INFORMED CONSENT: LEGAL ISSUES

Please read the main presentation in *Bioscope* called *Informed Consent: Legal Issues*.

We mentioned previously that legal standards for appropriate informed consent disclosure of information often differ from moral standards. In this section we examine legal standards. Unfortunately or not, there are many different legal systems in the United States. Each state has its own set of laws, and in each judges are bound by different precedents. In the United States, as in countries like Great Britain and Canada, the decisions of judges tend to make law. That is, new cases need to be decided, at least typically, in the same way as previous cases. Judges are often influenced by decisions in other states, but the influence on a judge of a higher court within the same state has more binding force.

Some states may have written code about informed consent, and judges in different states may have decided differently about what counts as appropriate informed consent. When we say that *there are different standards of appropriate information disclosure*, we mean that some state courts will tend to decide lawsuits based on one standard and some on another.

By the way, patients can bring a lawsuit against a physician or nurse if they believe that informed consent is not proper. Such lawsuits are relatively common, but they are difficult for the patient to win.

The first legal standard we cover about what should be covered in the informed consent process is called the *community of physicians standard*. Despite its name, it applies to all healthcare providers. Basically the standard maintains that healthcare providers should offer the information that is typically offered by other healthcare providers in similar circumstances. The standard is used in many states, maybe most.

The community of physicians standard has the strength that a physician or healthcare provider can often more or less know what sort of information is typically provided. The standard has an obvious weakness. Suppose providers typically give very little information. That would be considered improper from a moral point of view. Another problem is that healthcare providers might leave out risks that patients would find important.

Due to weaknesses of the community of physicians standard some state courts used the *reasonable physician standard*. Again this standard applies to all healthcare providers in those states. Simply stated, it requires disclosure of the information that a reasonable healthcare provider would offer. You already can see a weakness in the standard. What in the world would a *reasonable* healthcare provider offer? That is tough to answer. Basically, the reasonable provider would offer important information about a procedure. But what counts as
important? Significant risks should be disclosed. Risks involve probability. A low probability of a bad outcome makes it less likely that a physician should disclose a risk. Nevertheless, as the outcome is worse and worse the risk should be disclosed. So a very bad outcome with a small probability might need to be disclosed, or so a court might decide. The court might say that a reasonable healthcare provider would disclose such information. Court cases tend to indicate the kinds of things that judges want disclosed.

(By the way the main responsibility to engage in the informed consent process typically rests with a physician. Information about major medical interventions should be provided by the physician, legally speaking. If a physician delegates that task to someone else, perhaps a nurse as often happens, the physician puts himself or herself as well as the nurse at legal risk. However, nurses have the obligation to gain informed consent for nursing procedures and physical therapists for their procedures.)

The reasonable physician standard offers more protection for a patient. On the other hand, it puts the physician or other healthcare providers in a tough spot because it is more difficult to determine what a court would demand as reasonable disclosure.

The standards we have examined so far are from the perspective of the healthcare provider. Some courts, I believe in the minority, use standards developed from the patient's perspective. These standards consider the kind of information a patient would want to know. When that is determined, it provides the kind of information that should have been disclosed.

The first patient oriented standard is called the objective patient standard. This standard insists that information should be disclosed based on what a reasonable patient would want to know. It has the same strengths and weaknesses as the reasonable physician standard.

The subjective patient standard requires information that the individual patient wants to know. This standard is not frequently used. Its strength is that it attempts to give the patient what the patient wants to know. The weakness is that the patient might want to know irrelevant things or the patient might not want to know enough.

For good or bad, these four standards are all used in actual lawsuits in the United States today. To make matters more complex, some states may use a combination of these.

AN INFORMED CONSENT LAWSUIT

Some of you probably intend to become healthcare practitioners. I believe that healthcare providers should understand their legal obligations in order to protect
themselves and to provide better care as well. In this way the section on legal issues is quite important. The bottom line is that a healthcare provider can be successfully sued when providing care that does not meet the appropriate standards. Medical malpractice often involves failure to practice up to the appropriate standard of care. An informed consent lawsuit involves failure to provide an adequate informed consent process. Both medical malpractice and informed consent lawsuits involve similar considerations, at least typically.

Both kinds of lawsuits typically involve the claim of negligence. To be successful in informed consent lawsuit must have the following ingredients in order to demonstrate actual negligence.

It must be shown that the healthcare provider has a duty. This means that the provider have the responsibility to engage in the informed consent process. It might be shown that the healthcare provider was not the main person involved and thereby have no obligation to engage in the informed consent process. A nurse might claim that she or he had no obligation to attain informed consent.

Breath of duty must be proven. (Proven in a civil lawsuit means that the evidence tips in favor of one party or the other. In fact, the successful plaintiff should show there is at least a 51% chance that they are correct. You'll notice that this is a much lower standard than is found in a criminal proceeding, where a jury must decide beyond a reasonable doubt.) Breach of duty means that the informed consent process was not adequate. That would be based upon the appropriate standard in the state in which the lawsuit was brought.

Injury must be established. This means that if the informed consent process had been adequate the patient would not have suffered the injury in question. It also means that without an injury to the patient an informed consent lawsuit should fail. (We say should fail because sometimes cases succeed which do not adequately show all of the needed ingredients.) No matter how bad the informed consent process, if the patient suffers no injury a negligence lawsuit should fail.

Now to the tough ingredient to understand: causation. The lack of proper informed consent must have caused the injury. You might wonder how this could be. After all injury does not come by failure to say certain words. It usually comes because of medical circumstances or failure to provide adequate care. That's true. A patient might be treated perfectly adequately and yet suffer injury. There are known risks to many medical procedures, maybe all medical procedures, that occur despite the best care offered. So how can failure to provide information in the informed consent process cause an injury?

Suppose the patient were given good information. For example suppose a certain risk were fully disclosed. That patient might reject the procedure. If the procedure were rejected then the known risk to the procedure would not occur. In this way failure to provide information may be thought of as causing the injury.
By not giving information about a risk the patient might accept treatment that would be rejected if the risk were disclosed.

The final frames of the presentation in Bioscope cover key court cases that have developed legal guidelines about the informed consent process. Information about these cases should be carefully examined.

CASE STUDIES

In the case studies section, the first case, which you should read, deals with the difference between a negligence informed consent lawsuit and a battery lawsuit. So far we talked only about negligence lawsuits. They require things like causation and injury. A battery lawsuit is quite different. Battery is about an unwanted touching. People have no right to touch us without our permission. The touching need not cause us and injury. Whether or not it causes an injury people should not touch us without our permission, at least typically. For this reason a battery lawsuit need not show injury. It just needs to show that the offense of touching without consent took place.

Informed consent lawsuits are typically not brought as battery. That is because consent was provided, but perhaps not enough information was given. Some states are more likely to use battery than other states. But still it is the minority that allow battery claims when some consent is given. However, in most states when the informed consent process is bad enough, the case may be heard as a battery claim. When the case involves negligence instead of battery the healthcare provider has an advantage and the patient disadvantaged in the lawsuit. The main disadvantage comes from being forced to prove causation. It has to be shown that the patient would not have accepted treatment had the patient been told about a particular risk. The patient accepted treatment, so it's hard to say what the patient would have done in light of the disclosure of a particular risk. This may be made even more difficult if the most serious risk, for example, a chance of death from surgery, was disclosed. You can imagine how difficult it would be for a patient to argue that he or she would not have accepted surgery if they knew it might cause paralysis but actually accepted it understanding that it could cause death. It is possible to make that claim stick, but it's a difficult task. Reading the first case might help with the distinction between battery and negligence lawsuits.

Withdrawing consent during treatment is an especially difficult issue, legally speaking. Case five, from an actual court case, is about such a rejection. Please read it carefully.

Case six is interesting. It shows the difficult spot that nurses often find themselves in. Nurses are often told to do things that are not appropriate. Who's responsible under those circumstances? Very often it is the nurse. She or he is a professional who should practice under appropriate standards of care. Simply
saying that she or he was ordered to do something is often not a valid excuse. Healthcare professionals may have the moral and legal responsibility to reject orders to do things that are not in the patient's best interest.