Ulster Med J 2019;**88(1):**1-3

Guest Editorial

The Physician's Duty to Warn Their Patients About the Risks Associated with Medical Intervention: A Review and Discussion.

CG Leonard and JG Toner

Key words: Medicolegal; Consent; Ethics

ABSTRACT

Since the landmark case of Montgomery v Lanarkshire in 2015[1], much has been written in medical press regarding the implications for medical practice. The moral duty - varied though it has been over this time, has been discussed since the earliest days of the medical profession. The law has sought to define this duty in response to changes in society, and the nature of the relationship between doctor and patient. The moral and legal duty are intrinsically linked, but the latter must surely follow the former for "the law has little to do with morally required forms of communication in the clinic and in the research environment."[2] The common law nature of this process has resulted in an inconsistent and often tortuous path as societal standards have shifted. Accordingly, the ultimate definition of the legal doctrine, "informed consent," has changed since its relatively recent entry into the medicolegal vocabulary. These parallel shifts in the legal and moral duty to disclose risk have resulted in a confusing melee of evidence and recommendations for clinicians. We address the development of the law of "informed consent," as the legal mirror of the moral duty upon a clinician to disclose risk to their patient.

FROM DECEPTION TO CONSENT!

In Ancient Greece during the 4th Century BC, in the Hippocratic writings, patient involvement in decisions surrounding their treatment was considered undesirable. Physicians should inspire confidence; the discussion of risk was felt to erode confidence and even cause psychological harm.[3] On this basis the role of deception remained key to the doctor patient relationship during medieval times. Doctors at this time sought to offer comfort and hope whilst being manipulative and deceitful to affect a treatment or cure.[4]

Even as recently as the 18th and 19th centuries the majority of medical literature advocated avoiding disclosure of any information that may upset and thus harm the patient.[5,6] It was only in the early 1900's that this view began to change. In 1912, *Luka v. Lowrie,* [7] examined a case where a child underwent emergency amputation of a crushed limb. The parents were unavailable and the surgeon, prior to carrying out the procedure, consulted four other physicians. Each concurred with his medical opinion and the proposed course of action. The court ruled that had the parents been available, they would have agreed with the need for the amputation on the grounds of the multiple opinions sought. The "professional test," (later given the eponymous name "Bolam,") was born, and reflected the ongoing paternalistic nature of health care. Just two years later Justice Cardozo stated in *Schoendorff v. Society of New York Hospital,*[8] "every human being of adult years in sound mind has a right to determine what shall be done with his own body." In one sentence, so much of what we now consider normal practice was expressed. Justice Cardozo set the scene for the significant changes seen in the pursuit of patient autonomy during the 20th century.

The duty to disclose risk was subsequently deemed a part of the duty to disclose the nature and consequences of the planned treatment.[9] The moral duty between the doctor and the patient, was now encapsulated legally by two questions. Firstly, was there consent? Secondly was it adequate, or "informed consent?" In the same year as Schoendorff was decided, the courts in the United Kingdom heard *Bolam v Friern HMC* and brought about the eponymous test of consent, dependent upon the body of medical opinion. Despite this, more than twenty years passed before "informed consent," became part of the vocabulary of the English courts.[10] On both sides of the Atlantic, consent to surgery was now no longer, merely a consent to technical assault, but a consent based on a knowledge of the nature, risks and benefits of the treatment. Consent had been imposed upon a medical profession by the judiciary. Ironically, just as the paternalistic approach adopted by the medical community reduced the autonomy of the patient, these rulings were viewed as a reduction in the autonomy of the medical profession. It is perhaps not surprising that the response from the medical profession was critical. At this time there was limited judicial guidance or precedent to establish the legal definition of "informed consent," or indeed what actions by a doctor would satisfy the requirements of the courts. What little common law that did address this point was articulated in such broad terms that it did nothing to dissuade the view that the demands of informed consent were considered clinically impossible.[11] Legally, morally and clinically, there was then as now great uncertainty surrounding the practicalities of risk disclosure.

DEVELOPMENT OF THE LEGAL DOCTRINE: "INFORMED CONSENT."

Sidaway v. Governors of Bethlem Royal Hospital[12] afforded the House of Lords the opportunity to address and examine consent and the doctor's duty to disclose. The plaintiff underwent a spinal cord decompression for neck pain, and suffered paralysis the risk of which was established as at less than 1%, but about which she had not been informed. The House of Lords, judged that negligence was the most appropriate means by which to regulate a physicians duty to disclose information to their patients. The standard of care was predicated on professional practice but Lord Scarman, dissenting, introduced the possibility of the needs of the hypothetical 'reasonable patient.'

Subsequently in *Blyth v. Bloomsbury*[13] the Court of Appeal found in favour of the respondent based solely on professional practice approach but noted that some risks were so central to the decision-making process, that no reasonable doctor could withhold the information. *Bolitho v. City and Hackney Health Authority*[14] expanded upon *Blyth* that all expert evidence must stand up to logical analysis. These two conditions now established the parameters of the professional test, but neither increased patient autonomy.

Chester v. Afshar,[15] examined a case where the plaintiff having undergone spinal surgery, suffered cauda equina syndrome. She had not been informed of such a risk; which occurred in approximately one to two percent of cases. It was deemed that the plaintiff would have considered and pursued alternatives had she been made aware of this risk. A duty to disclose a "small, but well established, risk of serious injury or as a result of surgery," entered the medicolegal field in support of patient autonomy. The General Medical Council (GMC) referenced *Chester* in its guidance on consent published in 2008[16] and recommended that patients should be told of any possible significant adverse outcomes of a proposed treatment. In doing so the GMC advanced the cause of patient autonomy and patient centred decision making (whilst rescinding medical paternalism), ahead of the courts. The GMC guidance explained the need to listen, discuss, share knowledge and to maximise the opportunity for patients to decided for themselves. The GMC also supported the position that consent was a process rather than an event.[17] This wide ranging and detailed guidance on consent, has subsequently been reinforced within the broader GMC document, Good Medical Practice.

It was in this environment, that majority of current junior doctors have entered the profession, and thus will have been taught the shared model of decision making, that the role of the courts re-emerged. In the well-publicized case of *Montgomery v. Lanarkshire Health Board*, the plaintiff, whose son was delivered vaginally, was not aware of the increased risk of the significant complications the child suffered as a result of a vaginal rather than caesarean delivery. Her obstetrician had not disclosed the increased risk of shoulder dystocia and cerebral palsy owing to the plaintiff's stature, and diabetes.[18] The Supreme Court found in her favour, rejecting the majority opinion of *Sidaway* and instead bringing the dissenting view articulated by Lord Scarman to the fore. In doing so they established that patients should be told that which they would wish to know. The GMC, who intervened to make submissions as an independent party, were quick to clarify that this simply brought the law into line with the guidance already in place. However, just as followed the *Salgo* decision and in light of the changing environment of medical practice in the 1970s and 1980s, the response of the medical profession was varied its members voiced concern about the implications for clinical practice.[19]

THE CURRENT POSTION

The prudent patient or "reasonable person in the patient's position," test recognises that non-medical factors can affect the patient's decision. It enhances the patient's autonomy and revokes medical paternalism. The clear moral duty existing between doctor and patient is now supported by a clear legal and professional duty to disclose risk.

The ruling in *Montgomery* sought to clarify further issues relating to clinical practice. Firstly, that materiality cannot be measured as a percentage alone. The nature and effect of the risk, the benefits of treatment and any available alternative treatments are all relevant to an assessment of materiality. Secondly, and as a result of the aforementioned approach to materiality, there is now an established duty on doctors to engage in dialogue. Without dialogue between doctors and their patients, it would appear difficult, if not impossible, for a medical professional to comprehensively assess materiality for an individual.

Despite these clarifications the term "material risks" remains ambiguous to both legal and medical professionals. Post-Montgomery cases have been wide-ranging in nature and have done little to provide definitional clarity to "material risks." Such cases have frequently been dependent on factors beyond mere percentages of risk provided by expert evidence. Subsequently the test of materiality was further broadened as doctors were deemed to not be liable for every omission to which a patient subsequently complains.[20, 21] It seems reasonable to assume, that this uncertainty will be clarified as the common law position advances in the coming years. The prudent or reasonable person test, is currently open to interpretation. Until the test is clarified and refined, it may for a time obfuscate the approach to medical negligence cases. Although this uncertainty, combined with the paucity of such cases that currently find in favour of the plaintiff, is invariably of concern to practicing clinicians.

How then to proceed clinically? It is hard to imagine a valid means within medical practice of auditing the wishes of patient and population groups regarding disclosure of risk – consider for instance the challenge of simulating the position of the patient being given bad news or being offered surgery. *Montgomery* reinforced the current GMC guidance in relation to the nature of consent as a process, rather than an event.

Steps should be taken to reinforce and facilitate patient-led control of the amount of information they receive - (an exhaustive consent should not be mistaken for an informed consent.) The initial discussion with a clinician should be guided by the patient's wishes, but each patient should be provided other means of gathering information (such as through leaflets or websites) and they should be made aware that their consent can be revoked at any time prior to the procedure.

Mr. CG Leonard, ST7 in ENT, LLM Medical Law and Ethics and Mr. JG Toner, MA Medical Ethics and Law.

Department of Otorhinolaryngology – Head and Neck Surgery, Royal Victoria Hospital, Belfast

E-mail: mrcgleonard@gmail.com

REFERENCES

1. United Kingdom, Supreme Court. *Montgomery (Appellant) v. Lanarkshire Health Board (Respondent) (Scotland)*. Case ID UKSC AC 2013/0136. (11 Mar 2015). Available from https://www.supremecourt.uk/cases/uksc-2013-0136.html. [Last accessed November 2018].
2. Katz J. *The silent world of doctor and patient*. New York: Free Press; 1984
3. Murray PM. The history of informed consent. *Iowa Orthop. J*. 1990;10: 104-9
4. Southwick, AF. *The law of hospital and health care administration*. Ann Arbor. Michigan: Health Administration Press; 1988.
5. Percival T. *Medical ethics; or a code of institutes and precepts, adapted to the professional conduct of physicians and surgeons*. Manchester: S. Russell; 1803.
6. United Kingdom. English Reports. *Slater v. Baker and Stapleton*. 95 ER 860, 2 Wils. KB359; 1767.
7. United States. Supreme Court of Michigan. *Luka v. Lowrie*. July 11, 1912. 136 N.W. 1106, Michigan; 1912
8. United States. New York Court of Appeals. *Schoendorff v. Society of New York Hospital*. 211 N.Y. 215, 105 N.E. 92; 1914.
9. Caselaw: California. District Court of Appeal, First District Division 1, California. . 317 P.2d 170; 1957.
10. United Kingdom Queen's Bench Division 432. *Chatterton v Gerson*. QB 432; 1 All ER 257; 1981.
11. Kaufmann CL. Informed consent and patient decision making: two decades of research. *Soc Sci Med*. 1983; 17(21):1657-64.
12. United Kingdom. House of Lords. *Sidaway v Governors of Bethlem Royal Hospital*. 1 AC 871; 1985.
13. United Kingdom. Court of Appeal. Blyth v. Bloomsbury. AHA 4 Med LR; 1993.
14. United Kingdom. House of Lords. *Bolitho v. City and Hackney Health Authority*. AC 232; 1998.
15. United Kingdom. House of Lords. Appeal Court. *Chester v. Afshar*. UKHL 41 2004. , 1 AC 134; 2005.
16. General Medical Council. *Consent: patients and doctors making decisions together*. London: General Medical Council 2008. Available from: https://www.gmc-uk.org/-/media/documents/Consent___English_0617.pdf_48903482.pdf. [Last accessed November 2018].
17. United Kingdom. Supreme Court. *Montgomery (Appellant) v. Lanarkshire Health Board (Respondent) (Scotland)*. SC 11 [2015] 1 AC 1430; 2015
18. Sundar S. *Case based laws are turning into "emperors new clothes." Br Med J*. 2015. Available from: https://www.bmj.com/content/350/bmj.h1481/rr-23. [Last accessed November 2018].
19. Tyler F. *Supreme Court decision changes doctor-patient relationship forever*. Edinburgh: Balfour and Manson; 2015
20. United Kingdom. England and Wales High Court, Queen's Bench Division. *Spencer v. Hillingdon Hospital NHS Trust*. EWHC 1058; 2015.
21. United Kingdom. England and Wales High Court, Queen's Bench Division. *Mrs A v East Kent Hospitals University NHS Foundation Trust*. EWHC 1038; 2015.