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Primer on informed consent

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Consent is largely a function of state law, with many common threads weaving through the various statutes. All providers should be well versed in the laws of their state. Medicare regulations also play a role in consent standards.[1]

Protecting the rights of patients is paramount, but compliance with the law also protects providers. There is a significant interest in monitoring compliance with informed consent policies and regulations. Important regulatory and litigation risks exist in the failure of informed consent practices. Compliance efforts must be directed toward ensuring a robust program of informed consent and faithful adherence to organizational standards. How do we discover consent failures? Usually through complaints, regulatory sanctions, and/or litigation. All are best avoided!

Why is this a compliance issue?

Informed consent usually becomes an issue when something has gone wrong. Satisfied patients rarely raise consent issues. When the patient is injured or aggrieved, lawyers get involved, and then practices and policies are questioned. This may include a challenge to consent procedures. A pattern of failure to obtain informed consent may trigger false billing claims or other legal remedies.

Example: *A Michigan physician received consent and provided chemotherapy to hundreds of patients—many of whom he knew did not have cancer. This was done to increase billing and income. The consents were invalid, and the billings were false claims.*[2]

This was an extreme case, but no one responsible for compliance noticed until it was too late. Often consent issues are raised in malpractice actions and add to severe reputational and financial risks. Trust your physicians? Trust but verify.

Protecting the organization and protecting providers is a duty of compliance officers. Given the possible reputation and financial risks, this should be a priority in policy development, training, and documentation.

Defining consent

The Joint Commission defines informed consent as: "...informed consent in medical care is a process of communication between a clinician and a patient [or surrogate] that results in the patient's authorization or agreement to undergo a specific medical intervention."[3]

In longer form, the Commission says:

> Informed consent: Agreement or permission accompanied by full notice about

> the care, treatment or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient either consents to or refuses such a procedure or treatment.[4]

There are two types of consent: implied and express.[5] Implied consent is often appropriate for routine matters. Express consent is absolutely necessary for anything beyond routine.

Example: *Tom calls his primary care office for his annual physical. He arrives for the appointment, signs in, updates his insurance information, follows the instructions of the medical assistant, and is seen by the physician. Tom's actions imply consent.*

Example: *During the course of his physical exam, the physician decides Tom needs knee X-rays, lab work, and an EKG. Express written consent would be appropriate here.*

Obtaining express consent for every patient encounter is perfectly acceptable, as long as the consent is truly informed. Express consent, either oral or written, is a clear expression of intent and consent to receive care. Providers should seek written consent, which is preferred in most situations.

Patients (and surrogates) have, with just a few exceptions, the right to accept or refuse examination and treatment. A refusal of care should only be countermanded under specific unusual circumstances.[6]

Defining "informed"

Giving the marvels of modern medicine how do we define and measure "informed"? How does a person with two college degrees and years of clinical training talk to someone with a high school education or less? How does modern science translate to laymen's terms? How much information is enough, and how much is too little?

These are the necessary components of consent:

- A description of the nature and extent of the service,
- An explanation of the potential benefits,
- An explanation of the risks (e.g., minimal benefits, infection, death),
- An explanation of the alternative courses of action, and
- An explanation of the possible outcomes of doing nothing.

Consider practical consent problems, such as patient (or surrogate) confusion, stress, pain, provider influence (i.e., prejudice toward action), and family drama. All can complicate the process.

Provider duties

Providers should not examine, treat, medicate, perform imaging or lab testing, or perform surgery without informed consent. There are a very few exceptions, such as emergent situations and patient disability. Not only is receiving informed consent critical, but documenting informed consent is very critical. This is not just an individual provider issue—this is an organizational issue.

What conditions precede consent?

The first condition is legal competency. The patient must be an adult (typically defined as older than 18 years of age); cognitively competent; not under the influence of alcohol or drugs (including anesthesia); and, at a minimum, oriented to person, place, time, and situation.

One expert sums it up this way: legally competent, properly informed.[7]

Age

In general, minors need consent from a parent or guardian, but specific cases will be covered by policies and regulations. Consent is a complex issue for minors, and not all minors are treated the same, depending on age, mental status, and state law. Emancipated minors or married minors may be able to give their own consents, and many states have very specific laws on teen consent in reproductive rights issues.

Providers and staff should be fully briefed on informed consent involving minors. When in doubt in a specific case, delay may be the best action unless delay is not advised.

Mental and cognitive state

Mental and cognitive competency should be considered by providers. Measuring competency is not always easy.

Example: *Mrs. Smith is an 84-year-old woman with short-term memory loss, congestive heart failure, a hip implant, and a history of minor injuries from multiple falls. She falls again and suffers a compression fracture of T-12 vertebra. The orthopedic surgeon schedules a kyphoplasty. He explains it to Mrs. Smith on Tuesday, but when he visits pre-op on Wednesday, she is a little sketchy on just what is to be done, but she offers to sign anything the physician wants her to sign. Mrs. Smith definitely needs the surgery.*

Not an easy call. The best solution may be witnesses, from the nursing staff and/or the family, or better yet, both. A witness not included in the documentation is no witness at all.

Under the influence

Being in a hurry is a frequent but inadequate excuse for consent problems.

Example: *Dr. Smith usually sees a preoperative patient just minutes before beginning the surgery, and at that time asks for a final consent signature. In some cases, an anesthesia drip has already begun. In those cases, Dr. Smith could have problems, due to lack of capacity to give consent.*

There are many issues with the cognitively disabled and with the elderly, which will be addressed in detail in a later article.

Multiple consents

Surgery or complex procedures suggests two consents, one for the physician and one for the facility.[8],[9] The physician may secure the consent during an office encounter, and that is fine unless something has changed between the date of the office visit and the date of procedure. The responsibility for documentation falls to the surgeon and the office staff. The facility normally provides the anesthesiologist, and so consent should cover both the facility and the anesthesia discussions.

Surgery contingencies can be problematic. A surgeon receives consent to perform procedure X, and during the

surgery discovers something new, and then performs procedure Y.

Overly broad consent

Many patients sign broad "cover all" consent forms, sometimes before being face to face with key providers, thus missing the informed part of the equation. Sometimes the form has a fill-in-the-blank line for the procedure, and/or provides a general summary of risks and benefits. The form may have no time limit.

Legal counsel should be intimately involved in developing informed consent policies and consent documentation. Medical professionals should not attempt to draft their own informed consent forms or use boilerplate Internet forms. This method is very weak because of probable inadequacies in the "informed" requirement.

Example: *Sally checks into a hospital outpatient center for a major diagnostic procedure. During registration she is asked to sign an electronic keypad.*

> Sally: What am I signing for?
>
> Staffer: Informed consent, financial guarantor, and our HIPAA policies.
>
> Sally: I haven't been given information on any of this.
>
> Staffer: Well, I can let you read the standard information if you like (hands Sally a laminated 8 x 11 sheet with boilerplate language for all three issues).

This is not a failure by the staff member; this is a failure of training and supervision, and maybe a failure of policy. Staff performance is only as good as the training and policies provided by senior management.

Substitute consent provider

A surrogate, such as a highly qualified nurse, can provide the requisite information and accept the informed consent signatures.

Example: *George checks into the hospital for a cardiac catheter procedure. He has been briefed by the cardiologist, but he has not met the interventional cardiologist who will do the procedure. He is examined, prepped, and briefed on the procedure by a veteran cardiology nurse who then presents and explains consent forms and acquires the necessary signatures.*

This would be an acceptable means of obtaining consent, considering the qualifications of the nurse who did the workup. The cardiologist is still responsible for everything, including the informed consent.[10]

In many surgery settings, briefings and explanations would be done in the physician office, rather than the surgery facility. This is why two levels of consent (physician and facility) are preferred, with proper documentation for both.[11]

Patient surrogates

The type and qualifications of patient surrogates is a matter of state law. The potential surrogates include parents or those standing in the stead of the parents, such as foster parents, a spouse, a healthcare power of attorney (POA), a designee in a living will, a legal guardian, or other persons designated by state statute or by a state court.

A properly qualified surrogate may receive information and give consent in the stead of the patient, *if* the patient is unable to do so or is a minor. Confirming the qualifications of a surrogate may be problematic, particularly in an emergent situation, so a good faith assessment of the facts and circumstances may be required.

In most states a "significant other" is not treated the same as a spouse, and this may be problematic unless the significant other has been given a POA.

Single adults over the age of 21 are often in a twilight land with no spouse and no POA. Parents may be a de facto substitute, but it is much better to have a POA for a trusted surrogate. Again, purely emergent care requires no informed consent if the patient is not competent. If providers proceed on an emergent basis, this should be either abundantly clear (e.g., patient arrives by rescue squad and is unconscious) or thoroughly documented, and better yet, both.

Special issues of consent

Numerous areas and topics require special attention for informed consent compliance. All of these carry extra regulatory and litigation risk, and sometimes reputational risk:

- **Reproductive rights** are a major snarl of regulation, politics, and litigation, and executives, physicians, and operational and compliance personnel should be reviewed and possibly updated on current state and federal law, as well as organization policies.
- **Research** has its own protocols for consent. Everyone who works in a research role should be well-versed in the protocols, and compliance should be monitored on a regular basis.
- **Treating minors** is a sensitive area, and attention should be paid to the age and ability of the patient, as well as the comprehension of the parent or guardian. Minor children of divorced or unwed parents may have difficult issues with agreement to consent.
- **Elders** have many healthcare needs and often have cognitive impairments that require specific consideration and careful compliance.

All of these areas require the organization to pay constant attention to state laws, as well as federal regulations.

Compliance officer concerns

Compliance officers should look at several aspects of consent to be certain there are proper and adequate policies, forms, and training throughout the organization:

- Policies and procedures are up to date and appropriate;
- Policies and procedures are compliant with state law and federal regulations;
- Policies and procedures cover and anticipate difficult situations;
- Training and orientation adequately address the policies and procedures;
- Documentation, whether paper or electronic or both, is properly designed, and forms adhere to policy;
- Each clinical sector agrees about what constitutes "informed";
- Procedures exist for special and difficult cases, and especially to address difficult cases through

administrative and legal channels; and

- Procedures are in place for monitoring new laws, new regulations, and the impact of relevant court cases.

Compliance monitoring

Properly designed consent procedures do not guarantee compliance. The quality of information in an informed consent case is difficult to monitor, because the information was supposed to be passed in a conversation between provider and patient and then documented. The conversation is difficult to monitor. Monitoring the documentation is easier, but then there may be a problem with the veracity of the documentation.

In the era of electronic health records, the phrase "copy and paste" has become an issue. Copying and pasting a standard consent paragraph is legal poison, because some lawyer someday is likely to notice the identical language. (In the old days of dictation and transcription, the words "standard consent paragraph" were the same sort of poison.)

Conclusion

Informed consent is a patient-by-patient endeavor that requires a conversation specific to each patient. Proper compliance with policies and procedures can improve compliance, lower risk, and may increase patient satisfaction.

Takeaways

- All providers and healthcare organizations must understand the definition of and importance of informed consent.
- The risks to the organization for failing to meet consent standards could be a public relations nightmare.
- Providers should not examine, treat, medicate, perform imaging or lab testing, or perform surgery without informed consent, except in emergent situations.
- Implied consent is often appropriate for routine matters. Express consent is absolutely necessary for anything beyond routine.
- Compliance officers are responsible for seeing that proper and adequate informed consent policies and forms are used, and staff are trained throughout the organization.

1 Center for Medicaid and State Operations/Survey and Certification Group, "Revisions to the Hospital Interpretive Guidelines for Informed Consent," April 13, 2007, https://go.cms.gov/2FxBKAs
2 The United States Attorney's Office Eastern District of Michigan, "U.S. v. Farid Fata: Docket 13-CR-20600," http://bit.ly/2QA9XG1
3 The Joint Commission, "Informed consent: More than getting a signature," Quick Safety flier 21, February 2016, https://bit.ly/35ttX1e
4 The Joint Commission, *Comprehensive Accreditation Manual for Hospitals* (2016), glossary.
5 J. Stuart Showalter, *The Law of Healthcare Administration*, 5th ed. (Chicago, Illinois: Health Administration Press, 2007) Chapter 9.
6 Schloendorff v. Society of New York Hospital, 05 N.E. 92, 93, (N.Y. 1914).
7 Showalter, *The Law of Healthcare Administration.*
8 American College of Surgeons, *Statements on Principles*, revised April 12, 2016, https://bit.ly/380ZWrp

9 Pranit Chotai, Eunice Yuee-Dean Huang, and R. Shane Tubbs, "History and Philosophy of Surgical Informed Consent in Children," *ResearchGate*, February 2016. https://bit.ly/2R33T7Q

10 Dean M Harris, *Contemporary Issues in Healthcare Law and Ethics*, 4th ed. (Chicago, Illinois: Health Administration Press, April 1, 2014) Chapter 10.

11 Harris, *Contemporary Issues in Healthcare Law and Ethics.*