Get
Informed consent puts patients in the driver’s seat

By Mark Harris

Informed consent is integral to the delivery of safe, patient-centered health care. “As an ethical doctrine, informed consent is a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care,” explains the American College of Obstetricians and Gynecologists.¹

The ability of physicians or other health care providers to diagnose and treat patients is predicated on patients’ right to willingly accept or reject the medical care proposed by their providers. In turn, patients’ autonomy over their health care choices is influenced by how well they understand the treatment recommendations given to them.

“Informed consent to medical treatment is fundamental in both ethics and law,” according to the American Medical Association’s (AMA) Code of Medical Ethics. “Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care.”²

¹
²
informed consent

Ethical road map

When obtaining informed consent from a patient, a physician should meet several objectives throughout the process, according to the American Medical Association (AMA) Code of Medical Ethics:

- **Before:** “Assess the patient’s ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.”

- **During:** “Present relevant information accurately and sensitively, in keeping with the patient’s preferences for receiving medical information. The physician should include information about the diagnosis (when known), the nature and purpose of recommended interventions, [and] the burdens, risks, and expected benefits of all options, including forgoing treatment.”

- **After:** “Document the informed consent conversation and the patient’s (or surrogate’s) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.”

In a sense, informed consent can be considered an extension of the patient-provider relationship. For informed consent to be more than a formality, health care providers must rely on effective communication skills and shared decision-making between practitioners and patients.

The right of way

Informed consent requires efficiency and organization on the part of medical practices. Additionally, health care professionals must be knowledgeable and stay up to date on best practices. After all, informed consent poses different requirements for medical practices depending on the level or type of care provided.

“There are actually two types of patient consent agreements at work in health care,” says Andrew Hajde, CMPE, assistant director of association content for the Medical Group Management Association in Englewood, Colorado. “There is the implied or general consent when you fill out your paperwork at a medical practice that says you agree to be treated and [that consent] covers you broadly. If you’re going to the doctor for a routine physical, for example, there’s an implied or general consent that you’re agreeing to that kind of basic, noninvasive level of care.”

For more invasive types of medical care, there is a higher expectation of informed consent, explains Hajde. To note, invasive medical care, by definition, involves any use of instruments to cut or puncture the skin or otherwise enter the body. “Once you start getting into any type of invasive procedure or treatment [in which] there’s potential for a negative outcome [or] that could require more patient education, … you need a specific informed consent agreement for the procedure,” says Hajde.

Hajde and other experts emphasize that informed consent forms should be crafted to address each unique procedure or treatment the practice offers. “You need to have a form specific to the procedure being performed, not just a catchall form,” remarks David J. Zetter, CHBC, president of Zetter HealthCare in Mechanicsburg, Pennsylvania. “The whole idea behind an informed consent [form] is to provide the particular risks and benefits of every procedure or treatment to the patient, so they can make an informed decision on whether they want it done.”

With this in mind, a physician’s informed consent conversation with a patient should provide essential information about the recommended procedure:

- An accurate description
- Explanation of the risks, benefits, and potential for a successful outcome
- Possible alternative treatments, including the option of no treatment, and those treatments’ risks and benefits
- Any issues or anticipated problems that might occur during the recovery
- The expected time frame for the recovery

The informed consent form should document the patient’s understanding of these key aspects of the proposed medical procedure or treatment, as described by their physician or other rendering providers, says Zetter, a member of the National Society of Certified Healthcare Business Consultants.

Practice managers can find sample informed consent forms or templates, which are available from various sources, such as professional medical associations, insurers, and other groups. For example, the American College of Surgeons sells access to informed consent documents for more than 3,500 procedures and treatments.

While sample forms or templates can be helpful, providers should make sure the forms they adopt provide adequate detail and are used only for a specific purpose. In some cases, practices may need to customize or edit informed consent templates to apply them to a particular clinical setting, says Zetter. For example, he cites a dermatology practice he worked with that needed to create proper informed consent forms for some office procedures. “The practice was utilizing a couple of different injectable products and wanted to use the same consent form for the different products,” he reports. “Even though the products mostly did the same thing, there were different risks and benefits associated with each injectable. For this reason, the consent forms they used needed to specifically address these differences in the procedures.”

Borrowing consent forms from trusted colleagues and networking can be another
useful resource, suggests Zetter. However, following such advice requires caution. Practice managers must critically evaluate each form to make sure each is specific and customized to the practice’s needs. “You want to make sure you have very specific and accurate information on your forms,” adds Zetter. “You may need to either edit or follow it to a T.”

**Point in the right direction**

Informed consent expresses a philosophy of care that embraces patient knowledge and empowerment. Within this concept, medical care is viewed as a collaborative partnership between patients and providers.

In this context, one concern or possible barrier to informed consent is the issue of patient health literacy. How well do patients actually understand what they are being told by their providers about proposed procedures or treatments? In turn, providers should question whether informed consent forms are being written in such a way as to be not only detailed and comprehensive but also comprehensible by patients.

These concerns are valid. Patients often forget or misunderstand medical information given to them during an office visit, according to the Agency for Healthcare Research and Quality (AHRQ). Therefore, good communication and relationship skills are vital to the ability of clinical providers to mitigate any limits or gaps in the patient’s retained knowledge.

Of course, communication skills can always be learned or improved. One technique the AHRQ recommends for improving the informed consent process is the *teach-back method.* The technique involves asking the patient to summarize or repeat back key health information shared during their clinical appointments. This might include repeating back medication instructions or other directions for at-home care. Similarly, a patient might be asked to demonstrate care instructions they are expected to perform on their own (i.e., the *show-me method*). Moreover, staff may provide written handouts of this information or other key instructions discussed in the office.

Notably, the AHRQ suggests the teach-back method should be considered less a test of the patient’s knowledge and more of a measure of how well clinicians and staff are conveying medical information to patients.

Furthermore, effective communication skills require sensitivity to the patient’s cultural and language preferences. As necessary, medical practices should make interpreter resources available and provide informed consent forms in Spanish and other languages. Additionally, physicians need to allow patients time to think about treatment decisions and the information they have been given. Providers should also always encourage patients to ask questions.

The challenge of ensuring a patient’s fully informed consent can play a large role in acute or ongoing medical care. In these cases, providers need to continually check to make sure they are facilitating patient health literacy. Some evidence suggests informed consent practices in some specialties may benefit from periodic reevaluations by clinical providers.

For example, a national survey of 400 adults sponsored by the American Society for Radiation Oncology recently found about one-third of cancer patients experienced treatment side effects they wished they had been given more information about. Depending on the type of treatment (e.g., radiotherapy, chemotherapy, and surgery), common side effects included symptoms such as skin irritation, gastrointestinal symptoms, nerve damage, and fatigue. Generally, patients with severe side effects were more likely to say they felt less informed about what to expect from the treatments. Despite this feedback, about 9 of 10 patients reported satisfaction with their treatment decision.

Significantly, another recent nationwide study of 89 academic radiation oncology departments found informed consent forms rarely met recommended reading levels for patient materials. In fact, the study found that only 9 of 113 informed consent forms met the criteria for the recommended (i.e., eighth-grade) reading level for patients.

“Cleary, as technology improves, we’re seeing more automation to expedite processes in medical practices. This applies to informed consent when practices have templates for the different types of authorization forms and education resources automatically integrated into their electronic health records, or EHRs.”

“When a patient is diagnosed with a particular condition, [practices are] then able to make sure they get the exact informed consent to [patients] along with appropriate educational materials. This can expedite the physician’s ability to review with the patient any recommended procedures or treatments. Instead of digging through a filing cabinet of copies of papers or having printed resources and brochures all around for every topic under the sun, resources can be immediately available through the EHR.”

—Andrew Hajde, CMPE, Medical Group Management Association
**Pave the way**

An essential part of informed consent is ensuring that patients fully understand the treatment, risks, benefits, and alternatives. But certain barriers can hinder a patient’s understanding. Take action to avoid common issues while developing informed consent communication forms and materials and while communicating with patients and surrogate decision-makers:

- Provide sufficient basic information.
- Use everyday language instead of medical jargon.
- Consider the health literacy and cultural issues of patients.
- Make use of decision aids, interactive media, graphical tools.
- Use open-ended questions to elicit information regarding patients’ needs and preferences.
- Encourage patients to ask questions.

“The way that we structure our consent forms and the language that we use can have a profound impact on how useful they are for patients,” says Dr. Rooney, who was a senior medical student at the University of Illinois College of Medicine at the time of the study and is currently a resident in radiation oncology at the University of the study and is currently a resident in radiation oncology at the University of Texas MD Anderson Cancer Center in Houston. “There are national guidelines that any materials used for patients must be written anywhere from a sixth- to eighth-grade level. Unfortunately, that’s not the case right now. Our goal should be to try to move closer to that guideline from a readability perspective.”

Such critical assessments of informed consent practices remind clinicians to avoid thinking about the informed consent process in static terms or as practices written in stone. Accordingly, providers should think critically about ways to improve their informed consent process.

“Are we including all the content that patients want to see when they use a consent form?” asks Dr. Rooney. “Are we communicating in a way that’s meaningful? Are we using graphics? Are we using illustrations of possible side effects? These are all possibilities that can really improve how we communicate with our patients, making sure that, when they sign up for a treatment, it’s something they understand and that makes sense for them.”

Dr. Rooney adds that the informed consent form should be thought of as one element in an ongoing patient engagement process. “Signing and understanding the informed consent form is just a small piece of the process,” he says. “It’s really about engaging patients and making sure that these forms can be used as a resource to guide conversations and for patients to reference later should they have questions.”

For this reason, the informed consent process is not one that ends just because the patient has signed a form, remarks Dr. Rooney, but rather one in which reassessing and revisiting treatment strategies and decisions is necessary throughout the delivery of ongoing care.

“The patient’s understanding of the treatment can change and evolve, and I think it’s important to revisit their understanding at every visit,” concludes Dr. Rooney. “At every opportunity, you have to make sure that the patient is really in tune with their treatment and health care. I would recommend clinicians view informed consent as a process and that [they do] it in an iterative way every time they interact with a patient. I believe this is one way to hopefully improve the informed consent process.”

**Designated driver**

Generally, physicians or other licensed clinical practitioners are legally responsible for securing the patient’s informed consent, which is codified in state laws to varying degrees.9

“Informed consent requirements are going to vary somewhat by state law,” explains Hajde. “In some states, [the law specifies] that informed consent has to come from the physician. In other states, it might not be as specifically clear that informed consent has to be performed by the physicians themselves. However, I would definitely say, from a liability and malpractice standpoint, it really needs to be the physician that has these conversations with the patient.”

Hajde elaborates on this point. “The physician wants to make sure the patient is comfortable with all of the pros and cons—the potential for possible complications or adverse outcomes—for whatever procedure or treatment they’re doing,” he says. “This includes describing to the patient the potential alternative treatments or tests—if there are any—that they might be able to pursue. [The physician will] also want to make sure the patient understands the consequences of not accepting the test or treatment if they decide not to [receive] it. I don’t think any of this can be delegated to anyone else.”

This is not to say other members of the health care team, including medical assistants, do not have an important ancillary role to play in supporting the informed consent process. Office staff may take responsibility for obtaining some general administrative consents, such as to bill the patient’s insurance or sign a notice of privacy. Staff may also assist with completing the informed consent forms. For example, staff may witness the patient’s signature, once the physician or other practitioner has explained the procedure or treatment to the patient.10 Properly trained and credentialed staff can also perform aspects of patient education associated with informed consent.

In some circumstances, staff might ask a patient to verbally confirm what procedure is being done and why before...
When a consent form is signed, it becomes part of the encounter documentation,” notes Zetter. “Now, it is possible for properly trained staff to provide the informed consent form, as appropriate, to review it with the patient and have the patient sign the form. But ultimately, the physician or whoever the rendering provider is has to verify that the informed consent was done. If there is an electronic health record, the physician has to go through and review it. There should also be access records that state when the physician reviews that electronic document.”

**Decision-making detours**

Certain exceptions may affect standard informed consent requirements. Individuals considered mentally incapacitated, based on clinical or legal criteria, may require a surrogate decision-maker. “When a patient lacks decision-making capacity, an appropriate surrogate should make decisions with the physician,” according to the American College of Physicians.11

Treatment should conform to what the patient would want on the basis of written or oral advance care planning. If these preferences are not known, care decisions should be based on the best evidence of what the patient would have chosen based on the patient’s values, previous choices, and beliefs (substituted judgments) or, failing that, on the best interests of the patient.11

Additionally, children under the age of 18 are often legally unable to provide informed consent. The American Academy of Pediatrics (AAP) reports that informed consent for minors requires both parental permission and assent from the patient.12 The latter involves helping patients achieve a “developmentally appropriate awareness of the nature of [their] condition.”12

A physician or other provider is expected to make a clinical assessment of a young patient’s understanding of their medical situation, according to the AAP’s Committee on Bioethics.12 As such, the minor patient should be told what to expect from any proposed tests and treatments. The physician should also solicit the patient’s express acceptance of any proposed medical care. In turn, providers should be sensitive to whether the minor faces inappropriate pressure to accept testing or therapy.12

Finally, exceptions to informed consent requirements may apply in emergency medical situations, when time or a person’s incapacity makes it impossible to obtain formal consent to treatment.13

**A two-way street**

Informed consent protects not only the patient’s interests but the medical practice as well. “From a malpractice standpoint, informed consent protects the physician from being accused that the patient didn’t understand what they were going to do, including the risks versus rewards of going through with a procedure or not,” says Zetter.

Accordingly, Zetter emphasizes the informed consent process should allow the physician the opportunity to clearly document in the patient record the medical condition that warrants a recommended test, procedure, or treatment, while also verifying that the purpose and benefits have been explained to the patient.

With this in mind, office staff should consider the process of obtaining consent as less of a requirement for completing a routine checklist of tasks and more as an opportunity for both physicians and staff to build better rapport with patients, says Karen Nichols-Skoff, AAS, CMA (AAMA), office manager for Lawson Family Medicine and Aesthetics in Daleville, Virginia.

“The informed consent process is an extension of communication between the physician and the patient,” says Nichols-Skoff. “The process itself allows a patient about to undergo a procedure the chance to clarify concerns or questions at every stage of their encounter, with both a physician and staff.”

Following a clinical examination, Nichols-Skoff or the other medical assistant on staff will go over the informed consent form with the patient and serve as a witness to the patient signing the form.

“We will fill out the informed consent form and put in the diagnosis and whatever the physician is going to do, such as … ‘excision, lesion back,’” she says. “The form will describe what’s going to be done, anesthetic use, the risk of bleeding, infection, or scarring, what could happen if the procedure isn’t done, and what the possible alternatives to the procedure are.”

**Driver’s test**

Physicians are responsible for providing comprehensive information about treatments to secure informed consent. Additionally, they must verify that patients have adequate capacity for decision-making. Patients can demonstrate their ability to make an informed decision and provide consent in several ways, according to American Family Physician14:

- Prove their understanding of all aspects of the treatment, including benefits, risks, and alternatives—for example, by echoing what they learned from the physician
- Show they have considered each option, along with their accompanying benefits and risks—for example, by outlining how their reasoning led them to a specific choice
- Communicate their decision to the physician

CMA Today | JulAug 2020 13
The practice’s informed consent forms for procedures were originally adapted from another practice, reports Nichols-Skoff. Relevant details were filled in as necessary to suit their particular office information and procedures.

**Buckle up**

Informed consent is not only a legal and ethical responsibility but also a patient safety issue. Communication issues during the informed consent process are frequently at the root of serious adverse events in health care, reports The Joint Commission. Informed consent–related adverse events have included incidents involving wrong-site surgery, operative or postoperative complications, falls, and medication errors, among other events.

Fortunately, patients can be well informed about their medical treatment options when clinicians and other members of the health care team take the necessary steps to discuss, educate, answer questions, and otherwise engage with patients as they navigate often complex choices at every stage of their health care journey. This communication defines safe, patient-centered health care.

The ability of health care providers to successfully meet informed consent recommendations can go a long way toward establishing positive and effective relationships with patients that are built on mutual respect, communication, and a commitment to pursue the best possible health outcome for every patient.

**References**


