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Edited by Gail A. Van Norman

Excerpt

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Consent and refusal

Section 1
Chapter

1

Consent and refusal

Informed consent: respecting patient autonomy

Gail A. Van Norman

The Case

Allen, a 35-year-old man, presents for colectomy after a 20-year history of ulcerative colitis. He does not appear nervous, but is animated and friendly. His sister explains that Allen has developmental delay and is also fearful of needles. He has permitted the nurse to start an intravenous drip. Discussion of an epidural for anesthesia and analgesia with Alan will take extra time, and the anesthesiologist is also concerned that he may not have the necessary self-control to cooperate with an epidural. She decides to discuss only general anesthesia and patient-controlled analgesia with the sister.

Moral imperatives for informed consent in Western medicine and medical research are founded in the ethical principle of respect for patient autonomy. The term “autonomy” comes from the Greek *autos* (self) and *nomos* (rule). Originally used to describe political self-governance, “autonomy” also has come to be associated with individuals. This concept of self-determination has attained a powerful vocabulary in Western culture, evoking debates over liberty, privacy, free will, rights and responsibilities. Freedom to choose one’s destiny is a prominent Western ideology. There is broad moral and legal consensus that this freedom is essential when such choices involve medical treatment.

Of the four “foundational” principles in medical ethics – beneficence, nonmaleficence, respect for autonomy, and justice – the principle with the strongest influence in the United States is respect for personal autonomy. Many ethical questions in US medical practice will be answered by asking foremost what the patient *wants*, and not necessarily what the physician, family, or culture believe is *best*. Respect for autonomy is a key principle in other Western nations as well, but it is usually weighed against the other three principles. Thus, the same ethical question may be answered in other Western countries by asking not

only what the patient *wants*, but also what is *best* for them according to their family, society, and reasonable medical resources. Non-Western cultures often depart almost completely from an “autonomy”-based ethic of informed consent, and resort to a more “collectivist” decision-making model, in which families and groups make decisions together, based on obligations to care for one another, concepts of preservation of harmony, and values of group interdependence. (A summary of cultural aspects of medical decision-making in Pacific Islander and Asian cultures can be found in Table 1.1, and a detailed account of Native American medical decision-making is explored in Chapter 13).

Many countries have codified patients’ rights to be informed and to give or refuse consent regarding medical treatments (Table 1.2).

Although the Nuremberg Code is often cited as the origin of the modern physician’s obligation to obtain informed consent, legal precedents enforcing patients’ rights actually predate Nuremberg. In France, legal requirements for consent were established in 1910, and were reinforced by the French Supreme Court in 1942.¹ In the United States in 1914, the case of *Schloendorff v. Society of New York Hospital* established that “Every human being of sound mind and adult years has a right to determine what shall be done with his own body.”²

Autonomy

Informed consent involves the concept of “personal autonomy” – a patient’s ability to make choices – and “autonomous choice” – whether an autonomous patient’s choice is made freely. Respect for patient autonomy involves not only ethical obligations to respect patient choices, but also obligations to *promote* both patient autonomy and autonomous choice.

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Table 1.1. Values emphasized in medical decision-making in some non-western cultures*

Japanese	<ul style="list-style-type: none"> • Collective family interests take priority over individual interests • Harmony must be preserved • The family is responsible to care for elders • Caring for parents must be done with deep feelings of gratitude and happiness • Shintoism is prominent – mention of death is taboo, discussing terminal illness may cause <i>kegare</i>, or spiritual contamination
Chinese	<ul style="list-style-type: none"> • Confucian concepts of harmony, unity, survival of the family • Hierarchical family relationships • Elders treated with respect and protected from bad news • Discussing illness or death may cause it to happen
Vietnamese	<ul style="list-style-type: none"> • Concept of karma and fatalistic attitudes towards illness and death • Individuals do not control their lifespan, advance directives are de-emphasized • Saying “no” to a physician may be disrespectful and could create disharmony
Filipino	<ul style="list-style-type: none"> • Filial piety • Illness may be “deserved,” and seeking health care may be a “last resort” • Deference to the physician out of respect
Hawaiian	<ul style="list-style-type: none"> • Acceptance of medical condition • Western medicine is seen as autocratic • Holistic approach to health problems and collective decision-making
Samoaan	<ul style="list-style-type: none"> • A specific decision-maker is designated • A chief may be asked to listen to the case and offer judgment • Mistrust of Western medicine • Traditional Samoans do not want to be asked preferences, desiring instead a directive physician.

Summarized from: McLaughlin, L.A. and Braun, K.L. (1998). Asian and Pacific Islander cultural values: considerations for health care decision-making. *Health and Soc Work*, **23**(2), 116–26.

Autonomous persons

The terms “capacity” and “competence” are both used to describe a group of capabilities necessary for decision-making. In the US, “capacity” usually is used by medical experts to describe functional capabilities, and “competence” is a legal term. In the United Kingdom, the usage is reversed, and “competence” usually refers to functional capacity, while “capacity” is a legal term.³ In this chapter the terms are used interchangeably.

Capacity is a “threshold” element in informed consent. Without the ability to make decisions, a person is not autonomous. Capacity is task specific: patients may be fully capable of making medical decisions even if they are unable to care for themselves in other ways. Capacity waxes and wanes depending on many factors such as the patient’s medical condition, psychological state, level of stress, and ability to orient to unfamiliar surroundings. Although any diagnosis of compromised mentation can interfere

with competence, *no* diagnosis in a conscious patient invariably identifies incompetence. The presence of memory impairment, dementia, or mental illness, for example, does not prove a lack of capacity to make medical decisions.

Physician paternalism and bias pervades assessments of patient competence. Patients are often referred for competency evaluations simply because they refuse medical advice, although such refusals are not generally evidence of incapacity.⁴ In one study, noncompliant patients comprised almost two-thirds of referrals for competency evaluations, yet they were only slightly less likely than compliant patients to be judged incompetent by consultants. Patients who discharge themselves against medical advice from hospitals have a somewhat higher prevalence of alcohol abuse than the general population. However, studies have found that such actions are more often related to insurance status and lower income, or factors such as race (which might be associated with mistrust of physicians or

Table 1.2. Summary of patient rights to informed consent by country*

Country	Right to informed consent	Right to refuse treatment	Right to have written advance directives followed	Presumed consent in emergency situations if incapacitated	Therapeutic Privilege allowed	Patient can waive right to know
Australia	✓	✓	✓	✓	✓	✓
Belgium	✓	✓	✓	✓		
Bulgaria	✓	✓ – must be in writing		✓	Not recognized	✓
Canada ¹¹	✓	✓	✓		Controversial in common law ¹²	
Cyprus	✓	No explicit right to refuse	✓	✓	✓	
Czech Republic	✓	✓			✓ – at physician discretion	No express “right not to know”
Denmark	✓	Only to refuse blood products, or if in a terminal condition	✓ – only in specific circumstances		Illegal since 1998	✓
Estonia	✓			✓	Not recognized	
Finland	✓	✓		✓		
France	✓	✓				
Greece	✓	✓		Physician can override pt wishes		✓
Hungary	✓	✓	✓	✓		✓
Italy	✓	✓		✓		
Israel ¹³	✓			✓		✓

Table 1.2. (Cont.)

Country	Right to informed consent	Right to refuse treatment	Right to have written advance directives followed	Presumed consent in emergency situations if incapacitated	Therapeutic Privilege allowed	Patient can waive right to know
Japan ¹⁴	√ physician must inform patient or family				√	√
Latvia	√	√		√		
Lithuania	√	√		√		√
Luxembourg	√	√		√		
Netherlands	√		√	√		
New Zealand ¹⁵	√	√		√		√
Poland	√	No provision				
Portugal	√	√	No explicit rule, but would be acceptable under other laws	√	√	
Slovakia	√		√			√
Slovenia	√	√	√	√	√	√
South Africa	√	√				
Spain	√	√	√	√		√
Sweden	√	√				
UK ¹⁶	√	√	√	√	√	√
United States ¹⁷	√	√	√	√	√	√

* Obtained from the Centre for Biomedical Ethics and Law unless otherwise noted <http://europatientsrights.eu> and <http://www.kuleuven.be>

Spaces were left blank when there was no explicit provision in law according to the Centre for Biomedical Ethics and Law at the time of access to the website on March 1, 2010. Reader should note that provisions may nevertheless be implicit in other laws or regulations.

perceptions of disrespectful treatment) than to decisional incompetence.⁵

Physicians frequently judge patient competence based on their perception of the quality of a patient's decision. A recent study of physicians' attitudes toward patients who refuse cancer therapy found that physicians often regarded such decisions as "irrational," and therefore reflecting mental aberrations.⁶ Such judgments place the physician's own values, prejudices, and perceptions about medical treatment and quality of life before those of the patient, and do not reflect appropriate respect for patient autonomy. The same study found that patients refuse medical therapy based on personal values and experience more than on medical facts alone. Most experts believe that quality of life measures are at least equal in relevance to medical outcomes in determining if treatment results meet patient needs.

In general, competence to make medical decisions is adjudged to be present when the patient meets four criteria: they can communicate a choice, understand the relevant information, appreciate the medical consequences of the decision, and reason about treatment decisions (see also Chapter 4). These criteria generally can be assessed in pre-operative conversations with patients, and do not usually require expert consultation. When there is conflicting evidence about patient competence, however, a formal evaluation may be helpful.

The anesthesiologist in our introductory case made a hasty judgment about whether Allen was capable of participating in a complete discussion of options for his anesthesia care. An actual conversation with Allen would have revealed to her that he is employed, and lives independently – although these circumstances do not guarantee he has capacity for medical decision-making. When asked, he says that he needs to have surgery because of his sick intestines, and that he understands that he could get cancer if he does not have the operation. He also hopes that the surgery will reduce his pain and diarrhea. He does not fear anesthesia; he has been through several operations before without problems. Because of his religious beliefs he does not fear death. Allen appears to be an autonomous person with capacity to decide – or at least participate to a great degree – in decisions about his care, and should be given a complete description of his options in language aimed at his level of understanding.

Temporary incapacity

Many common clinical factors, both temporary and permanent, can impair the capacity to make medical

decisions. Examples include severe pain or anxiety, intoxication, head injury, organic brain disease, developmental delay, and young age. Criteria for capacity in such patients, however, are no different from in any other situation. Physicians have ethical obligations to promote autonomy by treating patients to restore capacity if possible. Anxious patients or those suffering from pain ideally should have anxiety and pain treated *prior* to informed consent discussions, because they may then be better capable of listening to options, discussing information, and making decisions. Patients retain autonomy even with premedication if they are able to meet the four criteria cited above. Withholding such treatment until a consent form is signed is cruel, probably coercive, and may cause such consent to be legally invalid as well.

If delaying surgery allows a patient suffering from a temporary incapacity to recover competence in a time frame such that the surgery is still meaningful, the surgery should be postponed. If an emergency surgery cannot be delayed for a patient with temporary incapacity, then the physician may need to locate a surrogate decision-maker, or proceed without consent in the best medical interests of the patient.

Autonomous choices

Three conditions must be met in order for an act (or choice) to be autonomous: a person must act with *intention*, with *understanding*, and *without controlling influences*.

Intention

Ethical theory regarding "intention" is complex, but generally speaking intentional acts require "planning," although not necessarily reflective thought or strategy. We do many things intentionally but without thought, such as reaching for a glass of water in order to drink, scratching an itch, or turning a page in a book.

Unintentional acts can result from accidents or habitual behavior, or even as a byproduct of an intentional act. Imagine that Mary presents with flank pain suggestive of a kidney stone. Her physician orders an intravenous pyelogram (IVP). After administration of the contrast agent and IV fluid, increased urine output washes the stone into the bladder. The IVP is negative, but Mary's pain is resolved. The physician intended to run the test to diagnose the cause of her pain and he intended to appropriately treat the condition responsible for it. Both things happened. The test

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was run according to plan, but pain relief occurred because of an unintended side effect of the test. Mary's pain relief was the result of an accident and not a result of intention, even though the outcome of the accident and the intended outcome of the physician's plan are the same.

Patients are asked explicitly and implicitly to consent to both intentional and unintentional acts by physicians. Intentional acts are broadly categorized as those acts that result in the expected outcomes. Unintentional acts are those acts that result in outcomes that are not expected or not desired, such as side effects, accidents, and medical catastrophes. When autonomous patients consent following adequate information about both the *known and intended*, and *known possible-but-unintended* outcomes of treatment (and they are not manipulated or coerced), then they can be said to have *intended* to consent to the potential unintended consequences of treatment. It would be difficult to assert that a patient *intended* to consent to outcomes about which they were not informed. A patient who is inadequately informed is therefore *not* making an autonomous choice because intention is a requirement for autonomous choice. Adequate information is key to promoting patient autonomy, but what constitutes "adequate information"?

What the physician must disclose

It was not until the mid twentieth century that a legal obligation to *inform* patients prior to obtaining consent was established. In *Salgo v Trustees of Leland Stanford Hospital*⁷ it was found that physicians must discuss risks and alternatives to treatment, as well as describe the procedures and their consequences. This finding was reinforced in *Canterbury v Spence* in 1972, which determined:

... it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification.⁸

Physicians argued that the courts had imposed an impossible burden: explaining *all* of the possible risks and outcomes of procedures would be tantamount to providing the patient with a medical education. Patients were neither knowledgeable, nor educable to the level of detail needed to make "competent" medical decisions. Subsequent court findings disagreed. In *Harnish v Children's Hospital Medical Center*, the duty to inform patients was further clarified:

A physician owes to his patient the duty to disclose in a reasonable manner all significant medical information *that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure.*⁹ [italics added]

Without knowing exactly what information is "material" to a patient, one potential strategy could be to simply recite as many relevant medical facts as possible to obtain consent and avoid liability later on. With regard to patient decision-making, however, it is important to understand that ***not all medical facts are material ones and not all material facts are medical ones.*** Patients base decisions on a number of matters, only some of which are medical facts. They also consider the potential medical and nonmedical outcomes of the treatment in the context of their lives, personal values, and personal experiences, as in the following scenario:

Ann and Sarah, each 39 years old, have a 1.5 cm breast cancer. Both are weighing the same options: lumpectomy with adjunctive chemotherapy, or mastectomy with chemotherapy. Each treatment is associated with similar cure rates. Ann decides to undergo lumpectomy based on her priorities of minimizing surgical recovery and disfigurement, as well as her confidence that the chance of recurrent cancer is small. Sarah also worries about disfigurement, but is more concerned about cancer recurrence because her mother died of breast cancer after protracted treatment and significant suffering. She requests bilateral mastectomies to ease her fears of experiencing bilateral cancer. Relatively few of the medical facts are actually material to either woman's decision – and even though the facts are the same in each case, the decision is not. The presence of cancer, recurrence rates, and the potential cure rates of each type of proposed surgery are material to both women. Potential disfigurement from the surgery is also material to both – and this becomes decisive for Ann. But for Sarah, other non-medical issues, such as her experience of her mother's death and how it affected her perceptions and fears about breast cancer and cancer treatment, are both material and decisive.

An exhaustive presentation of nonmaterial medical information not only dilutes medical information that is essential to a patient's decision, but also potentially neglects "non-medical" information that is also critical to the patient's decision. Physicians are expected to discuss the proposed treatment and reasonable alternatives. Common risks should be

discussed because they are likely to occur and the patient should be given a chance to consider those possibilities. Nausea and vomiting, pain, dental damage, sore throat, and adverse drug reactions are examples of some common risks that might be discussed. Serious risks, even if rare, should be disclosed because such serious harm may be material to the patient's decision. Stroke, blindness, major cardiac events, cardiac arrests, and death are examples of serious risks that could be addressed. Physicians should also attempt to discover what other issues are germane to the patient: asking the patient about their questions, fears and special concerns may uncover other questions that are important to clarify.

Autonomous choice: the effects of coercion, manipulation, and persuasion

Even when acting with intention and understanding, autonomous persons can make nonautonomous choices. The bank teller who is forced at gunpoint to hand over money is an autonomous person, but she is being forced by the robber to make a choice against her will – to give up the money or risk being killed. *She* is autonomous, but her *choice* is not. She acts both with intention and understanding, but is under the irresistible power of a controlling influence. In the informed consent process, physicians have ethical obligations to avoid controlling influences that invalidate autonomous choice.

Coercion

Coercion occurs if one person both *intentionally* and *successfully* influences another by making a believable threat of harm that is sufficiently severe such that the other person is unable to resist acting to avoid it. Because it controls the other person's actions and usurps autonomy, coercion is unethical. Even if it is not successful, attempting to coerce someone demonstrates a lack of respect for patient autonomy and is unethical.

Not all threats are coercive. For a threat to be coercive, the threatened person must understand it, believe that it will be carried out, and be unable to resist it. Threatened harms can include physical, psychological, social, legal, and financial harms, among others. Perceptions about what constitutes a believable threat and sufficient harm are subjective and vary from person to person – some threats are universal enough to

coerce almost any persons, while others are selective enough to only coerce a few. Furthermore, *circumstances* that restrict personal choice are not “coercive,” because circumstances are not persons and cannot have intentions. A patient who requires surgery to relieve a bowel obstruction is confronted with few viable choices and therefore is not entirely “free”, but a choice to undergo surgery can still be autonomous, because within the framework of the circumstances the person can act with intention, with understanding, and without being controlled by the will of other persons.

Coercion is not uncommon in anesthesia and surgical practice. Consider Mr. Forrest, an 85-year-old man with metastatic colon cancer, who has a large bowel obstruction, severe pain and discomfort, and requires palliative surgery. He has requested a do-not-resuscitate (DNR) order because of his terminal disease. Mr. Smith sincerely hopes to survive his surgery, but he understands that death is a risk. He knows that both his age and his diagnosis make his prospects of surviving a cardiac arrest grim. Furthermore, he believes that death under anesthesia, while not his *intended* goal, would be an acceptable and possibly humane outcome, and he consents to it. But the anesthesiologist refuses to proceed unless Mr. Smith rescinds his DNR order, even though cardiopulmonary resuscitation (CPR) is not integral to treating bowel obstruction *per se*. The anesthesiologist is presenting Mr. Smith with a credible threat of harm, and she certainly is capable of carrying out that threat by preventing surgery that will relieve Mr. Smith's pain. The threat is sufficiently severe that Mr. Smith ultimately is controlled by it and agrees to rescind his DNR status. The anesthesiologist has intentionally and unethically coerced him into accepting a treatment he does not want (CPR) and likely will not need, in order to obtain treatment that he both wants and does need (bowel resection). (For a more detailed discussion of DNR orders in the operating room, see Chapter 2.)

Persuasion

Persuasion is a noncontrolling (resistible) form of influence in which one person *intentionally* and *successfully* uses reason to induce another person to freely and willingly accept the beliefs, intentions, and actions of the persuader. Persuasion is an integral part of informed consent as, for example, when

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the anesthesiologist recommends epidural anesthesia over general anesthesia for an elective Cesarean section, due to the advantages of maternal–infant bonding immediately after birth, the possibility of epidural narcotic analgesia for postoperative pain relief and a perception of decreased risks to mother from pulmonary aspiration. For such a recommendation to qualify as persuasion and not manipulation, it must present accurate and balanced information, and must be resistible by the patient (that is, the patient can choose not to follow the recommendation).

Persuasion is entirely ethical. Patients expect physicians to make rational recommendations about medical treatments and alternatives. In fact, physicians may even be held legally liable and morally culpable if they do not at least attempt to persuade their patients to consent to treatments that are medically indicated.

Manipulation

Between persuasion and coercion lies a group of influential behaviors included under the broad definition of “manipulation,” including indoctrination, seduction, deception, omissions, and lies. In general, manipulation strategies work by either altering actual choices provided to patients, or by altering patient’s perceptions of their choices.

The degree of control exerted by manipulation (and therefore the degree to which manipulation interferes with patient autonomy) ranges from inconsequential to completely controlling. Not all attempts at manipulation succeed, but many if not all manipulative strategies involve deception, either through false or misleading information or omission of key facts. Manipulation is therefore unethical whether it is successful or not, because it both violates ethical obligations of veracity (telling patients the truth) and disrespects patient autonomy.

In the case introducing this chapter, the anesthesiologist has engaged in manipulation by not describing the benefits and risks of epidural anesthesia and analgesia, even though it is a common anesthetic alternative. Had she discussed this option, she would have discovered that Allen in fact had opted for an epidural for previous bowel surgery, and had done well. By omitting the discussion in order to meet her own goals, she has altered Allen’s actual choice, since Allen would probably have chosen to have an epidural if he knew it were possible.

Now, suppose instead that a patient who is a heavy smoker presents for total knee arthroplasty. The anesthesiologist wants to do a subarachnoid block (SAB). She does discuss both general anesthesia and SAB. However, she states that “spinal anesthesia is much safer in for knee replacements,” and “spinal anesthesia is much safer in smokers.” This is an example of manipulation by creating a false perspective of the patient’s choices. There is no strong evidence that SAB is safer for most surgeries or safer in smokers, and the statement inaccurately portrays the comparative risks and benefits of these two anesthetic options. Once again, this anesthesiologist has attempted to manipulate the patient, and has disrespected the patient’s autonomy.

Therapeutic privilege and waiver of informed consent

Two exceptions may exist to the rule that competent patients must have risks disclosed to them: the concept of therapeutic privilege and the idea that competent patients may waive their rights to be informed.

In evoking therapeutic privilege, physicians argue that it is ethical to withhold material information from patients in whom such disclosures would cause unacceptable harm, thus causing the physician to violate the ethical principle of nonmaleficence (avoiding harm). Accepting this general argument without restriction, however, is a prescription for paternalism. If the definition of “unacceptable harm” is framed too broadly, then physicians could conceivably justify withholding almost any information, because such disclosures are laden with at least some stress for most patients. Physicians even could use it as an excuse to “control” the decisions of patients whom they feel might refuse therapy after a full disclosure. If unacceptable harm is defined very narrowly as harm that causes the patient to become emotionally, psychologically, or intellectually incapable of making a decision, then therapeutic privilege does not technically violate the principle of respect for autonomy because full disclosure would render the patient non-autonomous anyway. The courts have recognized the risk of physician paternalism, and have reinforced the legal emphasis on respect for autonomy:

The physician’s privilege to withhold information for therapeutic reasons must be carefully circumscribed ... for otherwise it might devour the disclosure rule itself. The privilege does not accept the paternalistic notion

that the physician may remain silent simply because divulgence might prompt the patient to forego therapy the physician feels the patient really needs. That attitude presumes instability or perversity for even the normal patient, and runs counter to the foundation principle that the patient should and ordinarily can make the choice for himself.¹⁰

Waiver of disclosure by the patient is conspicuously different from therapeutic privilege. An autonomous patient may decide intentionally, with understanding, and without controlling influences by others, to waive their rights to have medical information, or may decide to have the facts disclosed to someone else, such as a family member. Because their choice is an autonomous one, respecting such decisions respects patient autonomy, and is consistent with ethical practice. Legal ramifications of patient waiver have not, however, been clearly resolved in case law.

Key points

- The ethical principle of respect for patient autonomy is firmly grounded in western ethical principles valuing individual freedoms.
- Capacity, or competence, is a threshold element necessary to being an autonomous person: patients have capacity to make decisions if they can communicate a choice, understand the relevant information, appreciate the consequences of the decision and can reason about their decision.
- Physicians have ethical obligations to respect patient autonomy, and to promote autonomy when competence can be restored in a time frame that still renders the medical treatment meaningful.
- Disclosure is not required to be comprehensive: rather, ethical and legal disclosure discusses the treatment, reasonable alternatives, common risks and serious risks, as well as anything the physician knows or reasonably should know is material to the patient in making their decision.
- Coercion and manipulation are unethical because they violate the principle of respect for patient autonomy, and because manipulation often involves deception and violates physician obligations of veracity.

- Persuasion does not manipulate or control patient choice, and is consistent with ethical physician behavior.
- Therapeutic privilege and waiver of consent are possible exceptions to informed consent, but only under very restricted circumstances.

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