

INFORMED CONSENT

The Informed Consent Discussion

The informed consent discussion is a dynamic conversation between a healthcare provider and a patient. The provider discloses the information needed to enable the patient (who has been deemed capable of making a complex decision) to voluntarily accept or refuse treatment. Respect for patient autonomy characterizes the informed consent discussion, through which the legal and ethical duty of the physician to the patient is fulfilled.^{1,2}

Establishing Capacity

In order for a consent to be valid, the consenting individual must be deemed competent to choose. **Competency** is a legal state contingent upon perceived mental **capacity**, the medical measure of decision-making ability. Throughout this module, we will use the terms interchangeably.¹

A patient lacks capacity if they are “unable to make a specific decision, at a specific time, because of an impairment of, or disturbance, in the functioning of mind or brain”.³ A lack of capacity can be temporary and may not extend to all decisions. In the event that any competency-based concerns arise, err on the side of caution; make every effort to demonstrate that an individual does not have the capacity to make medical decisions for themselves.

A competent patient should be able to:

- Understand the decision to be made and the information provided about the decision.
- Retain the information for long enough to make the decision. Cognitive aids have been shown to improve recall, and their use should, therefore, be considered during these discussions.¹
- Weigh the pros and cons of the information they have received as a step in the decision-making process.
- Communicate their decision – all forms of communication are considered valid.

Striking the proper balance between respecting patient autonomy and protecting those with cognitive impairments is a process reliant upon the assessment of competency.¹ This assessment should never be based upon age, appearance, assumptions about their condition, or any aspect of their behavior. Several tools that have been developed in order to identify delirium and/or other symptoms of cognitive impairment.

Key Elements of the Informed Consent Discussion

The informed consent discussion must contain certain key elements - regardless of the intervention for which consent is being obtained. Requisite points of conversation include: **indications, risks, benefits, and alternatives** (including the decision not to intervene and

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potential risks and benefits associated with this decision). The informed consent discussion is a conversation and should be conducted as such, with phasic flows of information and ample opportunities for dialogue.

Phase 1: Prior to entering into an informed consent discussion with a given patient, their medical records, diagnosis (if known), relevant laboratory tests, and imaging should be reviewed. The provider must ascertain the patient's personal history and cultural background, and determine if there is a need for interpreter services or other communication aids. If interpreter services are required, then the healthcare provider must provide appropriate provisions, either in the form of an in-person interpreter, video conference, or telephone. A family member should **NOT** act as an interpreter for the patient for medical decisions.⁴

Phase 2: Immediately upon approaching the patient, the provider should make an introduction wherein their role in the care team is clearly delineated. It is the professional duty of trainees, in particular, to disclose their status as a learner. The patient should be asked open-ended questions and encouraged to share their values, goals, and expectations. This is the foundation of shared decision making, a patient centric form of communication.⁴

Phase 3: This phase contains the core elements of the informed consent discussion. The healthcare provider delineates the patient's **indications**, or their current health concerns as they relate to the proposed procedure. The details of the procedure should be discussed in full. How will it be performed? By whom? How long will it take? It is often helpful to supplement verbal explanations with drawings or other visual aids. When describing the **benefits and risks** of the procedure (as they relate to the patient's condition), the provider should not neglect to disclose the risk that the procedure's goals are not met. Care should also be taken to outline the "reasonable" medical or interventional **alternatives**, including the option of no intervention (having elaborated upon the potential outcomes of the non-interventional course of action). This phase is generally concluded by setting post-procedural expectations, taking into account factors such as pain, length of recovery, limitations on activities, and quality of life.⁴

Phase 4: The final phase of the consent discussion should be a review and re-emphasis of the material covered therein. The provider should encourage the patient to seek clarification of any aspects of the care plan that remain unclear or concern-inducing. The physician should ascertain the patient's grasp of the relayed information by asking that they repeat the material in their own words. It should be made clear that the decision to proceed with an intervention is in the control of the patient and is contingent upon their consent. Upon consenting to the specified procedure, patients are typically asked to sign a document which is null and voided in the event that they change their minds.⁴

Special Circumstances

The following are special—but common—scenarios that a healthcare provider will encounter when attempting to conduct an informed consent discussion.

The pre-medicated or under extreme distress patient

Patients frequently require medication for pain-relief or sedation purposes prior to an intervention. Such medications can often be administered prior to the informed consent discussion. This can lead some providers to express concern about potent impairment in the patient's ability to make certain clinical decisions. To deliberately withhold pain medication from a patient in anticipation of the consent discussion, however, is arguably a "cruel and unusual" punishment, and could lead the patient to feel as though relief from their suffering is contingent upon their consent.⁵ Premedication may, in certain cases, enhance a patient's ability to make decisions by relieving their pain or emotional distress and permitting them to focus on the choice at hand. However, if the pre-medication limits the patient's ability to understand the information that is being provided, weigh the pros and cons of various courses of action, and communicate their decision, the patient is not competent to make a medical decision. The healthcare provider should return at a later time to complete the process or identify a surrogate. At no time should pain medicine be withheld from a suffering patient under the pretense of obtaining informed consent.⁵

The patient in labor

There is no universal consent protocol for planned vaginal delivery. It is assumed that giving birth vaginally is a natural physiologic process that, by definition, is not medical treatment. However, there can be associated risks, complications, and procedures that pregnant women can experience. According to the current evidence, pain, analgesia administration, and the emotional stressors of pregnancy do not diminish the capacity to give informed consent for women in labor.⁶ The state of labor and giving birth has not been shown to compromise the validity of a pregnant patient's informed consent decisions.⁶

The patient with known mental illness or organic brain disease

A patient's ability to consent is variable; one's shifting disease processes (and the ensuing changes in pharmaceutical interventions) ensure that finding the patient in a lucid state is not always feasible. The use of sedative medications and soporific medications should be mitigated - if safe - in order to induce a delirium-free state. Healthcare providers should conduct capacity assessments during periods of perceived lucidity. If the patient makes the same decision at disparate points of contact, they likely possess the adequate faculties to consent.

The patient with intellectual disability

When medical decisions are required, people with intellectual disability are potentially vulnerable to exploitation.⁷ However, "the dignity of people with [intellectual disability], based on their intrinsic value as human beings, requires respect and does not diminish with the absence or reduction of any ability".⁸ For each individual, capacity must be determined using the criteria as previously described in this module. If full capacity has failed to be determined, the patient should still be encouraged to take part in the decision-making process.⁸ Regardless of full or

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partial capacity, communication should be adapted to patient functioning level, and with the involvement of family and social support, as appropriate. And, if no pre-determined individual can be found, then a legal substitute is sought with the intention to find a candidate that can make decisions with the patient's wishes and best interest at the forefront.^{7,8}

Emergent procedures

Emergent procedures require the same standards of informed consent as procedures deemed routine. In the event a given patient is incapacitated, the authorized surrogate should be called upon to act on their behalf. Until a surrogate can be located, the care provider should attempt to act in the patient's best interest - in other words, "presume" their consent as opposed to obtaining it. Presuming consent is only permissible when the patient is unconscious or otherwise unable to consent, no surrogate is accessible to adjudicate, and the emergent procedure(s) would avert death or disability. Presumed consent should, in general, be avoided; the values and goals of the patient and the physician do not necessarily (and, in fact, rarely) align.¹ To give the patient autonomy in their healthcare decision-making process is to respect their person; however, beneficence may compel physicians to intervene when their bodily well-being hangs in the balance.

Minors

Children's involvement in the decision-making process (provided that the degree of control granted them is proportional to their developmental capacity) is, according to The American Academy of Pediatrics, advisable.⁹ The age of majority can differ depending on the state, usually either 18 or 21 years of age. The physician's responsibility to act in accordance with pediatric patient's autonomy may compel them to ask the parents to take the child's decision into consideration. In the event of an intra-familial inability to come to a consensus, the healthcare provider should offer their services as a negotiator.

Emancipated minors

Emancipated minors are generally youths that are under the age of 18, but over the age of 14, who have been deemed to have competence to make medical and legal decisions without the consult of parental or guardian consult. Each state has their own criteria, however, some minors that may be deemed to be eligible for emancipation are those who are in the military, self-supporting outside of the confines of their family home, married, pregnant or a parent, or so deemed by the court.¹⁰ The physician should approach these patients as they would any other patient with respect of their person and autonomy. Capacity must be ascertained and if there is evidence that the patient is unable to make a medical decision, then a suitable surrogate should be identified to facilitate the shared decision.

Healthcare Provider Influence

There are three categories of physician influence that superficially appear to be the same, but upon utilization can grossly affect the validity of the informed consent discussion. The first is **coercion**: the introduction of a controlling, credible threat to the patient. However, when presented honestly in an objective manner, legitimate medical repercussions of a course of action are permissible and appropriate. Coercion is not. The second iteration of unethical influence, **manipulation**, involves the selective (biased - not comprehensive) presentation of information. Lying, deliberately failing to relay crucial information, and engaging in conscious deception are all forms of manipulation. Conversely, the presentation of a logical, expertise-based argument for a certain course of action, known as **persuasion**, is an integral aspect of the consent process. To reiterate, coercion and manipulation are ethically wrong; however, persuasion, when presented as previously described, often fulfills the social obligation of trust that the patient has in their physician to offer advice and recommendation that is medically sound.⁵

References

1. Appelbaum PS. Assessment of patient's competence to consent to treatment. *New England Journal of Medicine*. 2007; 357: 1834-1840.
2. Quick_Safety_Issue_Twenty-One_February_2016.pdf. Available from: https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf
3. <https://www.medicalprotection.org/uk/articles/assessing-capacity>. Mental Capacity Act 2005 – Assessing capacity. 06/27/2016. Last accessed 4/17/19.
4. Ripley BA, Tiffany D, Lehmann LS, Silverman SG. Improving the Informed Consent Conversation: A Standardized Checklist that Is Patient Centered, Quality Driven, and Legally Sound. *J Vasc Interv Radiol*. 2015 Nov;26(11):1639–46.
5. Norman GV. Ethics in Medicine. University of Washington School of Medicine. 1998. <https://depts.washington.edu/bioethx/topics/infc.html#ques1>. Last accessed April 14, 2019.
6. Vernon G, Alfrevic Z, Weeks A. Issues of informed consent for intrapartum trials: a suggested consent pathway from the experience of the Release trial [ISRCTN13204258]. *Trials*. 2006 May 11;7:13.
7. Iacono T, Murray V. Issues of Informed Consent in Conducting Medical Research Involving People with Intellectual Disability. *J Appl Res Intellect Disabil*. 2003 Mar;16(1):41–51.

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8. Sullivan WF, Heng J, Cameron D, Lunskey Y, Cheetham T, Hennen B, et al. Consensus guidelines for primary health care of adults with developmental disabilities. *Can Fam Physician*. 2006 Nov;52(11):1410–8.
9. COMMITTEE ON BIOETHICS. Informed Consent in Decision-Making in Pediatric Practice. *Pediatrics*. 2016 Aug;138(2). Available from: <http://dx.doi.org/10.1542/peds.2016-1484>
10. Maradiegue A. Minor's Rights Versus Parental Rights: Review of Legal issues in Adolescent Health Care. *J Midwifery Womens Health*. 2003;48(3)

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