Communication and Informed Consent

America is a melting pot with myriad languages spoken, and many people don’t communicate effectively – in any of them. Factor in hearing and sight impairment; cultural, gender and geographic barriers to communication; lack of time; the woeful job that some medical schools do in training our prospective doctors to communicate; increasing and sometimes unrealistic expectations of care; and patients’ love affair with the Internet (and all the misinformation they find there), and obtaining truly informed consent becomes even more challenging. Fay A. Rozovsky, JD, MPH, DFASHRM, tackles this tricky topic in this issue of CCC Forum. (Please note that the remarks that follow represent the views of the presenter, and not those of Combined Coordinating Council, Inc., or its clients.)

At worst, informed consent is seen as a nuisance – nothing more than a piece of paper, but wise clinicians know that it is so much more than that. Informed consent is all about the bedrock of communication, and is the most effective patient safety arrow that we have in our quiver. Healthcare providers can use the communication process to identify and manage those at risk. When done correctly, the informed consent process provides a tool for setting realistic patient expectations.

The concept of informed consent dates back to 1912, when Schloendorff v. The Society of the New York Hospital became the touchstone case in consent law in the United States. The much-revered Justice Benjamin Cardozo, who would go on to become an Associate Justice of the United States Supreme Court, drew on the concept of autonomy and wrote in his decision that it is the patient who has the right to decide what will be done to her body.

Needless to say, this case has given rise to many more generations of case law. And, even though Justice Cardozo recognized almost a century ago that consent was far more than a piece of paper, too many contemporary clinicians view consent as a persistent problem and an administrative nuisance.

In an elective situation, a person may present with an illness or an injury or a complaint, or a suspected pregnancy. A nurse practitioner or a PA (physician’s assistant) takes a history, and then the doctor talks to the patient. The history is critical for delineating patient expectations and as a foundation for diagnosis by the physician. From this history, the doctor conducts an examination and dialog and then comes up with some findings and an outline of proposed treatment. And then we ask the patient to make a decision. Patients have an idea that this is a physicians who view a patient’s mere signature as “consent” are misguided. Patients resent this mindset... and so, quite frankly, do juries.

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Consent Concerns

Some of the following may not apply, depending on the nature of the practice, but you get the idea.

**Compliance.** A poor consent process can hamstring compliance before the patient ever leaves the office. I think of this as potential non-compliance. Consider the child with repeated asthma flare-ups because the parents can’t afford an inhaler. Or the guy who comes in with his blood pressure through the roof because he refuses to take medication that affects his sexual performance. Or the man who won’t take his MAO inhibitors because if he does, he can’t have a beer with the boys after work. The informed consent process may be the only way to predict whether compliance will be a problem and whether alternatives should be considered.

**Geographic barriers.** Idiomatic speech in certain regions colors communication and the ability to convey and interpret information. The parties simply are not speaking the same language, even when the language is English.

**Linguistic barriers.** The Limited English Proficiency (LEP) guidelines have come under great derision from many quarters, but they’re here to stay. Obviously, it’s difficult for a physician to work effectively if he or she can’t communicate with the patient. Details on the LEP requirements and suggestions for achieving compliance are available online at www.hhs.gov/ocr/lep/guide.html.

**Multiple consents.** Is it necessary to repeat the entire consent process each and every time a patient comes in for regular treatments? I’m thinking of patients who go to an ambulatory oncology facility for scheduled chemotherapy or radiology treatments. One approach is to do the big consent upfront, followed by a mini-consent – with appropriate documentation – each time a patient presents for treatment. For example, one could simply ask if anything has changed since the last appointment. Did the patient follow the recommended diet and any instructions? Did the person take any prescribed medicine, as directed? Does the patient recall the possible problems discussed earlier?

**Patient expectations.** Think of patient expectations as the volume control on a boom box and consent as the hand on that control dial. This is where healthcare providers lay it all out and use the consent process as a communication tool to bring patients’ expectations in line with reality. For example, patients don’t hear that there is less than a 50 percent chance of cure - they hear what they want to hear . . . that there’s at least a 50 percent chance of cure. This is where communicating what is becomes crucial.

**Surfing the net.** Patients may find too much of their medical information on the web, and some of what’s out there is snake oil. This is an “if you can’t fight ‘em, join ‘em” situation, and healthcare providers need to confront it head on. Physicians who have established solid communication with patients can help them sort the wheat from the chaff. Patients who want to protect a wonder-cure discovery from a cynical clinician will never mention it otherwise. Plus the doctor could lose patient trust for “holding back.” That’s why it’s best to join ‘em and give patients who want more information a list of trusted medical websites and offer to discuss their findings.

**Therapeutic privilege.** Physicians will sometimes encounter patients who are so emotionally fragile that the physician fears that disclosing risk-benefit information could send them over the edge. One solution is to request a consult by a behavioral management specialist to assess the patient’s ability to make necessary medical decisions without being adversely affected. If the specialist concurs, the physician proceeds with those aspects of informed choice that the patient can handle. The chart reflects the specialist’s concurrence, as well as what was discussed and what wasn’t mentioned. This is a recognized strategy and not a means of circumventing the system. This needs to be well documented in the chart. This must be done with a view toward the New York Public Health Law informed consent requirements.
Consent Conundrums

Case 1: A man is out in the New Mexico desert with friends enjoying his hobby of snake handling when his snake bites two of his fingers. The friends apply a tourniquet and rush him to the nearest emergency facility, which is 45 minutes away. During the consent process, the physician asks how long it has been since the snakebites and tourniquet (45 minutes) and explains the emergency treatment. The patient will receive a shot of antivenin at the base of the two fingers. The arm will be packed in ice and elevated, and then they will talk.

And they did talk, just as soon as the patient was stabilized. The doctor explained that the risk of gas gangrene increases exponentially with the length of time between the bite and the antivenin injection. He discussed the possible complications, went over the discharge summary instructions and sent the patient home.

The patient developed gas gangrene and lost the two fingers at the base of his hand. He sued for negligence, citing the lack of informed consent. The doctor should have told him about the alternative treatment of injecting the antivenin further up the arm.

The judge ruled for the defense, stating that no patient should expect the physician to delay treatment and go through all the elements of the consent process while the venomous poison of a rattlesnake is coursing its way through the patient’s body with each beat of the patient’s heart.

In other words, when someone presents with an asthma attack or a heart attack or a gunshot wound, but is still able to talk, the caregiver does that which is absolutely essential. The caregiver is not expected to go through the entire consent process, because the alternative is that the caregiver will have documentation of a very complete consent process . . . and a very dead patient.

Case 2: An 83-year-old WWII veteran with bilateral hearing impairment from nerve damage presents for elective surgery. The caregiver asks all the usual consent questions, and the patient answers “uh-huh” to each and every one of them. The problem is that no one did a routine assessment of the gentleman’s ability to understand or appreciate or even hear the information.

This is an example of when healthcare providers need to think beyond just complying with the law, and let common sense prevail and consider the more practical aspects of healthcare risk management and consent and patient safety. If they use these tools properly and communicate effectively, someone might pick up on the fact that this patient has a hearing impairment and cannot actively participate in the consent process without some kind of assistance.

Unfortunately, that didn’t happen in this case. The patient had his elective procedure and ended up with an

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routine process, but they’re wrong.

The doctor doesn’t have to detail every known risk and every known benefit - just the probable risks and benefits, any treatment alternatives and the risk of foregoing treatment altogether. Case law, statutes and regulations throughout the country have established that people are entitled to this information. In New York, providers are not required to disclose all possible risks and alternatives, just the most likely ones. Rare, obscure risks need not be disclosed.

A court in Connecticut found that even when an alternative is more fraught with risk than the recommended treatment, patients still have a right to know about that treatment option and all the possible risks and benefits associated with that alternative. Not all the courts are ruling this way, but it’s something to think about.

In a true emergency, caregivers do whatever is necessary to alleviate the emergency condition. When it comes to triage, patient care trumps paperwork. A real medical emergency is when someone presents in extremis. It’s a life-or-health-threatening situation. The person may be unable to interact with the caregiver. Time is of the essence – there’s no time to spare to find someone who might be legally empowered to act on this person’s behalf. So the caregiver does whatever the caregiver has to do. Consent is implied.
That's a true emergency. Most cases, however, are more a matter of the impracticality of consent or consent poorly obtained.

The accompanying boxes discuss the intricacies of the consent process. There are communication barriers that make the consent process such a challenge. There are strategies for obtaining a quality consent, ensuring that all healthcare partners understand and agree with the treatment plan and protecting all participants. And there are some case studies that highlight why informed consent is such an interesting aspect of the healthcare process these days.

If communication is done right, from the very first patient encounter, the physician will never lose rapport with the patient. Not even if there’s a bad outcome. If the lines of communication aren’t set up right – and the first caregiver encounter with patient or family is to discuss a negative outcome – it’s going to be an arduous task.

For all the things the law has given us since Justice Cardozo’s decision almost a century ago, the law doesn’t provide for the practicalities. As a result, it is incumbent upon healthcare professionals to use the law as a touchstone, but to set up an infrastructure of communication, so that we have an established process on which to rely when something bad does occur.
Creating Consent Compliance

**Take a good patient history.** Sounds real basic, and it is. But the fact remains that you cannot obtain informed consent without a good patient history.

**Ask the right questions.** For example: What kind of medication do you take? Instead of Do you take medication? Be as specific as possible and adjust the line of questioning as a clinical picture develops during the course of the discussion.

**Give the patient prompts.** For example: Do you use any herbal supplements? Do you use aromatherapy? Aromatherapy in particular could be significant if the patient has a respiratory problem.

**Ask the right follow-up questions.** If you get an ambiguous answer, revisit it. Ask the patient to help you understand what he or she is saying.

**Reconfirm the patient's comprehension.** Ask patients to repeat what you have just told them. This is a good way to pick up any misunderstandings.

**Reconfirm your comprehension.** Make sure you have the right information. If there are ambiguities in the patient history, the doctor needs to know before laying on hands or writing a prescription.

**Use confirmatory questions.** This is very important. If the patient doesn't respond promptly and appropriately, that's a stop sign. The patient may be clueless or overwhelmed. Sometimes it helps to break the information up.

**Get the family involved.** With the patient's permission, of course. The law doesn't recognize the concept of family-focused consent – yet – but the Joint Commission does. The point is that the patient is preoccupied, and those nearest and dearest may remember or know things the patient doesn't. The more information the physician has, the better the chances of avoiding risk.

**Address what's important to the patient.** This goes back to compliance. Patients want to know about cost and lifestyle changes and whether they can really do whatever is being asked of them. Physicians want to know if the patient can be compliant. The prompts here come from the history and any cues (hesitation, nervousness or fidgeting) during the consent discussion. If the physician’s recommendations aren’t realistic as far as the patient is concerned, compliance is doomed to failure. One then must consider any workable alternatives. Otherwise, the doctor gets the fudge factor – the patient says whatever he or she thinks the doctor wants to hear. This move sets everyone up on a trajectory for disaster.

**Tailor the conversation.** Educated patients like the big words and may feel patronized if you give them the “simple” version. The flip side also is true. It's all about putting the information into whatever framework works for the patient.

**Don’t gloss over the tough stuff.** Patients have the right to know when the risk includes death, disability or permanent disfigurement. They also need to know about possible lifestyle or occupational changes and the risk of foregoing a test or treatment. The only exception would be if the person's emotional condition precludes processing such information.

**Use a checklist.** I like the checklist approach. Pilots swear by it and don't taxi the plane until every item is checked off. Healthcare professionals try to keep it all in their heads – an unrealistic approach that sets people up for failure. A consent systems check based on a checklist gives healthcare professionals an excellent tool to ensure the process is done right. The checklist should work whenever a patient presents in whatever setting – even in an emergency room. The checklist questions also would further serve the cause of patient safety, acting as a prompt to raise red flags concerning systems that ought to be in place should something untoward occur. Moreover, the checklist would serve as a historical record that providers did what they said they did. And, if there is a bad outcome, the checklist could be used in the root cause analysis for a reviewable sentinel event and serve as a line of defense in the context of a potential cause of litigation. That's a lot of return on a single tool.

**A signature doesn't equal consent.** Physicians who view a patient's mere signature as "consent" are misguided. Patients resent this mindset . . . and so, quite frankly, do juries. No one in the legal community credits a piece of paper stuck under someone's nose while parked on a gurney waiting to go into the O.R. A detailed progress note that memorializes the consent discussion or discussions is much better – for both the physician and the attorney who may ultimately have to defend the case.

**Document it all.** Documentation protects everyone - the patient, the provider and the healthcare organization. The checklist approach discussed above is an excellent means of documenting the scope of the consent process. And one needs to document it all – what was discussed, what wasn't discussed, the rationale, the patient's (and family's) responses, what was followed, what wasn't followed. Everything.
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For questions concerning educational materials or programs, contact Rita Phelan at 212-643-8100.

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