

Informed consent for surgery: A historical review

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Summary

Background: Many surgeons see the process of obtaining informed consent for an operation from a patient beginning and ending with the signature of the patient on the consent form. Indeed this is not so as this process is deeper than that and all operating specialists need to understand the origin of this process, the developments and the areas where interpretations may be difficult. This is to ensure that implementation of the process of informed consent is mutually beneficial to both patient and doctor.

Method: Literature dealing with the origin and history of informed consent, its principles, various interpretations and experiences in various subspecialties was reviewed.

Results: The informed consent process arose from the proceedings of the Nuremberg trial in 1947 to ensure that such atrocities that were committed on human beings in the pursuit of medical research were never repeated. The basic tenet of the informed consent rests on the autonomy of the patient which is explained as being the legal embodiment of the concept that each individual has the right to make decisions affecting his/her well-being.

Areas of possible controversy which includes the interpretation of competence and understanding of the patient in the light of adequate information from the doctor were also highlighted.

Conclusion: It is apparent from the wealth of literature on this subject that there is still a problem regarding the lack of guidelines towards achieving the perfect informed consent.

Key-words: *Informed consent, Surgery.*

Résumé

Introduction: Un grand nombre de chirurgiens voient le processus d'obtenir le consentement averti pour une opération de la part du patient à partir du commencement jusque à la fin avec la signature de patient sur un formulaire du consentement. En effet, ceci n'est pas vrai parce que ce processus est plus profond que ça et tous chirurgiens spécialistes doivent comprendre l'origine de cet processus, le développement et les domaines où des interprétations pourront être difficile. C'est tout simplement d'assurer que la phase de mise en oeuvre du processus du consentement averti est toujours bienfaisante mutuellement aux patients et médecin les deux.

Méthode: Littérature qui étudie l'origine et l'histoire du consentement averti, ses principes, des expériences et interprétations diverses dans des sous spécialités diverses était passe en revue.

Résultats: Le processus du consentement averti est provoqué

par le procès du Nuremberg en 1947 afin d'assurer que telle atrocité qui ont été commises sur l'homme tout en poursuivant des recherches médicales ne sont jamais répétées. Le principe majeur du consentement averti repose sur l'autonomie du patient expliquée comme étant l'incarnation légale de la concept que chaque individu possède comme le droit de prendre des décisions qui altère le bien-être du soi. Les domaines de la controverse éventuelle y compris l'interprétation de la compétence et la compréhension du patient prenant en considération des informations adéquates de la part du médecin ont été également soulignés.

Conclusion: A la suite de cette littérature bien recherchée sur ce sujet c'est clair qu'il y a encore un problème concernant la pénurie des directives pour la réalisation du consentement averti parfait.

Historical review

Concern for the participation of a patient in the choice of his treatment stemmed from the horror of the Nazi experimentation on prisoners during the 2nd world war. The Nuremberg code, which resulted from a United States military tribunal in the German city of Nuremberg during the trial of 27 Nazi doctors in 1947, was instituted to ensure that such horrific practices never happened again. This code stressed that the voluntary consent of the human subject is absolutely essential. This was the first document to establish the autonomy of the patient.¹

Informed consent can be explained as being the legal embodiment of the concept that each individual has the right to make decisions affecting his/her well-being.²

This is also interpreted as guaranteeing each and every patient the right to self-determination.^{3,4} However in spite of the Nuremberg code many physicians ignored this concept of patient autonomy and this led to a spate of scandals e.g. The Manhattan project in 1946, the Willowbrook Hepatitis study in 1956, the Brooklyn Jewish Chronic Disease Hospital in 1963 and the Tuskegee Syphilis study from 1942-1972, to name a few.^{1,5}

Physicians started to sit up when the courts stepped in by making the physicians liable for not informing their patients before interventions are taken. The informed consent law developed from the intentional tort of battery, which protects the individual from unwanted physical touching of the body by one having neither express nor implied consent of the person touched nor a privilege to do so.²

In the medical setting this occurs when the physician performs a treatment without the consent of the patient, performs a substantially different procedure than the one for which consent was given, exceeds the scope of the consent

or a different physician than the one to whom consent was given carries out the procedure.²

There are records of court cases that have established and sharpened the awareness of the important role of informed consent in medical/surgical practice.

Schoendorff v Society of New York Hospital in 1914 was said to have established the doctrine of patient autonomy^{5,6} and this was many years before the 2nd world war, before the Nuremberg code, yet it seemed the message did not hit home. In December 1946 the Atomic Energy Commission (AEC) suspended the Manhattan Project in which hospitalized patients were injected with plutonium without their knowledge.

Among the standards ultimately established by the AEC was "Informed Consent".¹

A 1957 malpractice case of Salgo v Leland Standrod Jr University Board of Trustees was said to have popularized and established the doctrine of informed consent. This suit required the disclosure of the nature, consequences, risks and alternatives of a proposed procedure^{1,6}. The Kansas Supreme court in the case of Natanson v Kline in 1960 pioneered the use of the legal charge of negligence in informed consent cases rather than that of battery. The court also upheld the duty of disclosure (vide supra Salgo v Leland)⁵. One author ascribes the coinage of the phrase "informed consent" to the Kansas Supreme Court in 1966.⁷ Subsequently this "Doctrine of Informed Consent" seemed to place a great legal burden on the medical practitioners.^{2,7,8} In the United States, malpractice cases have increased markedly and these suits are usually against surgical specialities. Orthopedic surgeons, Plastic surgeons, General surgeons and Anesthetists are usually sued in that order. The highly competent surgeons have the greater likelihood of being sued since the more difficult and tricky cases will be referred to them.⁸

The doctrine of informed consent requires the physician prior to any diagnostic or therapeutic procedure which carries with it a reasonable possibility of harm to explain the risks of the procedure and its alternatives and to secure the **competent, voluntary and understanding** consent of the patient to proceed.³ (Emphasis mine).

Herein lay the points of controversy, which have made full implementation of informed consent contentious.

Several authors share the feeling that there is no prescribed method for satisfying the mandates of the doctrine of informed consent^{2,5,9,10,11,12}.

Disclosure

It is on record that the California Supreme Court noted that "one cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved"². Indeed no physician can avoid liability under the informed consent laws unless he/she discloses every known risk and alternative to every patient.²

Practicing surgeons and anesthetists know it is virtually impossible to enumerate every known risk about a procedure or the use of any anesthetic agent as new complications and idiosyncratic reactions come to light every day.

Several authors believe that improving the process of communication between doctor and patient will move us closer towards obtaining the ideal informed consent^{11,13} while others feel the process of informed consent actually interferes with this relationship¹². The lack of consensus about what constitutes full disclosure of a procedure is also problematic as individual surgeons have differing views^{13,20}, and different sovereign laws have different views; it is on record that British law on informed consent does not require as high a standard of disclosure as do American and Canadian law. British law allows that the patient is entitled to be informed according to the practice adopted by a competent body of the physician's peers rather than an absolute duty of full disclosure^{9,21}.

The risk of contravening the principle of non-maleficence by 'harming' the patient with too much information has been raised. Some authors have revealed that a lot of the information presented to the patient is not understood or is rapidly forgotten²², another antagonist of full disclosure feels that too much detail is counterproductive² yet some still believe that patients should be given the benefit of the doubt by giving them as much information as possible.²³

Voluntariness

It has been shown in a study that residents, especially first year residents, are unable to provide patients with correct appraisals of the risks, extent of surgery, alternatives and complications whilst taking informed consent.²⁵ For this reason it is debatable whether the autonomy of such patients is fully exercised since they are not provided with enough information to make an informed choice of either consenting to or refusing the operation.²³ Thus it is advisable that consultants take the trouble to have these informed consent discussions with their patients as this fosters a good doctor-patient relationship which many believe goes a long way in preventing malpractice suits.^{11,13,26,27} Paternalism which is explained as being the influence wielded over another in influencing decisions usually from someone with greater authority or influence over one in a subjugate position e.g. a doctor to a patient²⁸, in medicine has been said to be an inseparable part of the practice²⁹, yet how much of this affects the informed consent process is yet to be concisely determined as some feel that the hospital patient cannot be totally autonomous while others believe they can.²³

It has been shown that too much disclosure to patients may have adverse results²², yet one is required to let the patient know as much as possible²³. This dilemma is yet to be fully reconciled and as has been recorded above, different countries may interpret this differently.^{9,13,20,21}

Patient comprehension

Studies on 'competent' patients reveal that up to 60% do not remember major parts of the informed consent interview shortly after their operations and this recall worsens 4-6 weeks after the operation.^{14,15,16,17,18} These studies also shed light on the fact that patients who were younger, better educated and with greater than average IQ had better recall of the informed consent interview and thus were expected to comprehend and better exercise their autonomy.^{18,19} A way of

avoiding litigation is suggested by having written preoperative information about routine operations made available to the patients.^{14,15,17,19} This maneuver probably echoes the 'legal burden' as well as the interference that informed consent processes raise with the doctor/patient relationship.

"To be of benefit to the physician, the consent forms must help him in meeting his duty to inform the patient or in protecting him from a patient's claim that his was not an informed consent (or both). Consent forms are of no benefit to the physician or the patient if they are worded poorly or put to poor use"²⁴ Having the consent forms printed in a language which the individual patient understands agrees with the principle of bioethics^{30,31}. Some authors also prefer the forms to be specific for each procedure, although this does not eliminate possible allegations that the patient did not understand the form or was not given sufficient time to comprehend the nature of the procedure, however such allegations are tremendously weakened by proper use of a comprehensive form.³¹

In conclusion, a proper informed consent process requires information or disclosure (from doctor to patient), comprehension (by the patient), voluntariness (lack of coercion or persuasion), agreement or assent (in principle after opportunity to ask questions and ruminate), then consent.^{23,28}

This had been alluded to above in the history of informed consent as being a difficult thing to achieve as many studies have shown.¹⁴⁻²¹

It is apparent from the wealth of literature on this subject that there is still a problem regarding the lack of guidelines towards achieving the perfect informed consent. How much disclosure is appropriate? What is the best way to measure patient comprehension? Is the nurturing of a good doctor/patient relationship the panacea to litigation?

It has been a little under 100 years since the first acclaimed court case for lack of informed consent yet there still seems to be difficulty in packaging this process so that its implementation is uniform globally. It is probably better for surgeons to think of the informed consent process as "a wonderful opportunity to communicate their personal concern to the patient as a person, not just a sick gall bladder to remove"¹³

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References

1. Emanuel E J, Crouch R A, Arras J D, Moreno J D, Grady C. Ethical and Regulatory Aspects of Clinical Research. Readings and Commentary. 2003. The Johns Hopkins University Press Baltimore.
2. Merz J F. An empirical analysis of the medical informed consent doctrine: Search for a standard of disclosure. <http://www.fplc.edu/RISK/vol2/winter/merz.htm> pages 1-30. Accessed 2/12/05.

3. Herbert V. Informed consent- a legal evaluation. *Cancer* 1980; 46; 1042-1044.
4. Martin R M. Law and the minor patient. *Southern Medical Journal* 1982; 75: 1245 - 1248.
5. Beauchamp T L, Fadden R R. A history and theory of informed consent 1986. New York. Oxford University Press.
6. Poland S C. Landmark legal cases in bioethics. Kennedy Institute of Ethics Journal 1997; 7: 191-209.
7. Brown R H. Consent. *Pediatrics* 1976; 57, 414 - 416.
8. Brown R H. The pediatrician and malpractice. *Paediatrics* 1976; 57: 392 - 401.
9. Plumeri P A. The Gastroenterologist and the doctrine of informed consent. *Journal of Clinical Gastroenterology* 1983; 5: 185-187.
10. Goodman R S. Legal liability and orthopedic surgery-Informed request. *Orthopedics* 1984; 7: 1764-1766.
11. Buehler D A. Informed consent - Wishful thinking? *Journal of Bioethics* 1982-1983; 4(1-2): 43-57.
12. Lidz C W, Applebaum P S, Meisel A. Two models of implementing informed consent. *Archives of Internal Medicine* 1988; 148: 1385-1389.
13. Edwards W S, Yahne C, Thomas G, Orr Memorial Lecture. Surgical informed consent: What it is and is not. *American Journal of Surgery* 1987; 154: 574-578.
14. Robinson G, Merav A. Informed consent: Recall by patients tested postoperatively. *Annals of Thoracic Surgery* 1976; 22: 209-212.
15. Wade T C. Patients may not recall disclosure of risk of death: Implication for informed consent. *Medicine, Science and Law* 1990; 30: 259-262.
16. Herz D A, Looman J E, Lewis S K. Informed consent: Is it a myth? *Neurosurgery* 1992; 30: 453-458.
17. Layton S, Korse J. Informed consent in oral and maxillofacial surgery: A study of the value of written warnings. *British Journal of Oral and Maxillofacial Surgery* 1994; 32: 34-36.
18. Hekkenberg R J, Irish J C, Rotstein L E, Brown D H, Guillane P J. Informed consent in head and neck surgery: How much do patients actually remember? *Journal of Otolaryngology* 1997; 26: 155-159.
19. Lavelle-Jones C, Byrne D J, Rice P, Cuschieri A. Factors affecting quality of informed consent. *British Medical Journal* 1993; 306: 1273.
20. McManus P L, Wheatley K E. Consent and complications: Risk disclosure varies widely between individual surgeons. *Annals of the Royal College of Surgeons of England* 2003; 85: 79-82.
21. Brahm D. Informed consent does not demand full disclosure

- of risks. *Lancet* 1983; 2 (8340): 58.
22. Wallace L M. Informed consent to elective surgery: The 'therapeutic' value. *Social Science Medicine* 1986; 22: 29-33.
23. Kottow M. The battering of informed consent. *J Med Ethics* 2004; 30: 565-569.
24. Moore R M Jr. Consent forms- how, or whether, they should be used. *Mayo Clin Proc* 1978; 53: 393-396.
25. Angelos P, da Rosa D A, Bentram D, Sherman H. Residents seeking informed consent: are they adequately knowledgeable? *Current Surgery* 2002; 59: 115-118.
26. Krause H R, Bremerich A, Rustermeier J. Reasons for patients' discontent and litigation. *J Cranio-Maxillofacial Surg* 2001; 29: 181-183.
27. Neale G. Informed Consent. *Gut* 2000; 46: 5-6.
28. Beauchamp T L, Childress J F. *Respect for autonomy*, Chapter 3, in *Principles of Biomedical Ethics*, 5th Edition, Oxford University Press 2001; 57-103.
29. Jay Katz. *Reflections on Informed Consent: 40 years after its birth*. American College of Surgeons Committee on Ethics. 1997 Ethics and Philosophy Lecture.
30. Committee on Bioethics. *Informed consent, parental permission and assent in pediatric practice*. *Pediatrics* 1995; 95: 314-317.
31. Weber T J. *The expanding requirement for informed consent in the practice of dentistry*. http://www.gkslaw.com/dentistry_informed_consent.html. Accessed 2/12/05.