

SECOND EDITION

INTRODUCTION TO FLEXIBLE BRONCHOSCOPY

Informed Consent Synopsis

HENRI G COLT MD

with contributions from Jay Jacobson, Alan Goldman, John Knippa and Eric Edell



THE BRONCHOSCOPY EDUCATION PROJECT SERIES

Informed Consent

Synopsis

Description

- Informed Consent requires that medical doctors provide a patient with all relevant information about a proposed procedure or treatment prior to obtaining the consent of the patient to carry out that procedure or treatment.
- Informed consent protects patients by providing them with complete information on which to make an informed decision.
- Informed consent may also, at times, protect health care providers from liability (with exceptions) provided that the procedure is properly executed according to the prevailing standards of care in the community and without negligence.
- The informed consent process gives health care providers and patients an opportunity to consider and re-consider the diagnostic and therapeutic strategies being proposed, as well as the possible risks and benefits of such procedures and to prepare, as needed, for procedure-related adverse events.
- Informed consent assures that patients truly understand the elements of the procedure, as well as the consequences of undergoing or refusing to undergo the intervention. It follows that physicians must disclose any and all conflicts of interest or compensation gained from any treatments or research being proposed.
- Informed consent, therefore, is more than just informing patients about the risks and benefits of a proposed intervention or research project. It is a *process of communication* between a patient and a physician that results in the patient's authorization and agreement to undergo a specific medical intervention. During this dialogue, the physician who is performing the procedure; not a delegated representative, should disclose and discuss: (1 and 2) The patient's diagnosis and relevant clinical issues, (3 and 4) the purpose and nature of the procedure, (5 and 6) the risks and benefits of the procedure, (7 and 8) the risks and benefits of alternative procedures (including financial costs), (9) the risks of not performing the procedure or any of its alternatives, (10) the patient's understanding of the procedure in their own words*.

* Patients can be asked the following FIVE questions: (1) What is the medical problem? (2) What procedure or treatment has been recommended? (3 and 4) What will happen to you with and without the treatment? (5) What is the reason for the decision?

Consent should be Voluntary, Informed and Effective

- From a legal and ethical standpoint, consent for a medical procedure should be *voluntary, informed* and *effective*.
- For consent to be *voluntary*, the environment must be free of compelling forces that drive the decision in one direction and negate the patient's ability and freedom to choose. Doctors should always be aware they may intentionally or unintentionally coerce patients to make a particular decision.
- To be *informed*, a person must be given information about the procedure relevant to their individual situation.
- To be *effective*, the person undergoing the procedure should be able to demonstrate, in his or her own words, their understanding of the procedure. Merely asking a person if they understand and receiving a "yes" or a head nod in response is generally considered insufficient.
- Patients with decision making capacity demonstrate a correct understanding of the nature of the medical problem, its treatment and prognosis, and have a reason for their decision.
- In some countries, informed consent needs to be documented by signatures from patients, witnesses, and health care providers on a specially-designed document approved for use by the institution's medical and risk management committees. The validity in court of such documents is debated, however, and in some North American institutions, physicians are counseled to additionally describe the informed consent process in their dictated pre-procedure notes.

Competency and Capacity

- Another prerequisite to informed consent is having the mental capacity to make a reasoned choice. Sociologically, *competence* is defined as having sufficient ability to make choices such that personal autonomy remains intact. Legally, *competence* is a state in which an individual's decision-making ability is adequate to meet the demands of a clearly specified decision-making task. A person may therefore be competent in some endeavors but not in others.
- Legal standards of competence to consent to procedures include the ability to understand information that is provided, the ability to appreciate one's own situation in light of the information provided, the ability to reason with the information provided, and the ability to express a choice. Curiously, only the

abilities to understand information and to express a choice are universally held as legal standards upon which to base a determination of competence.

- Technically, medical professionals lack the legal authority to determine competence, and instead are able to determine whether a patient has decision-making *capacity*. A patient may, for example, be capable of making the decision to refuse to undergo a procedure, yet be found legally incompetent to handle their personal finances. Often, a physician's assessment of decision-making capacity guides legal determinations of competence, and it is frequently the physician's finding of incapacity that causes alternative forms of consent to be sought.
- For patients who are obviously and permanently impaired who don't refuse treatment, physicians turn to family members to make the decision they believe the patient would have made or, if that's unknown, the decision that would be best for the patient. When patients, who have been functioning independently and making their own decisions, refuse treatment for a dangerous and serious condition, doctors and concerned family members understandably question the patient's ability and right to make what seems to them to be an irrational and self-destructive decision. Before they can force an expressly unwanted medical intervention, physicians should attempt to understand the patient's reasons and *capacity* to make such decisions.
- It is reasonable to question whether decisional competence and capacity are truly preserved in a medical emergency. There are considerable conscious and unconscious barriers, as well as intellectual and emotional, to assimilating information during an acute illness, trauma, or life-threatening event.
- It is generally accepted that patients who received sedatives or narcotics as part of a treatment plan for respiratory insufficiency, intubation, pain, or high-grade anxiety should not be asked for permission to perform invasive procedures.
- Sometimes, even the stress of illness may suffice to alter the decision-making capacities of otherwise reasonable individuals. Studies of patients with acute myocardial infarctions, for example, suggest that psychological or physical stress alone may compromise understanding. Assessments of decisional abilities are also difficult in patients with suspected neurologic or cognitive impairment accompanied by communicative dysfunction (after a stroke, trauma, or burn injury for example), especially when there is limited time in which to institute a treatment plan. Other settings are emergency procedures required for survival.

Surrogates and Emergency situations

- In children (when a patient is under 18 years of age in the United States, unless married or otherwise considered to be an "emancipated minor") or if an adult

patient is mentally or physically incompetent, incapacitated, or if no Health Care Directive exists, a parent or other guardian can usually give surrogate consent or “permission”, assuming that the surrogate has decisional capacity and legal empowerment to give such consent for medical care.

- The surrogate should act with the patient’s best interest in mind and according to what the patient would have wanted had the patient been able to participate in the decision-making process.
- In the United States, when there is no guardian, the provisions of Section 59 of the Guardianship and Administration Act of 1993 apply: Consent must be obtained from a spouse, including a legal de-facto spouse, a parent, a sibling over 18 years of age, a son or daughter over 18 years of age, or a person (not being the guardian) who acts *in loco parentis*.
- In emergency situations, physicians can proceed without obtaining consent when treatment is needed urgently to save a person’s life or to prevent serious damage to a person’s health and (i) the treating health care provider does not have any knowledge of a prior refusal by the person to the treatment, (ii) the patient has not appointed a Medical Agent, (iii) the patient has not appointed an Enduring Guardian, and (iv) there is no Guardianship Order with a guardian appointed by a Guardianship Board.
- When patients are temporarily mentally impaired or even unconscious, and medical decisions must be made quickly, physicians often proceed despite their patient’s impaired or absent decision making capacity. Such action may be justified by the concept of *implied consent* (acting with the patient’s best interest in mind and according to what the patient would have wanted had the patient been able to participate in the decision-making process).

History of Informed consent

- *Informed Consent* is the legal embodiment of the concept that each individual has the right to make decisions affecting his or her well-being. The “Doctrine of Informed Consent” may have been originally derived from the 1947 Nuremberg Code which required that doctors obtain the voluntary informed consent of a subject prior to conducting medical experimentation.
- During the Nuremberg trials, it was discovered that Nazi doctors had performed medical experiments on prisoners and work camp detainees. As a result, Human Subjects Institutional Review Boards and ethics committees were created in order to protect the rights of both patients and research subjects.

- Institutional Review Boards also help assure compliance with the 1964 World Medical Association's Declaration of Helsinki formulation of an international code of ethics to address concerns about the preservation of autonomy, beneficence, non-maleficence, and justice for all human research subjects.

Procedure-related anxiety and the informed consent process*

- A patient's emotions and psychology have considerable impact on the informed consent process.
- Patients are significantly more likely to report procedure satisfaction if they see a familiar face, such as one of their health care providers, prior to the procedure and if they receive detailed information about their procedure from that same individual.
- Race, ethnicity, gender, socio-economic status, education, a patient's previous experiences with physicians, and health care system culture, also impact a patient's emotional and psychological well-being
- Regardless of medical environment and practice setting, the potentially coercive powers of family members, friends, other physicians, and ancillary health care providers capable of influencing a patient's decisions cannot be denied.
- Procedure-related anxiety is a complex, subjective response thought to be influenced most importantly by a patient's temperament and understanding, or lack of understanding, of their illness and the proposed intervention.
- Educating patients about the procedure may be the single most important and most easily manageable pre-procedure factor in lowering emotional concerns and procedure-related discomfort. Such educational interventions might be ideally delivered during inpatient or outpatient consultation, rather than at the time of the procedure itself.
- Obtaining proper informed consent and lowering a patient's procedure-related anxiety are not easily combined. It is well recognized that illness changes a person's perception of oneself and of others, often also altering a person's traditional value system. This places patients in a position of weakness as compared to their empowered health care providers, family members, and previously empowered selves.
- Too much information, or information provided in an inappropriate fashion, potentially increases procedure-related anxiety. Procedure-related emotional distress is frequently based on a patient's belief that medical procedures will cause pain, disability, or even death. Feelings of anxiety and fear are often accompanied by a sensation of helplessness and loss of control, sometimes

exacerbated by memories of emotional suffering, physical pain and even grief prompted by previous medical encounters.

- The person with disease, is after all, very different from the same healthy person living prior to disease. In the unfamiliar and often intimidating surroundings of a sterile procedure room, surrounded by strangers busily going about their business, many patients might even begin to think of themselves as victims rather than participants in their medical care.

* Excellent examples of informed consent issue are found in the following feature films: *The Death of Mr. Lazarescu*, *Extreme Measures* and *A Beautiful Mind* (Colt et al., *The Picture of Health: Medical Ethics and the Movies*, Oxford University Press, 2012).

References

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Note: This synopsis is authored by Henri Colt MD, with help from Jay Jacobson MD, Alan Goldman MD, John Knippa PhD, and Eric Edell MD.

