

WHAT IS INFORMED CONSENT? WHO IS COMPETENT TO GIVE IT?

Over the course of this lecture, you'll be learning to:

1. Distinguish between express, tacit, and implied consent.
2. Explain what "competence" is, and how it is assessed.
3. Describe different standards governing the disclosure of information to patients.
4. Explain when a choice counts as "voluntary."
5. Reflect on the importance of informed consent in medicine.

VARIETIES OF INFORMED CONSENT

The principle of respect for autonomy requires that medical staff get **informed consent** to carry out treatments or research on **competent** patients¹. Because of this, it is important to know what we mean by these terms:

- **Express consent** occurs when a person gives explicit verbal or written indication that they agree. This is the "paradigm" of consent both in medicine and the law, and it should be obtained whenever possible.
- **Tacit consent** occurs when a patient effectively "consents" to some action by *failing to object* in certain circumstances where they clearly understood that they could stop the action by objecting (and in which no one is pressuring them to agree).
- **Implied consent** occurs when the person's past choices provide strong evidence that they *would* agree, were they capable of doing so. (For example, suppose that Jones is unconscious and cannot give explicit consent to a blood transfusion. If he has agreed to blood transfusions in the past, this would be grounds for assuming implied consent).
- All of these are different from **presumed consent** (what any "rational" person *should* agree to).
 - A number of bioethicists and legal scholars have argued that that this isn't really a form of consent at all. So, for example, suppose a car accident victim comes in to the ER unconscious, and needs life-saving treatment. However, we have no idea who this person is. Should we treat? Almost everyone would say "Yes!". Some would argue that this shows respect for presumed consent ("Who wouldn't want their life to be saved?"). The critics of presumed consent argue that we don't really need to appeal to consent at all in this case—we can just appeal to principles like nonmaleficence or beneficence.

Consent can be either **specific** (for a certain procedure) or **general** (for "any treatment needed"). In general, patient autonomy is best respected by *explicit, specific consent to the treatment proposed*. By contrast, presumed, general consent has often been abused ("I *presume* these children would agree to participate in this risky experiment...").

What does it mean to be "competent" to provide informed consent? Competence can be generally be defined as "the ability to perform a task"; different people may be more or less competent to do different tasks, or to make different sorts of decisions. It is closely related to autonomy, and is required for informed consent. In each case, we need to establish **standards** that allow us to say "A person with condition C is/is not competent to complete task T." We then to establish **tests** that allow us to determine whether or not a given person meets this standard.

Some factors that are relevant to determining incompetence include the inability to (a) rationally explain or defend one's choice, (b) understand relevant information about risks or benefits, or (c) behave as a minimally rational person would behave. Different people have argued for different (and incompatible) standards. In general, it is reasonable to require *more* or *stronger* evidence for a patient's competence as the seriousness of the procedure increases. For example, we might be satisfied with a 10-year-old's competence for choosing his or her own cough medicine; by contrast, we would not allow the child to decide on serious surgery.

TWO CONCEPTS OF CONSENT

B-C argue that there two *types* of consent that often get confused by medical professionals, by patients, and even by lawyers and administrators), sometimes with bad results.

- **Informed consent as autonomous authorization:** "An informed consent is an individual's *autonomous authorization* of a medical intervention or participation in research." This requires careful consideration of the *individual patient*.
- **Informed consent as (legally or institutionally) effective consent:** "*conformity to the social rules* that require professionals to obtain legally or institutionally valid consent from patients before proceeding with diagnostic, therapeutic, or research procedures."

These two things are related, but they are importantly different. For example, a person may fully consent in the first sense even if the rules governing the second sense prohibit her from doing so. An example: a 19-year old might give fully informed consent to donate organs to save a sibling, even if state laws or hospital policies say she has to be 21. Conversely, there are MANY cases of medical staff who get patients to sign all the correct paperwork (sense 2), even though these patients don't really understand or agree to the medical procedures they describe.

¹ For more on informed consent, see Nir Eyal, "Informed Consent," in *The Stanford Encyclopedia of Philosophy*, ed. Edward N. Zalta, Spring 2019 (Metaphysics Research Lab, Stanford University, 2019), <https://plato.stanford.edu/archives/spr2019/entries/informed-consent/>; Christine Grady, "Enduring and Emerging Challenges of Informed Consent," *New England Journal of Medicine* 372, no. 9 (February 26, 2015): 855–62, <https://doi.org/10.1056/NEJMr1411250>.

While the first sense of consent is something like the “primary” sense of consent (and it’s the idea that the laws and policies in sense 2 are all “about”), this doesn’t mean we should simply ignore the second sense. In general, medical professionals need to be concerned with BOTH versions of consent, since they mutually reinforce each other. The first sense has to do with making sure the particular patient with whom one is working really knows what is going on; the second sense is about maintaining a rule-following culture where patients and staff have clear idea about how things “ought” to work.

INFORMED CONSENT IN THE LAW

Most state/federal laws (and most hospital policies) require that patients be told at least the following FOUR things:

1. The **nature of the procedure** that they are being asked to consent to. (For example, they should understand the basic differences between chemotherapy, radiation, surgery, hormone therapy, etc.). The patient should also be told the (likely) time frame.
2. The magnitude and probability of various **risks**. Basically, they should be aware of both what kinds of *harms* this procedure might cause, and how *likely* these harms are.
3. The **alternatives** to the proposed procedure, together with information about benefits/risks.
4. The expected **benefits** of this procedure. The patient should not be given unrealistic ideas of what the procedure can accomplish.

While it is undeniably important to write up informed consents documents that technically meet these requirements (and to present these to patients in an appropriate manner), it’s often much more difficult to determine (1) whether a patient is actually **competent** to give consent, and (2) whether they actually understand all of the above. This is because patients are generally NOT medical professionals with detailed knowledge of medical procedures. In the rest of this lesson, we’ll be thinking about what this means for medical professionals.

WHAT INFORMATION SHOULD I DISCLOSE? WHAT COUNTS AS “RELEVANT”?

In order to obtain informed consent from a competent patient (or from a surrogate for an incompetent patient), medical staff must **disclose** all relevant information. But how do we determine what’s relevant? Again, there are competing standards:

- The **professional practice standard** holds that you are required to disclose only the sort of information that other people in your profession normally disclose. The problem: What if the majority of professionals “agree” to give patients inadequate information (historically, this has certainly been the case)? This is the current law in many states.
- The **reasonable person standard** holds that you should disclose information that would be relevant to a (hypothetical) purely rational person. The problem: While this is better than the professional practice standard, it risks ignoring the differences between patients. In recent years, some states have adopted this standard.
- The **subjective standard** judges disclosure by “the specific informational needs of the specific person.” Problem: While this is an ideal *moral* standard for judging disclosure, it probably won’t work as a *law* or *guideline*. It can serve as a valuable supplement to the professional practice or reasonable person standards, however.

Withholding Information. In *some* circumstances, it is both legally and morally OK to withhold information. These cases include instances of the **therapeutic privilege** (when giving the person the information would cause them severe and unnecessary pain, or would undermine their ability to behave rationally) or **research** (when telling the patients all of the info would ruin the study). In these cases, the patients’ “right to know” must be balanced carefully against other moral principles, and all alternatives must be carefully considered. For example, it is almost never OK to withhold info simply because you think it might make a patient refuse a treatment. In the long term, failing to disclose relevant information will undermine patients’ trust in their medical staff, which can lead to bad outcomes.

HOW MUCH UNDERSTANDING IS REQUIRED FOR INFORMED CONSENT?

Almost no one can understand *everything* relevant to making a particular choice. In the context of informed consent, **understanding** requires that people have “acquired pertinent information and have relevant beliefs about the nature and consequences of their actions.” Some common barriers to understanding often include:

- **Assessing risks and benefits.** Both patients and medical staff are often confused by statistical data such as mortality, morbidity, and survival rates; specificity and sensitivity; and so on. In these cases, information should be presented in multiple ways.
- **Failures of imagination.** Patients often fail to predict how much they will dislike negative outcomes (such as postsurgical recovery), or enjoy positive ones (such as long-term health).
- **The “therapeutic misconception.”** Many patients believe that their participation in experimental research is likely to improve their *own* chances for recovery, even though research is primarily directed at helping *future* patients.

WHEN IS A CHOICE VOLUNTARY?

A person acts **voluntarily** if “he or she wills the action without being under the control of another person or condition.” A person can be controlled (in whole or part) by three different sorts of **influences**:

- **Coercion** occurs if and only if “one person intentionally used a credible and severe threat of harm or force to control another.” Actions undertaken because of coercion are not voluntary, and coercion is justified only in extreme cases (e.g., to prevent severe harm from coming to the patient).
- **Persuasion** involves appeal to reason, and need not undercut voluntariness.
- **Manipulation** involves types of influence (lying, withholding information, exaggerating, etc.) that are neither coercion (which threat-based) or persuasion (which is reason-based). It can undercut voluntariness, and should generally be avoided.

REVIEW QUESTIONS

1. Give an example of express, tacit, implied, and presumed consent.
2. In your own words, describe the difference between the three standards of disclosure discussed above.
3. Give an example of coercion, persuasion, and manipulation. How do these interfere with a person's ability to consent?
4. In the last few years, many colleges (as well as a few states) have adopted a "Yes means Yes" (or **affirmative**) policy of sexual consent². This means that, *for the purposes of campus affairs* (such as student discipline), sexual activity requires something like express consent by both parties. Before this, campus policies often allowed for somewhat weaker forms of consent (closer to implied or tacit consent, as we have defined them here). Why do you think that campuses have adopted this policy? What are the potential benefits of doing so? The drawbacks?

BIOETHICS AND THE LAW: CANTERBURY V. SPENCE³

"The record we review tells a depressing tale. A youth troubled only by back pain submitted to an operation without being informed of a risk of paralysis incidental thereto. A day after the operation he fell from his hospital bed after having been left without assistance while voiding. A few hours after the fall, the lower half of his body was paralyzed, and he had to be operated on again. Despite extensive medical care, he has never been what he was before. Instead of the back pain, even years later, he hobbled about on crutches, a victim of paralysis of the bowels and urinary incontinence. In a very real sense this lawsuit is an understandable search for reasons.

The context in which the duty of risk-disclosure arises is invariably the occasion for decision as to whether a particular treatment procedure is to be undertaken. To the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential...A reasonable revelation in these respects is not only a necessity but, as we see it, is as much a matter of the physician's duty. It is a duty to warn of the dangers lurking in the proposed treatment, and that is surely a facet of due care. It is, too, a duty to impart information which the patient has every right to expect. The patient's reliance upon the physician is a trust of the kind which traditionally has exacted obligations beyond those associated with armslength transactions. His dependence upon the physician for information affecting his well-being, in terms of contemplated treatment, is well-nigh abject...

In our view, the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision. **Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.**

...

Of necessity, the content of the disclosure rests in the first instance with the physician. Ordinarily it is only he who is in position to identify particular dangers; always he must make a judgment, in terms of materiality, as to whether and to what extent revelation to the patient is called for. He cannot know with complete exactitude what the patient would consider important to his decision, but on the basis of his medical training and experience he can sense how the average, reasonable patient expectably would react. Indeed, with knowledge of, or ability to learn, his patient's background and current condition, he is in a position superior to that of most others -- attorneys, for example - who are called upon to make judgments on pain of liability in damages for unreasonable miscalculation."

In this important court case, the state adopted a "reasonable person" standard of informed consent (i.e., that the physician should tell patients those facts a reasonable person would want to know). They held that this standard was *objective* (it did not vary between patients), and they held that it was NOT determined by "medical practice" (that is, it was not determined by what most medical staff believed was right). Do you agree with the court? Do you think that the patient [Canterbury] deserved to win the case?

² Janet Napolitano, "Only Yes Means Yes: An Essay on University Policies Regarding Sexual Violence and Sexual Assault," *Yale L. & Pol'y Rev.* 33 (2014): 387.

³ *Canterbury v. Spence*, 464 F. 2d 772 (Court of Appeals, Dist. of Columbia Circuit 1972).