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Ethical and Legal Manifestations of Informed Consent

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Abstract. Informed consent to medical/surgical treatment, or "permission granted in the knowledge of the possible consequences" is an important, and sometimes contentious and controversial component of clinical practice. From an ethical, legal and philosophical perspective; informed consent has significant implications for health care providers. The three principal elements of informed consent are 1) thorough presentation of information, 2) patient's capacity to comprehend (competence), 3) patient's voluntary willingness to undergo or refuse treatment. The history of informed consent is highlighted by precedent-setting legal cases (Schloendorff v. Society of New York Hospital [1914]), the atrocities of World War II and subsequent 1947 Nuremberg Trials and, current HIPAA regulations and guidelines. Informed consent involves shared decision-making between provider and patient. Including patients acknowledges and safeguards patient autonomy such that health care decisions are made based on respecting individual preferences, goals, values, beliefs, objectives, and desires. Providers act as advocates for patients' rights. These are fundamental premises of today's patient-centered care.

Keywords. informed consent, ethics, law, medicine

Introduction

With foundations in ethics, law, and philosophy, informed consent is a component of ethical clinical practice with significant implications for all health care providers. Underlying principals forming the foundation of informed consent are 1) adequate and thorough dissemination of information, including alternatives, 2) capacity of the patient to comprehend (competence), 3) voluntary willingness of patient to undergo or refuse treatment, without coercion or duress. New Oxford Dictionary defines informed consent as "permission granted in the knowledge of the possible consequences." A precedent-setting case (Schloendorff v. Society of New York Hospital [1914]) involved a surgeon who removed a fibroid after the patient had consented to examination under ether but requested no surgery be performed. The court found "every human being of adult years and sound mind has a right to determine what shall be done with his body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." This landmark decision established the legal doctrine that a competent person may consent to, or refuse intervention after being provided necessary information to make a decision. Today, that surgeons' action would constitute battery. To be liable, invasive treatment without consent does not require physical injury, only lack of permission (Calfee 1994). In another precedent-setting case, (Salgo v. Leland Sanford, Junior. University Board of Trustees [1957]), trans lumbar

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aortography resulted in a patients' paralysis. As a result of that case, the explanation of the risks of a procedure became a required component of informed consent. Today, failure to explain risks constitutes negligence. In the mid-1960s, the US Food and Drug Administration, National Institutes of Health, and institutional review boards formulated policies for research to protect human research subjects. In 1972, a child suffered serious complications following a thoracic laminectomy. Preoperatively, when the mother asked if the operation was serious, she was told "not any more than any other operation." In the suit that followed, the judge wrote that because most patients have little understanding of medicine, there exists a need for "a reasonable divulgence by physician to patient" (Canterbury v. Spense [1972]). This ruling introduced the patient-oriented standard that includes a requirement to disclose risks and alternatives necessary to affect the decision of a "reasonable person." International law significantly contributed to defining informed consent. In 1947, 20 Nazi physicians were tried in Nuremberg, Germany, for atrocities performed on prisoners in the name of furthering medical science (Vollman 1996). Those remain the most blatant abuse of the physician code of ethics. Experimentation without consent and acts of cruelty to others has occurred throughout the world. Prisoners and mental hospital patients were used as subjects to test theories without knowledge or consent (Rothman 1991). The Nuremberg Code of Ethics established the rights of subjects in research experiments and ethical responsibility of the researcher.

There are three exceptions to the requirement of obtaining IC. Most notable is "when immediate intervention is necessary to prevent death or serious harm to the patient." (ACER 1997) The rationale being consent is implied when a patient presents for emergency care. Providers must make three important judgments: treatment is necessary, can't be delayed and the patient would consent to the treatment. For example, intra- arterial thrombolysis after acute stroke may preclude obtaining IC. The patient may not be able to sign and family may not be available. Informed consent to treat raises unique issues in emergencies when time is of the essence. Patients may also waive their right to consent, delegating decision-making to the physician or to others. Clinicians may modify the consent process, including withholding information, if a full disclosure might have an adverse effect on patient condition (therapeutic privilege; Slater v. Hehoe, [1974]). This exception considers the potential, negative physical effects of a patient's precarious emotional or mental state.

Discussion: More than a professional responsibility, IC is a means of respecting and promoting patient autonomy and countering paternalism. As stated in the ACR Code of Ethics, "Radiologists should be aware of their limitations and be willing to seek consultations in clinical situations where appropriate. These limitations should be appropriately disclosed to patients and referring physicians." Specialty societies have specific standards and policies on IC including indications for obtaining consent, recommended qualifications and expected responsibilities of personnel obtaining consent, and specifications and documentation of the consent process for elective and emergency procedures.

One of two standards dictate the required degree of disclosure: 1) reasonable person standard: requires providing the amount of information a reasonable person would want to know to make an informed decision. 2) professional standard: information a reasonable provider in the community would disclose under similar circumstances (Beauchamp 1997). Yet, patients vary in ability to make decisions about complex medical situations. They may not understand everything presented to them. The level of understanding required should be proportional to the risks of the procedure. Although patients do not need to understand the procedure as well as providers, they need enough information to adequately understand benefits, risks and alternatives. Many question whether consent to medical procedures can ever be truly informed. A complex procedure with myriad technical details and potential options precludes full

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disclosure. Too little information may result in potential legal consequences. Too much information may be confusing and intimidating. Providers may not know a patients' specific goals and values, or which alternative best suits their needs.

The autonomous nature of physicians leads some to argue they should be making decisions; reinforcing the traditionally paternalistic nature of medicine. Encyclopedia of Bioethics considers IC the antidote to paternalism ("practices that restrict the liberty of individuals, without their consent, where the justification for such actions is the prevention of harm they will do to themselves or production of benefit for them they would not otherwise secure.") Many physicians continue to practice under the notion "I know what's best for my patient, don't question me!" Patients come for their expertise - and they're trained to make the best decision. Many physicians lament "the good old days" when they were empowered to make decisions while patients acquiesced -"whatever you think is best, Doc." Discussing options and expressing uncertainty about selecting treatments may appear to diminish expertise. Patient-centered care and patient education has "moved the goal posts."

Busy providers may oppose or resent the consent process, considering it an onerous requirement imposed by lawyers; requiring little attention. The task may get delegated to the most junior and least experienced team member. Junior staff are often the busiest, more interested in simply documenting consent. Such a perfunctory consent process may satisfy the law, but not its intention. Consent should not be viewed as a defense against liability but rather a forum for education and information exchange. In some cases, patients don't choose the provider performing a procedure. The brief conversation about consent may be the only opportunity to meet. After the procedure, this brief discussion may be all a patient remembers.

A patient's willingness to consent is influenced by many factors, including rapport with provider, provider's ability to allay patients' fears, and description of risks. As more clinicians interact less directly with their patients in the interest of efficiency, patients may feel pressured to sign consent forms without sufficient time to contemplate options and consequences. Consent forms may be written with legal terminology too complicated to understand, written to protect against litigation rather than inform. Educational materials given to the patient and their family before the procedure create an opportunity to evaluate the information carefully.

Many factors affect a patient's ability to understand and reason. Medications, diminished mental capacity, altered mental status, ability to communicate, comprehension, understanding implications of the illness, ability to weigh risks/benefits/alternatives. Determining patient competence/capacity to consent requires judgment. Family members may assume decision-making, adding subjectivity based on individual goals and values.

Without a uniform manner of obtaining IC, there is no uniform consensus on the level of disclosure. Providers explain procedures, risks, benefits, and alternatives in various styles. Patients may not possess enough knowledge to ask truly meaningful questions. Patient indifference makes it difficult to know how much information a patient really wants, especially if patients view consent as simply a legal process.

Informed consent is more important as new, more complicated procedures are performed. We ascertain that adequate clinical trials are performed to deem a procedure safe and ensure adequate training. Weekend courses to credential clinicians are commonplace, but who should perform new, high-risk procedures? How many of a certain procedure should one be required to perform under direct supervision before performing them unsupervised? Must we reveal how few times we've performed a procedure? Is it realistic to have a formal credentialing process for each individual, and each new procedure?

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The availability of alternatives to procedures may be controversial with regard to safety, cost, contrast considerations, radiation dose, insurance coverage, etc. The American College of Radiology "ACR Appropriateness Criteria™" are a helpful guideline. When alternative, safer options are available to answer a clinical question, providers are obligated to tell their patients about them. For example, MR is readily available, yet myelography (safe but invasive) is still performed frequently, despite "Appropriateness Criteria" recommending MR over myelography in all clinical conditions evaluated (ACR). Occasionally, an insurance company approves one exam over another. Third party payers affect informed consent.

Technologic advances raise questions related to IC. Is the device FDA approved? Is it approved for the proposed use? Under FDA approval process 510(k), (Prokopetz 2013) manufacturers need only show their device is similar to an existing approved product. To decrease time taken to approve new devices or drugs, FDA Modernization Act of 1997 (Sharav 2003) allows them to be marketed before clinical trials are completed. Once approved, its use may not be monitored. Ethics dictate we reveal details to patients and document the conversation. For example, a woman developed a hemorrhage following AVM embolization. The FDA, despite use in Europe, did not approve the embolic agent. A lawsuit was filed alleging she would not have consented to the procedure had she known the material was not FDA approved. The lawsuit was withdrawn after defense expert's testimony that radiologists were divided whether the IC process should include discussion of FDA regulatory status of the embolic agent and that it was not unreasonable to omit this information in IC discussions. Most decisions addressing informed consent and non-FDA approved devices held that FDA regulatory status need not be included in the IC process (Smith 1999).

Of interest in teaching hospitals is trainee supervision. Trainees need hands-on experience performing procedures independently. At busy institutions, these procedures are performed without significant or direct supervision by experienced attendings. Should patients be told a first-year resident is performing their procedure? How many fully informed patients would not give consent and insist on someone with more experience? How much detail about the physician's credentials should be discussed before the procedure? Are patients familiar enough with details of training and certification? How much experience is necessary to safely perform a procedure? Medicare regulations requiring direct supervision of trainees performing procedures may improve patient care short-term. Will training programs suffer long term? (CMS)

Performance of a procedure by someone in a group less qualified than another is often unavoidable due to scheduling. Is it ethical, honest realistic or practical to tell a patient the person more qualified to perform their elective procedure returns from vacation tomorrow? Must the patient be told the larger group across town has a partner with specialized training? Does informed consent include divulging a provider has not done that procedure in 6 months? How much information will, or should, be shared with the patient is variable.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) seeks to assure health insurance portability, reduce healthcare fraud and abuse, enforce standards for health information and guarantee the security and privacy of health information. It addresses issues relevant to providers such as security and protection of individually identifiable patient information. (Shalowitz 2006). Protecting patients' right to privacy of healthcare information should be a priority. When there’s a need to access patient information for research purposes, should one obtain patient consent? An IRB may waive obtaining patient consent to use their personal health information for research purposes. There may be instances where consent should be obtained nonetheless. Although several journals require patient consent before publication, most do not. Failure to obtain consent may be considered an ethical, if not legal,

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breach of privacy and confidentiality. If no identifying information is revealed, perhaps consent does not need to be obtained?

Informed consent should be tailored to individual situations. It should be considered a virtue, not an obligation. Obtaining a signature on a form is not the ultimate goal. Clinicians have an ethical obligation to obtain informed consent. Even if not fully informed, consent must be ethically sound. Clinicians should not negotiate with patients or manipulate the decision-making process. Consent under duress is the antithesis of voluntary choice. Provider recommendations and guidance are welcome and often powerful. This influence must be monitored.

Informed consent involves shared decision-making between clinician and patient. Including patients in the decision-making allows them to make health care decisions based on their individual preferences, goals, values, beliefs, objectives, and desires. Clinicians do their part to acknowledge and safeguard patients' autonomy; arguably the most important concept in informed consent. By maintaining a strict regard for the preferences of their patients, clinicians advocate for patient rights. Minors are unable to provide legal consent; usually via a parent or legal guardian. This assumes the parent will place the best interests of the child in decision-making. However, one can find religious, cultural, and social positions that may place the parent in direct opposition with the provider when defining what is in the best interest of the child. The provider is charged with providing care that the minor needs, regardless of what the parent or guardian may specify as being in the child's best interests based on those beliefs. In situations where parental beliefs are at odds with the physician and standard of care, legal relief may be a last resort, assuming custody of the child to provide the appropriate standard of care (Bartholome, 1995). Such is the case in Jehovah's Witness families who refuse blood transfusions for their children. Courts have consistently ruled in favor of transfusion when medically necessary, despite the parents' objections (Guichon & Mitchell, 2006).

Conclusions

A signed consent form may provide very little protection against litigation. It cannot absolve a provider from responsibility. Although most states do not require consent be in writing, there should be written evidence consent was obtained. Clinicians should not wait until they are sued to carefully evaluate their consent process. If we speak openly with patients, and treat them with respect, sensitivity, and compassion; they are less likely to become future plaintiffs. An appropriate consent process contributes greatly toward increased patient satisfaction; a vital component of adding value to the experience of our patients.

References

[1] (ACER) Am College of Emergency Physicians (1997) Code of ethics for emergency physicians. Ann Em Med 30:365-72
[2] American College of Radiology "ACR Appropriateness Criteria™" 1996, reviewed 2015. www.acr.org
[3] American College of Radiology, Code of Ethics. www.acr.org
[4] Bartholome, W (1995) Informed Consent, Parental Permission, Assent in Ped Practice. Pediatrics, 95, 314-317.
[5] Beauchamp, T (1997) Medical Ethics, 2nd ed Veatch R, editor. Jones and Bartlett 197-8
[6] Calfee (1994) Ambulatory Surgery & Outpatient Procedures: Advances in Nursing Practice: Amer Healthcare Inst
[7] Canterbury v. Spense, 1972
[8] Centers for Medicare & Medicaid Services, HHS, 42 CFR § 415.208

Technium Social Sciences Journal
Vol. 8, 753-758, June 2020
ISSN: 2668-7798
www.techniumscience.com

[9] Guichon, J, Mitchell I (2006) Medical emergencies in children of orthodox Jehovah's Witness families: Three recent legal cases, ethical issues and proposals for management. Pediatric Child Health, 11(10), pp. 655-658.
[10] Prokopetz J, Katz J, Losina J, et al (2013) Preceding the Procedure: Medical Devices and Shared Decision-Making Arthritis Care Res Jan; 65(1): 148–151.
[11] Rothman D (1991) Strangers at the Bedside: A history of how law and bioethics transformed medical decision making. Basic Books Inc.
[12] Salgo v. Leland Sanford, Junior. University Board of Trustees, 1957
[13] Schloendorff v. Society of New York Hospital, 1914
[14] Shalowitz D, Wendler D. (2006) Informed consent for research and authorization under the Health Insurance Portability and Accountability Act Privacy Rule Ann Intern Med. 2;144(9):685-8.
[15] Sharav V (2003) The impact of the Food and Drug Administration Modernization Act on the recruitment of children for research. Ethical Hum Sci Serv. 5(2):83-108.
[16] Slater v Hehoe, 1974
[17] Smith J, Berlin L (1999) Off-Label use of medical devices AJR 173; 539-542
[18] Vollman J, Winau R (1996) Informed consent in human experimentation before Nuremberg. 313: 1445–9