



THE IMPORTANCE OF PHYSICIAN DIRECTED INFORMED CONSENT

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The process and scope of procedural/surgical informed consent has changed dramatically with emerging technologies, expanding medical knowledge, updated outcomes data and increased recognition of patient autonomy. With the paradigm shifting towards ethical considerations of patient care and active involvement of patient's in their treatment, medical practices and laws have evolved to guide communication standards between the patient and physician. The delivery of all relevant information should enable the patient to make an informed decision regarding the procedure, while preserving the core principles of patient understanding and free consent, devoid of coercion or manipulation.^{1,3} Additionally, education and counseling delivered during the informed consent should relieve the patient's safety concerns related to procedures and to address patient knowledge deficiencies, present other alternative plans or procedures, as well as any possible perceived coercion related to noninvasive and invasive procedures. The intent of this thesis will be to further explain the rationale for the performing provider, attending physician or surgeon, to be the sole person ultimately responsible for providing the patient with the goals, risks and benefits of the proposed treatment or intervention; and for the words and actions of any other medical team member (such as medical students or residents) that may assisting during the informed consent process.

Guidelines and regulations

According to guidelines from 410 ILCS 305/3, "informed consent means where a health care provider has implemented opt-in testing, a process by which an individual or their legal representative has been notified verbally or in writing that the test is planned, has been given the opportunity to ask questions and the opportunity to decline testing."² Encouraging active involvement of the patient and/or surrogate offers the medical layperson the opportunity to gain a deeper understanding of complex medical conditions along with the evaluations and management, thereof. The education and presentation of other alternative treatment plans represents an empowerment of the patient, which promotes a shift from paternalistic medical decision making towards one that encourages a more autonomous approach where the patient weighs his/her options before a decision is made.

There are inherently differing interpretations among health care practitioners regarding the elements of informed consent, and thus a higher degree of standardization is required in order to provide the necessary information that the patients and/or medical decision makers (i.e. residents and fellows), must discuss in order to make potentially complex decisions. This is the legal, not ethical, obligation of the profession where standards have been provided by accreditation organizations such as The Joint Commission, American Board of Medical Specialties, Centers for Medicare and Medicaid Services and the American Medical Association.³ The code of federal regulations state that, "...the practitioner, who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment, must explain in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonable foreseeable associated risks, complications or side effects;

¹ Deiter P. (2008). Informed consent and consent forms. *The Permanente journal*, 12(2), 53–54. doi:10.7812/tpp/07-065

² 410 ILCS 305/3

³ Jessica J. Flinn, *Personalizing Informed Consent: The Challenge of Health Literacy*, 2 *St. Louis U.J. Health L. & Pol'y* 379 (2009)

reasonable and available alternatives; and anticipated results if nothing is done.”⁴ 21 CFR 50.20 provides guidelines which state that the information that is provided to the patient and his or her family member should be in a language that is understandable to the subject entailed.⁵ “Patients are not in a position to judge whether the information provided is complete but they may certify that they understand the statement in the consent document and are satisfied with the explanation provided by the consent process.”⁶ Nevertheless, in daily practice, other members of the care team (i.e. – medical students, nurse practitioners) who are not directly performing the procedure/surgery to which the patient is consenting, may be the only members of the care team providing this information to the patient. However, according to the regulation above, only the surgeon or person performing the procedure to be the one responsible for a complete and understandable informed consent process.⁷ “Failing that, liability may be imposed on a non-disclosing doctor for the material risks of the medical procedure that eventuate. The jurisdictions are divided on whether the required disclosures should be determined in accordance with professionally based standards of what a reasonable medical practitioner would be expected to disclose, or by lay standards based on what information a reasonable patient would deem material.”⁸

One case that illustrates this issue is the *Shinal v Toms*⁹ case. The conclusion of this case determined that the “physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent”.¹⁰ This case resulted in the change of institutional (University of Pittsburgh Medical Center) and statewide informed consent policy stating “attending physicians are responsible for obtaining informed consent, advanced practice providers or medical students may not obtain informed consent, and nurses may not obtain informed consent.”¹¹ “Medical residents may not be in the position to offer the level of care to patients that an experienced physician, particularly a specialist, could provide.”¹² As such, while other members of the care team can and should be involved in the consent process, the primary attending physician responsible for the patient must satisfy his/her central role in any informed consent.

Risks and benefits provided by performing physician

In addition to standardizing the role of the provider in the informed consent process, medical education provided by the practitioner(s) must be conveyed in a manner that is both understandable to the patient and omits any potential institutional bias to sway the patient’s opinion to serve the institutions. This in and of itself, is a challenging barrier to creating a standardized

⁴ 38 CFR § 17.32

⁵ 21 CFR 50.20

⁶ FDA: A Guide to Informed Consent: *Guidance for Institutional Review Boards and Clinical Investigators*. Jan 1998. Retrieved from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent>

⁷ *Cobbs v. Grant*, 8 Cal. 3d 229

⁸ ARTICLE: THE STANDARD OF CARE FOR RESIDENTS AND OTHER MEDICAL SCHOOL GRADUATES IN TRAINING, 55 Am. U.L. Rev. 683, 718

⁹ *Shinal v. Toms*, 640 Pa. 295

¹⁰ *Id* at 10

¹¹ Samuel D. Jr. Hodge; Maria Zambrano Steinhaus, *The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain a Procedure to the Patient May Be Delegated*, 71 Ark. L. Rev. 727 (2019).

¹² A. Antoine Kazzi et al., *Emergency Medicine Residency Applicant Educational Debt: Relationship with Attitude Toward Training and Moonlighting*, 7 Acad. Emergency Med. 1399, 1405 (2000)

informed consent given the lack of a universally defined format among differing facilities – a discrepancy that arises due to differing practitioners, administrators, and most of all, patient population. Hoegen et al. further elaborates on this impediment when she states that, “...thresholds for determining the content of information conveyed to patients before surgery are informal and unsettled, particularly in addressing newly discovered risks of otherwise well-established surgical and anesthetic interventions”.¹³ This especially poses a unique challenge to those with language and literacy barriers. In an article written by The Joint Commission, barriers on informed consent include: Ineffective provider-patient communication, lack of shared decision making, lack of consideration of the health literacy of patient, lack of consideration of cultural issues and, lack of basic information on the consent form.¹⁴

Still, it is universally agreed upon that at minimum, the physician should provide the salient benefits, risks, and alternatives of any given procedure considering the current movement in procedural safety and outcomes. For example, a physician may judge the rarity of a potential complication to be completely eclipsed by the perceived benefit and ease of an otherwise “necessary” intervention, and he/she may therefore opt to forego educating the patient on this potential complication. However, these omissions may result in rare but potentially severe, debilitating or undesirable complications. In *Bang v Charles T. Miller Hospital*, Bang underwent a routine procedure for an enlarged prostate in which his spermatic cords were unexpectedly severed. The physician failed to inform the patient of possible sterilization as a risk during the procedure. Because the patient’s intervention was not considered emergent, it was deemed that the patient should have been informed of all potential risks, consequences, alternatives, and benefits and the case was ruled in favor of Bang.¹⁵ In a move to further elucidate the physician’s responsibility of a safe informed consent process, U.S. courts mandated physicians to explain surgical procedures and obtain informed consent prior to the proposed intervention or face liability for damages in breach.¹⁶ These legal precedents illustrate the importance of fully disclosing uncommon or rare complications and the importance of eliminating provider or institutional biases in order to provide a safer healthcare setting.

Educating patients and the difficulties of population-based demographics

Another impediment to appropriately educating the patient is exemplified in the consent form itself. Grady et al. aptly describes consent forms as “increasingly long and complicated, obscuring important details, and are often designed to serve the interests of the institutions”.¹⁷ In order to rectify this pitfall, there has been a movement towards reducing the length and removing advanced medical terminology from the forms in order to facilitate understanding for the patient

¹³ Kendra L. Hogan, Katie J. Schenning & Kirk J. Hogan (2018) Trouble in Mind: Healthcare Informed Consent, Surgery, Anesthesia, and the Aging Brain, *Journal of Legal Medicine*, 38:2, 221-270, DOI: [10.1080/01947648.2018.1473184](https://doi.org/10.1080/01947648.2018.1473184)

¹⁴ The Joint Commission. *Informed Consent; More than getting a signature*. Issue 21. Feb 2016.

¹⁵ *Bang v. Charles T. Miller Hospital*, 251 Minn. 427

¹⁶ *Id* at 15

¹⁷ Christine Grady RN, PhD., Steven R. Cummings MD., Michael C. Rowbotham MD., Michael V. McConnell MD., MSEE., Euan A. Ashley F.R.C.P., D.Phil., and Gagandeep Kang MD., PhD. *The Changing Face of Informed Consent*. *The New England Journal of Medicine*. 376:9. Mar 2, 2017.

and family because “language used by physicians can be confusing to patients”.¹⁸ Specifically addressing the informed consent form, Centers for Medicare and Medicaid Services (CMS) updated their guidelines to state that informed consent policies should be in place with an executed informed consent form prior to any procedure or treatment that requires an informed consent.¹⁹ CMS also includes minimum policy requirements as to what the informed consent must include; who may obtain the informed consent; in what setting the informed consent is required and how it may be obtained (i.e. two physicians’ signatures attesting medical necessity in the event of an emergency in the event the surrogate is not available); circumstances where a patient’s representative may provide consent; what is considered an emergency case, circumstances where a patient’s representative will give consent, and a description of the proposed surgery and the anesthesia to be used.²⁰ Thus, collaboration among the major medical societies is imperative to further standardize informed consent and the language used on the form(s).

In the absence of a standardized approach to assessing the patient’s level of understanding of conveyed medically complex issues, practitioners may not be able to adequately anticipate the degree to which that information is understood by these patients. The quantity of information retained by a patient is a small proportion during their consult or during the consent process.²¹ “When the patient and provider speak different languages, the process of informed consent necessarily becomes more complex, as the informed consent discussion must be conducted either in a language the patient understands, or through an interpreter.”²² There is more evidence in a study demonstrating that “36% of patients had low levels of understanding in which only 8% had substandard MMSE (mini mental state examination) and where male patients demonstrated lower levels of understanding the consent process where the reason is unclear.”²³ In 1993, the National Literacy Survey revealed 48% of adults were literacy challenged, where the Spanish speaking population had more difficulty with understanding. About twenty percent of the United States population suffers low literacy skills - they read at the sixth-grade level or below, and twenty-seven percent lack general reading ability that hinders their lifestyle to function adequately in society. In order to make consents universally understandable, consents were made to be written at no higher than a seventh or eighth-grade reading level.^{24,25} These studies demonstrate that even among patients who would be expected to reasonably process the mental ability to understand information conveyed to them, the breadth of the education content is not easily retained.

¹⁸ Allan L. Naarden, MD, FAAN., John Cissik, PhD. *Informed Consent*. The American Journal of Medicine. (2006) 119, 194-197

¹⁹ *OR Manager*. Vol 23 NO.6. June 2007

²⁰ CFR 482.13 (b) (2)

²¹ A.D. Yeoman, M.J. Dew, L. Das, S. Rajapaksa. *Role of Cognitive Function in Assessing Informed Consent for Endoscopy*. Postgrad Med J 2006; 82:65-69. Doi: 10.1136/pgmj.2005.034710

²² Yael Schenker MD, Frances Wang MS, Sarah Jane Selig, Rita Ng MD, Alicia Fernandez MD. *The Impact of Language Barriers on Documentation of Informed Consent at a Hospital with On-Site Interpreter Services*. J Gen Intern Med. Nov 2007. 22(suppl 2): 294-299. DOI: 10.1007/s11606-007-0359-1

²³ *Id* at 22

²⁴ *Id* at 22

²⁵ David I. Shalowitz & Michael S. Wolf. *Shared Decision-Making and the Lower Literate Patient*. 32 J.L. Med. & Ethics 759, 759 (2004).

The safety of an informed consent and the patient's autonomy to decide

Further complicating this assessment are the terms “competence” and “capacity,” whose definitions differ vastly and whose application by medical practitioners has added to the complexity of defining the ability of their patients to understand the content of their education. “Competence” refers to a patient’s legal authority to make decisions, usually those 18 years of age and older.²⁶ However, in the event the mental status of the patient is affected or jeopardized, the patient may be deemed incompetent by legal authority. On the other hand, the term “capacity” refers to a determination made by medical professionals that a patient has the ability to appropriately participate in the informed consent process, reasonably understand his/her medical condition, elect an option of alternative proposes, and acknowledge the potential benefits and risks of his/her choice for treatment.²⁷

The issues preventing the creation of a safer, standardized informed consent process do not stop at the provider requirements, educational impediments, or assessment of patient and surrogate understanding. Another central component of the informed consent process is the patients right “to determine what shall be done with his own body,”²⁸ a right that is deeply rooted in the aforementioned ethical concepts and, like the informed consent, is considered an essential “cornerstone” of good medical treatment.²⁹ By extension, this also includes the right to forego care or procedure(s) that the providing physician perceives as “necessary” medical treatment and evaluation. Salvi, Schostok & Pritchard, a law firm in Illinois, elucidated the potential violations or shortcomings that could be subject for a lawsuit. These include the physicians obligation to inform the patient about material risks of the procedure and/or treatment plan with particular attention to disclose and explain the risks; secondly, the potential liability for obtaining the patient’s consent for a procedure and/or treatment plan that he/she would have otherwise refused if the responsible physician had provided information that would have led the patient to reconsider the proposed intervention; and lastly, the physician’s liability if the patient suffers a negative outcome as a result of a procedure performed after a deficient informed consent.³⁰ Surgeons must fulfill their obligation to inform their patient accurately, completely and clearly. An example of such a case is that of *Howard v. University of Med. & Dentistry of N.J.* in which in order to meet the damages element of a lawsuit based on lack of informed consent, the party must show there was a causal connection with what was disclosed and the injured sustained.³¹

In the case *Sekerez v. Rush University Medical Center*, the patient was diagnosed with terminal cancer and had refused to receive further medication after having received an initial treatment. Despite his refusal for further treatment, he received another three doses of the same medication and died shortly thereafter. This case resulted in a ruling favoring the defendants, and the physician responsible for administering further refused treatments was charged with medical

²⁶ Colleen E. O’Leary MD., Regina S. McGraw RN, JD. *Informed Consent Requires Active Communication*. APSF Newsletter. Spring 2008, pg 4.

²⁷ *Id* at 26 - Colleen E. O’Leary MD., Regina S. McGraw RN, JD. *Informed Consent Requires Active Communication*. APSF Newsletter. Spring 2008, pg 4.

²⁸ *Schloendorff v. Soc. N.Y. Hospital*, 105 N.E. 92 (N.Y. 1914)

²⁹ *Id* at 16

³⁰ Salvi, Schostok, & Pritchard. *Lack of Informed Consent*. www.salvilaw.com

³¹ *Howard v. Univ. of Med. & Dentistry of N.J.*, 172 N.J. 537

negligence and medical battery,³² with the lack of informed consent cited as an “encroachment of a person’s body integrity and constituted a battery”.³³ Statutes and regulations in Illinois specifically state a patient with decision making capacity may revoke their medical care at any time by using any means expressing the intent to revoke. In the case of *Sekerez v. Rush University Medical Center*, the hospital clearly failed to comply with regulations on the informed consent process stipulated in Illinois law.³⁴

The above case highlights the importance of honoring a patient’s autonomy throughout the informed consent process, taking into special consideration that the patient’s impression, support, and consent of the proposed plan may fluctuate, as his/her experiences, understanding, and/or mental status change. Despite the patient’s status and if the patient has the capability of making his/her own decision, surgeons must learn to communicate and hold a conversation with their patients and allow them to make decisions. Katz explains autonomy as the ultimate authority resides with the patient on their treatment decisions. Since it is their body that is at stake and must entrust it with their surgeon, only *they* should be able to decide what should be done to them.³⁵ “Beneficence, on the other hand, requires not only that we treat persons autonomously and that we refrain from harming them, but also that we contribute to their welfare including their health. Thus, the principle asserts the duty to help others further their important and legitimate interests - to confer benefits and actively to prevent and remove harms, and to balance possible goods against the possible harms of an action.”³⁶ “It is the physician's obligation to enhance, empower, and enrich the patient's capacity to be autonomous - to become a reality, patient autonomy requires cooperation and assistance from the physician. In short, it requires the physician's beneficent attention to make the patient's autonomy an authentic, as well as an independent, reality.”³⁷

In 1972, *Cobbs v Grant* rendered the informed consent a nondelegable duty of the surgeon or the health care professional responsible for the procedure or other proposed interventions. The decision made by the court stated “the decision whether or not to undertake treatment is vested in the part most directly affected: the patient. The physician has the duty to make certain the patient possesses adequate information to enable an intelligent choice.”³⁸ Thus, it should be considered standard practice to constantly discuss options and potential consequences – both desired and undesired – to allow the patient’s continued involvement in their medical care and for practitioners to honor the wishes of the patient’s desired course of action.

Literacy of patients

Since an informed consent plays an important role in the landscape of medical treatments, it is imperative to be certain that the patient has the capacity to understand and has an actual understanding of what is being communicated.³⁹ The U.S. Department of Health and Human

³² *Sekerez v. Rush Univ. Med. Ctr.*, 954 N.E.2d 383, 2011 Ill. App. LEXIS 714, 2011 IL App (1st) 090889, 352 Ill. Dec. 523

³³ Erin Sheley. *Rethinking Injury: The Case of Informed Consent*. 2015 BYU L. Rev.63, 68 (2015)

³⁴ *Id* at 32

³⁵ Jay Katz, M.D., *Informed Consent - Must It Remain A Fairy Tale?* 10 J. Contemp. Health L. & Pol’y 69 (1993)

³⁶ Thomas L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 148-49 (2d ed. 1983)

³⁷ Edmund D. Pellegrino. *Patient and Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship*, 10 J. Contemp. Health L. & Pol’y 47, 53-55 (1994)

³⁸ *Cobbs v Gant* 8 Cal.3d 229, 1972

³⁹ BMA and the Law Society. *Assessment of Mental Capacity*. London: BMJ Books, 2004: 116-36

Services (HHS) defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."⁴⁰ Health literacy impacts one's ability to understand and use health information such as instructions provided by the physician, informed consent documents, insurance forms, and health information communicated in general.⁴¹ While the health literacy of the patient is not a legal component of the doctrine of an informed consent, understanding and incorporation of the patient's health literacy plays an essential role in the process of obtaining an informed consent to ensure full patient understanding to make certain the patient fully comprehends the terms of the consent.⁴² This is because low health literacy – that is, poor patient understanding of written or spoken medical advice and potential adverse health outcomes⁴³ - can compromise the patient's ability to make an informed consent, and that treatment to which he/she is consenting may, in essence, actually be against that patient's wishes or whose implications (both positive and negative) may be beyond that patient's comprehension. In recent years this has even been described as a "silent epidemic" as the providers are often unaware of the patient's understanding and health literacy levels.⁴⁴

Provider assessment of patient understanding of medical concepts is central to the informed consent process – distinct from the patient's cognitive state – and often misleads clinicians as "adequate cognitive function does not predict a high level of understanding of the informed consent process."⁴⁵ Suffice it to say that, factors other than cognitive dysfunction are at play when attempting to explain low levels of understanding."⁴⁶ Additional time and effort may be required for those who do not speak English, in which utilization of an interpreter would be required to ensure adequate understanding.⁴⁷ Time constraints or not, however, it ultimately behooves the physician to engage the patient in the consent process; for "if a signed consent form is used as evidence that a conversation between the patient and physician took place, then listening, speaking, and nonverbal communication skills are essential parts of the informed consent process."⁴⁸

To help guarantee the patient's understanding, one communication technique is to ask the patient to summarize back the important aspects of the disclosed information. This includes inclusion of an interpreter to properly discuss the components of the informed consent and procedure to patients who are limited by language barriers. "For patients who do not speak English, additional time and effort may be required to find a consent form in the patient's primary

⁴⁰ HEALTHY PEOPLE 2010, *supra* note 12, at 11-20

⁴¹ Brietta Clark. *Using Law to Fight a Silent Epidemic: The Role of Health Literacy in Health Care Access, Quality, & Cost*. Annals of Health Law. Vol. 20, Issue 2, Summer 2011. Article 6.

⁴² Jessica J. Flinn, Personalizing Informed Consent: The Challenge of Health Literacy, 2 St. Louis U.J. Health L. & Pol'y 379 (2009)

⁴³ Agency for Healthcare Research & Quality, Literacy and Health Outcomes: Summary 1, 1 (2004), available at www.ahrq.gov/clinic/epcsums/litsum.pdf (last visited Apr. 16, 2009) [hereinafter AHRQ Report]

⁴⁴ Erin N. Marcus, The Silent Epidemic--The Health Effects of Illiteracy, 355 New Eng. J. Med. 339, 340 (2006)

⁴⁵ *Id* at 21 (Yeoman AD, Dew MJ, Das L, Rajapaksa S. *Role of cognitive function in assessing informed consent for endoscopy*. Postgraduate Medical Journal. 2006 Jan;82(963):65-69. DOI: 10.1136/pgmj.2005.034710)

⁴⁶ *Id* at 21 - Yeoman AD, Dew MJ, Das L, Rajapaksa S. *Role of cognitive function in assessing informed consent for endoscopy*. Postgraduate Medical Journal. 2006 Jan;82(963):65-69. DOI: 10.1136/pgmj.2005.034710

⁴⁷ *Id* at 22 – Yael Schenker MD, Frances Wang MS, Sarah Jane Selig, Rita Ng MD, Alicia Fernandez MD. *The Impact of Language Barriers on Documentation of Informed Consent at a Hospital with On-Site Interpreter Services*. J Gen Intern Med. Nov 2007. 22(suppl 2): 294-299. DOI: 10.1007/s11606-007-0359-1

⁴⁸ *Id* at 42 - (Jessica J Flinn)

language, obtain the services of an interpreter, and ensure adequate understanding.”⁴⁹ This essential component of the consent should also be documented on the consent form, including the signature of the interpreter, if applicable.⁵⁰ “A recent examination of the burdens of medical decision making on modern patients, published in the New York Times, reveals that hospitals employ ‘patient advocates’ to help patients make sense of the treatment information they receive and to provide guidance as patients make difficult treatment choices.”⁵¹

One such factor may be retention of information relevant to the consent. A study conducted assessing the cognitive function for endoscopic procedures registered a low level of information provided to them just minutes before signing the consent.⁵² As the consent conversation has become an already elaborate process with physicians trying to convey in understandable terms medically complex information while attempting to understand the multilayered components that factor into patient understanding, it is no surprise that patients often feel left behind.

Add to these impediments the rapid shift towards administration-driven requirements for physicians to increase productivity, which threatens to compromise an already abbreviated process. In order to accommodate to the high volumes of patients visits and procedures, interactions between physicians and patient are now limited to an average of seven minutes.⁵³ The abbreviation of patient-physician conversations impedes the ability to adequately and appropriately convey relevant information, and may not allow for properly assessing the patient’s level of understanding. In fact, this culture shift promotes the overwhelming of patients with too much information being relayed in a short amount time, resulting in poor patient retention as alluded above.⁵⁴

All of these aforementioned deficiencies in the informed consent process have led to patient driven claims that fall under the battery cause of actions, namely that the physician failed to disclose adequate information to the patient prior to obtaining consent.⁵⁵ This is based on the ideal patient-physician interaction in which “shared decision making...in which doctor and patient work in tandem to help the patient arrive at an autonomous decision, with the doctor acting as the medical expert and the patient acting as expert as to his/her values and preferences.”⁵⁶ The concept and goal of shared decision making between the patient/surrogate and the healthcare team is of working together and coming to a mutual agreement on the best treatment for a patient’s goals and needs. This gives a degree of control and autonomy to the patient/surrogate and by engaging them in active participation will make them both more likely to choose the best option for their needs and more confident in the shared decisions that have been made. The pressure to maintain volume and productivity places a significant burden on the clinician furthered by the lack of lawful accountability of the facilities in which consents are taking place: “One of the fallacies on which

⁴⁹ L.S. Karlinger, E.J. Perez-Stable, G. Gildengorin. *The language Divide. The importance of training in the use of interpreters for outpatient practice.* J Gen Intern Med. 2004 Feb; 19(2):175-83.

⁵⁰http://www.medicalmutualgroup.com/documents/11446/532520/InformedConsent_CD_8WitnessAndInterpreter_d07.pdf/37ff0373-0c8d-4d5c-ac28-721f32d0b666. (Visited Feb 1, 2020).

⁵¹ Jan Hoffman. *Getting Help: Patients Turn to Advocates, Support Groups and E-mail, Too*, N.Y. Times, Aug. 14, 2005, at A19

⁵² *Id* at 21 (Yeoman AD, Dew MJ, Das L, Rajapaksa S. Role of cognitive function in assessing informed consent for endoscopy. Postgraduate Medical Journal. 2006 Jan;82(963):65-69. DOI: 10.1136/pgmj.2005.034710.)

⁵³ Peter Brensilver, *E-Formed Consent: Evaluating the Interplay Between Interactive Technology and Informed Consent*, 70 Geo. Wash. L. Rev. 613, 625 (2002)

⁵⁴ Ken Berger. *Informed Consent: Information or Knowledge?* 22 Med. & L. 743, 747 (2003)

⁵⁵ Scaria, 227 N.W.2d at 650

⁵⁶ 81 Notre Dame L. Rev. 1203

the law bases its determination that hospitals are not subject to informed consent liability is its assessment that hospitals are not involved in the informed consent process. Despite the fact that hospitals are responsible for coordinating complex medical treatment for their patients, the law regards hospitals as merely the facility in which medical decision-making takes place between the doctor and a patient.”⁵⁷ This is to say that in spite of the many impediments being placed on clinicians to treat more patients, and the consequential diminishment of quality informed consent, hospitals are regarded as independent entities not otherwise subjected to the same level of legal accountability that clinicians are held.

Is a signed consent enough in the healthcare setting?

“A signed consent is only as meaningful as the exchange of pertinent information that it memorialized.”⁵⁸ A description of the patient’s condition, nature of proposed treatment, expected results including the indication that the treatment success cannot be guaranteed, the right to refuse and approach alternative options and the risks and benefits of any procedure should be provided to the patient.⁵⁹ In *Doe v University of Chicago Medical Center*, a complaint was filed for medical negligence on the basis of failure to inform the patient of the risks associated with accepting a kidney from a donor that was considered high risk and contracting HIV after the transplant. The plaintiff had declined two previous donor kidneys due to the histories of the donors and had proper information been provided, the current ailment could have been avoided. Furthermore, there was no documentation in the medical records of counseling that the patient received pertaining to the donor’s high-risk status, although he was in fact aware that the donor was high risk.⁶⁰

Case *Doe v University of Chicago Medical Center* shows the importance of documentation in medical records of all conversations between the parties involved. According to this case, the consent requirements also include that if there are to be other person(s) participating in the conversation(s), the informed consent documentation must also include the identity and responsibility of other persons involved during the informed consent process.⁶¹ The ruling further delineates that “hospitals that employ personnel to assist patients in their decision making process, should have a duty to assure that these individuals are qualified to provide medical decision making assistance and that those employees are scheduled by the hospitals such that there is reasonable access to such help regardless of the time of day.”⁶²

The *Shinal vs Tom* case prompted quick changes to policies and procedures, specifically adding a section noting who can obtain an informed consent. It highlighted three statements: Attending physicians are responsible for obtaining the informed consent and must sign the consent after the discussion takes place; advanced practice providers or medical students may not obtain an informed consent; nurses may not obtain informed consent. It also goes on to note that residents, fellows, and other healthcare professions as listed above may assist in the process of an informed consent by serving as a witness or presenting the informed consent form.⁶³ This goes

⁵⁷ *Id* at 56 - 81 Notre Dame

⁵⁸ *Lenahan v. Univ. of Chicago*, 348 Ill. App. 3d 155, 808 N.E.2d 1078 (2004)

⁵⁹ 8 Am. Jur. Proof of Facts 2d 145 (Originally published in 1976)

⁶⁰ *Doe v. Univ. of Chi. Med. Ctr.*, 2014 IL App (1st) 121593

⁶¹ 410 Ill. Comp. Stat. Ann. 50/3

⁶² *Id* at 56 - 81 Notre Dame L. Rev. 1203

⁶³ Samuel D. Jr. Hodge; Maria Zambrano Steinhaus, *The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain a Procedure to the Patient May Be Delegated*, 71 Ark. L. Rev. 727 (2019)

without saying - an informed consent is a two way street. “Patients must listen to what the doctor is explaining and ask questions if they do not understand, or if they desire more comprehensive information.”⁶⁴

Utilizing residents and/or fellows in teaching hospitals

Understanding that not all healthcare settings are the same, patients seeking procedural care in teaching facilities must accept the possibility that residents/fellows (medical trainees) will participate in their care under the supervision of the attending physician.⁶⁵ In an article written by Dempsey, he explains the reason as to why patients and families should fully understand the informed consent and procedure about to take place and the team members that will play an integral role in the process by repeating the informed consent in different settings and different times until he is satisfied that the patient and family are knowledgeable and know what is to be done. While explaining the informed consent, his team, including the residents and students, are identified and explained how they will be participating in the patient’s care. This allows families and patients to welcome trainees to be a part of their care because the physician introduced and explained the roles of each of these individuals.⁶⁶ One must also keep in mind that residents (trainees) can be either licensed or unlicensed given their years of completed residency and if they have chosen to further specialize. “When medical residents fully disclose their status, including their experience, training, education, and credentials, to their patients, then their performance should be judged by a standard of care commensurate with their actual level of post-graduate medical training, education, and experience. Licensed residents should in addition, and as a minimum, be held to the standard of a licensed general practitioner. A resident who affirmatively misstates or fails to disclose his status should not be permitted to avail himself of the standard that is commensurate with his limited experience and training.”⁶⁷ In *Alswange v. Smego*, defendants were asked to consider a lack of consent regarding a procedure performed with the participation of a medical resident. The court concluded the issue could be raised based on the absence of communicating the identity and qualifications of the resident in the surgical procedure and the policies of the teaching hospital lacked this requirement for an informed consent claim.⁶⁸

In the healthcare industry, teaching institutions face the conflict of providing patient with the best quality care while utilizing novices (trainees). The residency training program does alleviate potential harm through the supervision of these trainees by their attending physicians. Teaching hospitals tend to have better outcomes as residents are obligated to complete rounds on their patients, answer pages, ask questions and closely supervise their patient’s care; whereas, in private institutions, the time an attending physician will spend on rounds, asking questions,

⁶⁴ *Understanding Informed Consent and Your Rights as a Patient*, FindLaw, <https://healthcare.findlaw.com/patient-rights/understanding-informed-consent-a-primer.html>. (Visited 2/1/2020)

⁶⁵ Marc D. Ginsberg. *Informed Consent: No Longer Just What the Doctor Ordered?* Revisited, 52, Akron L. Rev. 49 (2018) pg 81

⁶⁶ Robert J. Dempsey, MD, FAANS. *Counterpoint: Concurrent? Overlapping? Simultaneous Surgery? A Question of Informed Consent*. AANS Neurosurgeon: Vol. 26, No. 1, 2017

⁶⁷ *Id* at 8 - ARTICLE: THE STANDARD OF CARE FOR RESIDENTS AND OTHER MEDICAL SCHOOL GRADUATES IN TRAINING, 55 Am. U.L. Rev. 683

⁶⁸ *Alswanger v. Smego*, 257 Conn. 58, 776 A.2d 444 (2001)

following up with staff and other faculty, is minimalized.⁶⁹ Many patients may voice their preference to be treated and/or examined only by an experienced physician. In a study conducted regarding medical students, 39.4% of patients believed they had the right to refuse the involvement of medical students, 65.1% would allow students to be in the operating room, 58.6% believe it's important for future physicians to examine patients, 18.7% will allow medical students to examine them and only 5.7% would allow a male medical student to examine them dependent on which part of the body was to be examined.⁷⁰ These statistics highlight a range of patient opinions regarding trainees in the medical field and it shows the mindset of patients and their comfort level without the presence of an attending.

Full disclosure

Based on the above statistics, if the physician will be utilizing a resident or fellow to perform or help perform the procedure under their guidance and supervision, it is necessary to fully disclose this information to the patient and make it evident on the informed consent form because an "operating surgeon is construed to be the performing surgeon".⁷¹ "Surgeons have a special responsibility to supervise resident training because of the unique characteristics of surgical conditions and operations."⁷² Should the attending surgeon merely assist the resident or other physician in performing the operation, it is the resident or other physician who becomes the operating surgeon. If the patient has not been informed to the identity of the operating surgeon, this situation is known as "ghost surgery."⁷³ It has become an ethical standard that another physician may not perform a procedure if the patient has no knowledge of their anticipated participation from the consent process. "If a resident or other physician is to perform the operation under non-participatory supervision, it is necessary to make a full disclosure of this fact to the patient, and this should be evidenced by an appropriate statement contained in the consent. Under these circumstances, it is the resident or other physician who becomes the operating surgeon."⁷⁴

Given the aforementioned, the law of medical malpractice allows for the protection to patients' by the rules that prevent substandard conduct and compensates those that fall victim to medical malpractice which is measured by the standard of care held for healthcare providers.⁷⁵ Take case *Rush v. Akron General Hospital* for example. In this case, a resident that was not yet licensed working in the Emergency Room had treated a patient with a glass wound. The patient's wounds were treated however, two pieces of glass remained in the patients shoulder that were left undetected by the resident. The resident was not filed in the lawsuit as an individual, but it was brought into question if the resident could be held negligent and if the standard of care should be

⁶⁹ *Id* at 8 - ARTICLE: THE STANDARD OF CARE FOR RESIDENTS AND OTHER MEDICAL SCHOOL GRADUATES IN TRAINING, 55 Am. U.L. Rev. 683

⁷⁰ Talal Al-Khatib, Sanaa Bin Othman, Basem El-Deek. *Patient's Perception Toward Medical Student's Involvement in Their Surgical Care: Single Center Study*. Nov 23, 2016. Vol. 2016. Article ID 8234841. <https://doi.org/10.1155/2016/8234841>

⁷¹ 44 No. 2 DRI For Def. 27

⁷² American College of Surgeons. *Statements on Principles* Revised April 12, 2016 Accessed at: <https://www.facs.org/about-ac/s/statements/stonprin#iia>

⁷³ *Id* at 53 - 44 No. 2 DRI

⁷⁴ Substitution of Surgeon without Patient's Knowledge or Consent, Am. Med. Ass'n, AMA Code of Medical Ethics E-8.16 (1994), <http://www.ama-assn.org/ama/noindex/category/11760.html>

⁷⁵ *Id* at 5 - ARTICLE: THE STANDARD OF CARE FOR RESIDENTS AND OTHER MEDICAL SCHOOL GRADUATES IN TRAINING, 55 Am. U.L. Rev. 683

evaluated.⁷⁶ Although this allows some protection to those training in the medical field, residents should be taught the importance of being thorough and careful when providing care. Teaching hospitals must withhold the standard of care they advertise. Patients come to the hospital expecting quality care by the chosen physician, however, when the primary physician allows the resident to handle the care without their presence, the standard is no longer met.⁷⁷

Concurrent procedures

Not only is informing patients on who will be participating in their care important, it is also important for patients and families to know how many cases their physician has scheduled that day and if there are concurrent procedures scheduled that may overlap theirs. In many instances, medical residents, fellows or physician assistants are the ones to open and close incisions and finish noncritical aspects of the procedure as the physician moves on to the next one scheduled.⁷⁸ An article written by the *Boston Globe*, described operations where “surgeons divided their attentions between two operating rooms over several hours, failed to return to the operation when residents or fellows needed assistance, or failed to arrive on-time for surgeries, leaving residents or fellows to perform surgeries unsupervised or resulting in patients under anesthesia for prolonged periods. Not only that, but patients were not informed their surgeries would run concurrently with another, resulting in hospitals patient consent processes to get questioned.”⁷⁹ “Advocates of concurrent surgeries argue that this longstanding practice enables timelier access to high skilled, in-demand surgeons by freeing up their time to perform more specialized operations, helps train medical professionals by pairing senior doctors with residents or fellows, and improves the utilization of operating facilities.”⁸⁰

The American College of Surgeons revamped their guidance to be compliant with CMS’s billing standards relating to concurrent surgeries. CMS guidance states the supervising surgeon must be present in the same room “when practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term ‘supervision’ would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.”⁸¹ However, in order to stay compliant with CMS guidelines, ASC separated concurrent and overlapping surgeries into two categories. “Concurrent or simultaneous surgeries is when the critical components of the operations for which the primary attending surgeon is responsible are occurring at the same time and overlapping surgeries is when the critical components of the first operation have been completed and the primary attending surgeon performs critical portions of a second operation in another room. Furthering, if the surgeon does have an overlapping surgery, the surgeon relinquishes their responsibility for being immediately available to an assigned backup surgeon once she/he begins the second operation”⁸²

⁷⁶ Rush v. Akron Gen. Hosp., 1957 Ohio App. LEXIS 968

⁷⁷ Robert J. Dempsey, MD, FAANS. *Counterpoint: Concurrent? Overlapping? Simultaneous Surgery? A Question of Informed Consent*. AANS Neurosurgeon: Vol. 26, No. 1, 2017

⁷⁸ Michelle Mello, Edward Livingston, The Evolving Story of Overlapping Surgery, JAMA Surgery, July 18, 2017

⁷⁹ Abelson J, Saltzman J, Kowalczyk L, Allen S. *Clash in the name of care*. Boston Globe. October 25, 2015

⁸⁰ US Senate, Committee on Finance. *Concurrent and overlapping surgeries: Additional Measures Warranted*. <https://www.finance.senate.gov/download/finance-concurrent-surgeries-report>. Published December 6, 2016.

⁸¹ CMS, State Operations Manual, Section A-094

⁸² *Id* at 73 – US Senate,

“CMS’s COPs and corresponding interpretive guidelines, while not specific to concurrent or overlapping operations, require hospitals to take certain steps to ensure that patients consent to planned surgeries. For example, this guidance states that a well-designed informed consent policy should include a discussion of a surgeon’s possible absence during part of the patient’s surgery, during which residents will perform surgical tasks, and that the informed consent policy should assure the patient’s right to refuse treatment.”⁸³ Accordingly, Rickert warns “discussions between surgeons and patients about overlapping surgeries will involve euphemisms, incomplete information, and oblique discussions.”⁸⁴ In the event the primary surgeon has to leave the room, requirements from CMS state if the “primary surgeon is not immediately available to assist when needed, the surgeon must designate a backup surgeon.”⁸⁵ Elaborating on the aforementioned, Mello and Livingston discussed how overlapping policies on surgeries and consent practices were inadequate - the surgical departments should define the critical operational parts rather than individual surgeons, inform patients of an overlapping case but also have the patient consent to this knowledge and lastly, for hospitals to have a documentation of the surgeons’ room entry and exit times to actively monitor their compliance with the policies.⁸⁶

A case from 1998 was awarded to the plaintiff in relation to the patient not only not being informed on which person(s) would be participating in their care during the procedure, but also that the surgeon had four different surgeries scheduled at the same time. “The chief resident of the ENT program performed the surgery on Mrs. Watkins. Dr. Eliachar, who was listed in the operation records and discharge summary as the performing surgeon, allegedly supervised periodically the work of Dr. Guay (resident) as the Dr. Eliachar moved between the adjoining operating rooms.”⁸⁷ Complicating the case more, the patient was intubated by a nurse anesthetist rather than the anesthesiologist himself. There was no record of the anesthesiologist being present for the extubating portion post procedure nor record of the surgeon being present to assure the patient was breathing ok and woke up from the general anesthesia without any complications. The patient’s post extubation complications put her in a vegetative state in which a complication such as this, should have never occurred. The court awarded the case to the “husband and guardian, compensatory damages for fraud and battery, damages for loss of consortium, and punitive damages.”⁸⁸

The informed consent discussion between the physician and patient must include: “The nature of the illness and natural consequences of no treatment, nature of the proposed operation including the estimated risks of mortality and morbidity, discussed and described common complications, risks and benefits of the proposed procedure, alternative forms of treatment including nonoperative techniques, and a discussion of the different qualified medical providers who will participate in their procedure and respective roles.”⁸⁹ Informed consent must include a process that facilitates the subject’s comprehension of the information and allows adequate opportunity for the subject to ask questions and consider whether or not to participate (45 CFR 46.116 and 21 CFR 50.20). “Proceeding with an invasive medical procedure in the absence of

⁸³ *Id at 73* - US Senate,

⁸⁴ James Rickert. *A Patient-Centered Solution to Simultaneous Surgery*. Health Affairs Blog, June 14, 2016

⁸⁵ *Id at 73* – US Senate

⁸⁶ Michelle Mello, Edward Livingston, *The Evolving Story of Overlapping Surgery*, JAMA Surgery, July 18, 2017

⁸⁷ *Watkins v. Cleveland Clinic Found.*, 130 Ohio App. 3d 262

⁸⁸ *Id at 87* – *Watkins v. Cleveland Clinic*

⁸⁹ *Id at 72* - American College of Surgeons. *Statements on Principles* Revised April 12, 2016 Accessed at: <https://www.facs.org/about-acs/statements/stonprin#iia>

informed consent violates one of the most fundamental norms—both legal and ethical—of medical practice and is thus clearly unacceptable except possibly in a life-threatening emergency.”⁹⁰

In conclusion, the process of providing an informed consent is a nondelegable duty of the surgeon or the health care professional responsible for the procedure. The patient has the right to refuse care as part of or result of information provided during the informed consent. There are many challenges not only in Illinois, but throughout the country involving medical literacy and language barriers which health care professionals should take seriously and use appropriate interpreter services to allow a full understanding, not only for the patient, but for the surgeon to answer any questions they may have. This process must include the incorporation of any novice involvement from residents or fellows that will be participating in their care with the introduction of who they are – even discussing the possibility that the responsible surgeon may not be present throughout the entire procedure but will delegate the responsibility appropriately. There is always a risk of legal liability for fraud, battery and punitive damages. To best avoid any potential lawsuit, a full disclosure to the patient or legal guardian must be made transparent and written down for proof of full disclosure.

⁹⁰ JW Berg, PS Appelbaum, CW Lidz, L. Parker. *Informed Consent: Legal Theory and Clinical Practice*. 2nd ed. New York: Oxford University Press, 2001.