may perceive consent as nothing more than obtaining a signature on a form to protect them. Consent is about more than this.

The law operates above and its powers of improving consent as the  
wants are somewhat limited. It only springs into action  
once something has gone wrong. However, it is supposed to  
be prescriptive and as such is supposed to lay down guidelines  
for future conduct. Its power resides in its symbolic nature.

Reflects on the interesting phrase 'we are obliged to tell you  
this'. Upon hearing this patients seemed to switch off.  
Firstly, does it suggest medical practitioners would not provide  
the patient with the information if they were not legally  
required to do so? Secondly, does the phrase 'we are  
obliged to tell you this?' de-emphasize the importance  
- the information as when patients hear it is 'just something  
they have to do', they may not pay enough attention and  
listen to the information in the manner they should.

was some excellent examples of consent. The consultants  
did go out of their way to put patients at ease and  
tried to adapt easily to the type of patients they were dealing with.  
For example when dealing with older patients they spent more time  
with them and refused to let relatives make decisions for them.  
In the same breath they dealt with older, younger patients  
in appropriate manner; seemed happy to answer questions  
relating to work, infringements and other care. Also dealt with  
patients who were clearly intoxicated.

plus an encouraging practice included the way in which things  
- explained to patients. There was a fair amount of ~~listening~~  
being paid to risks. However, greater attention paid to explaining  
treatment itself. Often diagrams were used to enhance understanding  
risks were nearly always explained in the context of benefits and  
a need to undergo the treatment that was recommended.



# APPENDIX 5

Teaching Hospitals   
NHS Trust

**Consent Form 1**

**Patient agreement to investigation or treatment**

**Note: Use this form for adults or children who are competent and able to consent for themselves.**

**White copy to be given to patient**

**Pink copy to be retained in notes**

**Patient details (or pre-printed label on BOTH copies)**

Patient's surname/family name .....

Patient's first names .....

Date of birth .....

NHS number (or other identifier) .....

Special requirements .....  
(e.g. other language/other communication method)

**Name of proposed procedure or course of treatment** (include brief explanation if medical term not clear)

.....  
.....

**Statement of health professional** (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to this patient. In particular, I have explained:

The intended benefits: .....

.....

Serious or frequently occurring risks: .....

.....

Any extra procedures which may become necessary during the procedure, e.g:

Blood transfusion .....

Other procedure (please specify) .....

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided .....

This procedure will involve pre-operative assessment to determine the appropriate type of anaesthesia required.  
**Yes/No**

General and/or regional anaesthesia

Local anaesthesia

sedation

**Healthcare professional signature:** ..... **Date:**.....

**Name:**..... **Job Title:** .....

**Contact details** (if patient wishes to discuss any issues related to the procedure / treatment) .....

**Statement of interpreter** (where appropriate) .....

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

**Signed:** ..... **Date** .....

**Name (PRINT)** .....

WHITE COPY ACCEPTED BY PATIENT: YES / NO (PLEASE CIRCLE)

PINK COPY RETAINED IN NOTES

13/01/2011 10:00:00 AM

**Statement of patient**

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described in this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. This only applies to patients having general or regional anaesthesia. Information regarding anaesthesia in general can be found on [www.youranaesthesia.co.uk](http://www.youranaesthesia.co.uk)

I understand that any procedure in addition to those described in this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

.....  
.....

I understand that tissue removed as part of my treatment may be used for teaching, education, quality assurance or audit in addition to diagnostic purposes.

I consent to the use of residual tissue following diagnosis for Research YES ..... NO..... (Please tick)  
(If NO the healthcare professional will inform Histopathology. The department will respect the patient's wishes.)

Patient's signature ..... Date .....  
Name (PRINT) .....

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people /children may also like a parent to sign here (see notes).

Witness signature ..... Date .....  
Name (PRINT) .....

**Confirmation of consent** (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Healthcare professional signature: .....	Date .....
Name (PRINT) .....	Job title .....

Important notes: (tick if applicable)

- See also advance directive/living will (e.g. Jehovah's Witness form)
- Patient has withdrawn consent (ask patient to sign/date here) .....

## What a consent form is for

This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an *aide-memoire* to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

## The law on consent

See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at [www.doh.gov.uk/consent](http://www.doh.gov.uk/consent)).

## Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf and a **separate form (Consent form 2)** is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

## When NOT to use this form

If the patient is 18 or over and is not legally competent to give consent, you should use Consent form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if

- They are unable to comprehend and retain information material to the decision; and/or
- They are unable to weigh and use this information in coming to a decision.

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

## Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient's notes.

# APPENDIX 6

Your Ref:  
Our Ref: PS DB RMM

Rob Hayward  
Lecturer in Law  
Law Department  
Sheffield Hallam University  
City Campus  
Horward Street  
Sheffield  
South Yorkshire  
S1 1WB

14 July 2005

Dear Rob Hayward

**Bolitho v City & Hackney Health Authority**

You wrote to me on 17 June 2005 and I have been extremely rude in not replying but unfortunately I have been up to my ears in Trials and the like.

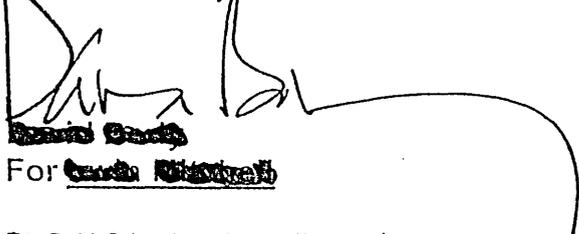
I am enclosing for your attention two pages which were used as a part of the submissions in the House of Lords when we did **Bolitho**.

The first is a considered view of the content of the test as it then stood and the second is a statement what we felt the test ought to be including as you will see, a suggestion that ideally the test should contain a clear criterion of the least risk to patient.

I hope this is a help and if you would like to discuss this further, please do not hesitate to give me a call.

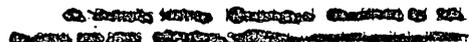
With kind regards,

Yours sincerely

  
For David Green  
David Green@irwinmitchell.co.uk

Birmingham Leeds London Newcastle Sheffield

telephone 

  
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## A Fair and Practical Application of the Bolam test

1. The Plaintiff must prove, on the test in Hunter v. Hanley ((1955) Scots Law Times 213), that the Defendant was negligent in all of the circumstances of the case (Maynard v. West Midlands Regional Health Authority (1984) 1 WLR 634).
2. If the Defendant's case is that the practice was accepted as proper by a body of medical opinion, the evidential burden is on the Defendant to raise the Bolam test.
3. The mere existence of such a practice is not determinative on the issue of breach of duty.
4. If the Bolam test is raised as relevant in any particular case, there is a duty on the court to determine whether the practice stands up to analysis, i.e. is reasonable. On this question, medical expert evidence may be highly persuasive but is not necessarily determinative. A practice is unreasonable if it exposes a Plaintiff to a risk of harm which is unnecessary and thus unjustifiable.
5. If the practice does withstand scrutiny then the court should find the practice to represent a responsible body of medical opinion (this is synonymous with a finding that the practice was reasonable in the circumstances)<sup>1</sup>. This will be the result in many cases.
6. If the court is faced with two bodies of responsible medical opinion (i.e. that have withstood scrutiny) the court cannot prefer one to the other.
7. However in cases where the alleged negligence is a failure to disclose adequate information prior to obtaining consent, there may be cases where a court can reach its own view as to what is responsible medical practice notwithstanding a common view within the profession as to what would have been proper in the circumstances (see Lord Bridge in Sidaway v. Bethlem Royal Hospital (1985) 1 AC 871).
8. The importance of the Bolam test is that it accommodates different opinions and practices within a profession (this is implicit in the speech of Lord Scarman in Maynard v. West Midlands RHA [1984] 1 WLR 634 at 638). But such views are only accommodated as reasonable if they themselves withstand scrutiny.

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<sup>1</sup> Throughout the "responsible" in "responsible body of opinion" refers to the practice and not to the eminence or qualifications of the medical expert witnesses supporting the practice.

