“Common factors cited by plaintiffs for pursuing litigation included dissatisfaction with cosmetic outcomes and perceived deficits in informed consent. These factors reinforce the importance of a comprehensive, preoperative informed consent process in which the specific potential risks and outcomes are presented by the surgeon to the patient to limit or avoid postsurgical allegations.”

— “Analysis of Factors Associated With Rhytidectomy Malpractice Litigation Cases,” by A. Kandinov et al., JAMA Facial Plastic Surgery, February 9, 2017

Informed Consent: Ensuring It Really Is Informed

The issue of informed consent comes up frequently in medical professional liability (MPL) lawsuits—but in a tricky way. The suit will cite a major claim, “medical malpractice,” and it will list the facts making up that claim. Or it will assert “professional negligence.” You don’t usually see cases where there is a formal allegation of “failure to obtain informed consent.”

However, if you read through the full text of complaints, you will find something related to informed consent almost every time: often, the patient is angry about something that happened that he hadn’t expected. Or he may be upset about some kind of...
Informed consent is actually a cycle of back-and-forth communications, possibly over several conversations.

Emily Clegg, risk consultant for UMIA Insurance, Inc. (UMIA) works with healthcare professionals to reframe informed consent as a process of communicating, rather than as a form. Here is some guidance about what can be done to address this issue. But first, an illustrative example of what can go wrong.

Case study. A middle-aged man, David Cobbs, is suffering from abdominal pain and nausea. He goes to see his family physician, who diagnoses a stomach ulcer. The doctor brings in a surgeon, and both doctors recommend surgery. On the morning of the procedure, Cobbs is given a stack of forms and told to complete them. He signs them, and then goes into the procedure. It goes well and recovery is uneventful.

But then, Cobbs begins to feel severe pain in his abdomen. He goes back to the hospital, and the physicians there discover that he is suffering from internal bleeding due to a severed artery that arises from his spleen. Because of the seriousness of this event, he goes back into surgery for repair of the artery.

Subsequently, this becomes an MPL case. When the case went to trial, the defense said that the severed artery is a risk in his type of surgery, even though doctors of course try to avoid it.

The patient countered, “No one told me that.” A month later, patient Cobbs again begins to feel pain, and a second stomach ulcer was diagnosed, and a third surgical procedure is done. He again recovers uneventfully. But internal bleeding again ensues; the cause is discovered to be absorption of a suture.

At trial, the provider explains that this can happen sometimes; doctors don’t want it to happen but it does. And once again, the patient counters, “But nobody told me.”

In this case, all of the care was done well, and the patient was treated appropriately; but there was an unfortunate chain of events. What is lacking here is communication with the patient about what could have happened. And there is a lack of respect for the patient in not telling him what to watch for, what could happen.

From this case, Clegg draws out three “lenses” for examining informed consent. The first is the patient safety lens: Are we being careful in patient selection? Can a better informed-consent process reveal that a given procedure isn’t right for a particular patient? And every patient needs to understand what’s going on—what to watch for, and what to do if he is feeling that something is wrong when he gets home.

The second lens pertains to the physicians’ ethical duty. They have an ethical obligation to communicate with him.

The third lens is risk mitigation. Many lawsuits stem from breakdowns in communication: A patient was unhappy, or perhaps had unrealistic expectations or experienced an unexpected outcome, or had lingering questions that were never answered.

Focusing more attention might help avoid these issues. In regard to the patient in the case above, he should have been monitored for complications all along the way; he should have been told what the team would be watching for next, what the team would be worried about, and the possibilities for what could happen in each phase. With that, he might have not ended up filing a lawsuit.

The cycle of informed consent

Clegg coaches providers about reframing informed consent as a cycle. There’s a reason why she calls it a “cycle.” Informed consent is not an end point; it’s not a check box; it’s not a result. Informed consent is actually a cycle of back-and-forth communications, possibly over several conversations. Note that this does not pertain to the minor, routine encounters in medicine, and we’re not talking about emergency care. Don’t start thinking about the cycle in an emergency situation—just care for the patient.

But it is critical to think about informed consent whenever there is a chance of a complication, or a reaction—or if the treatment the physician is giving will mean a lifestyle change for the patient. These are the kinds of things that should make a doctor think about informed consent.

Clegg explains that it would be a lot easier if the legal world would give healthcare professionals a checklist of the informed consent procedures needed. But unfortunately, that doesn’t exist. It’s more of a professional judgment issue that a physician needs to think through—if there are life or lifestyle changes involved or a chance of some sort of reaction.

For the first step in the informed consent cycle, physicians need to consider if a particular patient has the capacity to make an informed consent decision at all.

The second part of the cycle is communication. Providers should consider, what do I need to say? What is important to this patient and his or her life going forward? Clegg advises that a reasonable, patient-centered approach will serve providers better than worrying about
might have different rights than a minor in Utah. The states all have different laws about what a minor can consent to is defined by state law. A minor in Oregon is 16 or older, but it gets a little harder to say when it is a 16-year-old. In fact, what a minor can consent to is defined by state law. A minor in Oregon might have different rights than a minor in Utah. The states all have different opinions about what they think a minor should be able to consent to. Also, consider the particular status of the minor: is this minor pregnant? Is this minor married? Is this minor emancipated from her parents? A teenager’s buy-in to her care plan is essential for her to comply and heal, but her capacity may be limited by state law.

The third part is comprehension: does the patient understand everything—are we getting everything through? How can we be sure? How can we check that the patient understands?

Finally, we reach consent. But consent is much more significant than a signature on a form. Consent is an agreement that we have communicated, explored questions, shared mutual expectations, and we reached a plan together.

Focus on the form misses the point
A common question from facilities focuses on the informed consent form: Does it look good? Does it cover everything I need? But in fact, focusing on the form per se is missing the point, which is the conversations you need to have with the patient.

Consider the basic timeline of a surgical patient: pre-op visit, signing of forms, the procedure, post-op period in the hospital, discharge, and post-op visit to a clinic. Where should the informed consent conversations happen? They should happen at every step along the way.

As Clegg advises, informed consent starts at the initial visit, where the physician asks: How do you feel about this plan? What questions do you have? Then, at the pre-op visit, ask, what questions do you have now? Has anything changed? How are you feeling at this point, and do you understand what is about to happen?

It’s not just one moment in time, remember; it’s an ongoing cycle. But note that during the post-op period, the conversation changes, slightly. If the doctor has done a good job of informed consent upfront, and communicated well, he can start by saying “Remember we talked about this; remember we were worried about this; we were watching for this.”

Capacity for informed consent
The basic issue is this: Can this person who’s right in front of me make a valid choice? “Capacity” and “competence” are sometimes used interchangeably. But “capacity” probably pertains to the person’s state at the moment; if they are intoxicated, they can’t provide a valid informed consent, whereas competence is more of a legal term. But in either case, the questions are the same: Is this person of a legal age? Can this person understand me? Can he understand the situation and make a decision? Can the patient deliberate, and be able to give consent?

What should be done in dealing with minors is a very common capacity problem. Clegg notes it’s not an issue when the patient is a 6-year-old, but it gets a little harder to say when it is a 16-year-old. In fact, what a minor can consent to is defined by state law. A minor in Oregon might have different rights than a minor in Utah. The states all have different opinions about what they think a minor should be able to consent to. Also, consider the particular status of the minor: is this minor pregnant? Is this minor married? Is this minor emancipated from her parents? A teenager’s buy-in to her care plan is essential for her to comply and heal, but her capacity may be limited by state law.

And then, consider the other end of the age spectrum: a senior with diminishing mental capacity. If the patient is older, and the conversations aren’t quite clicking the way they used to—if the physician is seeing signs of this, he can’t ignore them. But maybe it’s really a communications problem; maybe what is needed is a spouse or adult child to help out. On the other hand, if it’s a competence issue, the healthcare professional may need some help from the court. And he should always bring up the topic of having an advanced directive.

There may also be language barriers. Does the patient understand what the team is saying? Or, if the patient is not a native English speaker, the physician may need the services of a professional translator; family members as interpreters may be add their own comments along with the translation.

Conversation basics
Once we are confident in capacity, Clegg focuses next on the provider’s side of the conversation: What do we need to say? In the legal sphere, most state laws and court opinions look for the diagnosis, the nature of procedure, the material risks, the available alternatives for treatment, and alternatively, the risks of doing nothing. But the big question is always this: What material risks does the doctor have to disclose? Do they need to mention every possible risk, so that it sounds like the end of a pharmaceutical commercial? No, not necessarily; that’s not really the standard that courts are looking for.

The language usually seen when it comes to a lawsuit, and what the courts are talking about in evaluating it, relates to the high-severity things, the high-frequency events, and whether or not it is a substantial or significant risk. The test is, what would a reasonable patient or a provider want to know?

So the standard comes down to two things, reasonableness and the standard of care. Clegg advises, however, that physicians should not think about informed consent in terms of what a court or a jury might think about it; instead, they should consider a more patient-centered approach. The specificity of information, for example, needs to be tailored to the patient. What might the patient be worried about? What does he not understand? What might the patient be concerned about during the post-op period?

Also, if providers can remember to be human, that can eliminate many communication problems. They should sit down with the
Comprehension

Next, Clegg focuses on the recipient of the information: the patient. How do we make sure that the patient isn't just shaking his head when a physician speaks? The first thing Clegg coaches on is thinking about the language we use. Certain words and phrases don't mean the same thing to everyone. If a doctor says, "you'll be back to work," does that mean the same thing to an accountant as is does to a groundskeeper? If I tell someone they will feel better, what does that mean to them? "Better," compared to what? If he says there will be "minor or minimal scarring," what does that mean? And if he says the "pain will be minor or minimal," is that based on my experience, given that he has perhaps seen some serious pain and also some severe scarring? Or is it based on this patient in particular, who's never seen any of that?

Or if he says to a knee-replacement patient that post-surgery, they'll be just as good as new. But it's an artificial joint that they will be getting; they're not going to be as good as new.

Another tricky word is "textbook." If a doctor tells the parents of a child after a surgery that it was "textbook," what does that imply — that recovery will be quicker? That there will be no complications? That everything will be wonderful? It's essential to choose the language, the descriptive terms that are used very carefully.

Next, simple strategies can check whether our information is getting through to the patient. Clegg points UMIA's providers to the National Quality Forum's teach-back technique. That involves the doctor asking the patient to verbalize what he's told them, in their own words. If he has to go through the mental steps needed to accomplish this, it makes the information stick: The doctor has just described the treatment plan; how would the patient describe it to his family? The physician can ask, how are you going to manage this at home — can you show me how you are going to do this at home? How they respond will give the doctor tremendous insight into how well the patient has been comprehending what his doctor has been saying.

The National Quality Forum studied this "ask a question and see what you get back" technique, and found that it took only one extra minute, but gave three times greater recall and comprehension of what patient, look him in the face, listen to what he is saying, and learn his name and the names of his family. Surveys repeatedly indicate that patients don't feel like their providers are really listening; they feel like they need a connection with that person.

In any event, Clegg admonishes that ultimate responsibility for communication cannot be delegated. The entire team can play an important role in sharing information and answer questions. But the responsibility for ensuring the patient's understanding always falls on the physician.

Forms still matter

Reframing informed consent as a robust conversation instead of a signature on a form does not mean the forms are not important. The consent form and the medical record are the evidence that a conversation took place. They are the proof a physician carefully discussed the risks and benefits, answered questions, and the patient elected to proceed. But in weighing the importance of the form, Clegg advises that a good form will help your defense in a lawsuit, but a good conversation may avoid the lawsuit in the first place.

Another strategy Clegg recommends to check for comprehension is to use the care team. They can participate in the communication, and they can also wave red flags. They may come in the form of unrealistic expectations, as when a patient says, "I'm going to get my life back!" Or, "I'm going to be good as new after my total knee surgery." Team members should be empowered to speak up about these comments.

Videos, online education, informative apps — any approach that will support communication and also support comprehension is terrific.

As the options for education aids grow, it is interesting to hear what juries think of their use. Clegg points to a study in the Journal of Law and Medical Ethics asking that question with mock jurors. They were told that the physician and the patient had talked, but that the patient then refused cancer screening, repeatedly. Upon hearing this, the mock jurors simply could not believe that the patient refused cancer screening. They thought, there's no way that the physician could have given adequate informed consent, if the patient refused something that could have saved his life. Less than one in five jurors believed that the physician could have met the standard of care.

A second group of mock jurors were told the same scenario: physician and patient talked about cancer screening, patient said no thanks, but this time the group was told that doctor and patient had watched a video. Then the jurors were shown that video, which outlined the pros and cons of this particular screen. This time, 94% of the mock jurors said that the physician met the standard of care. The video explained the complexities of the decision about screening, and also showed that the using video showed that the doctor had showed an extra measure of concern for the patient's well-being.

This article is based on a webinar presented by Emily Clegg (email eclegg@umia.com) for UMIA and MMIC, February 8, 2017, "Informed Consent: More than a signature." To view the webinar, visit UMIA.com or MMICGroup.com.