Frequently Asked Questions On Informed Consent for Procedures

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What is a valid consent process?

"Informed consent" is a technical term first used in a medical malpractice United States court case in 1957[1]. In the clinical context, it applies to situations in which an individual patient agrees to undergo a medical procedure, based on their understanding of an explanation offered by a health-care professional. In doing so, they give permission for healthcare providers to undertake actions consistent with that specific medical procedure.

A process of informed consent has at its heart the key ethical principle of *autonomy*, with preservation of the patient's ability to make an independent decision, while understanding the entailed risks and benefits.

A valid consent depends upon three main elements - disclosure, capacity and voluntariness. *Disclosure* encompasses the amount and accuracy of information provided, while *capacity* covers both *competence* (i.e. the ability to make and communicate a rational choice, including evidence of consideration of the reasoned consequences of that choice) and *comprehensio*n (understanding of what has been said).

Assessing the adequacy of comprehension can be challenging, in that it may be affected by emotional and psychological states, cultural and religious belief, language barriers, concurrent illness, or impaired cognition.

Impaired cognitive function in turn, may be a consequence of the patient's baseline state (e.g. dementia), chronic disease, intoxication, medication or any combination thereof.

Voluntariness means that the patient is making an autonomous decision, free of coercion.

Being fully informed has been considered an overly ambitious goal by some, who offer the more sanguine target of 'reasonable assurance that a patient […] has not been deceived or coerced'[2].

Is a separate anesthesia consent necessary?

It's reasonable to consider that anesthesia is a component of procedural healthcare – not an end in itself. Nonetheless, in some circumstances provision of anesthesia might encompass either more risk or a different set of risks than the interventional procedure concerned. Consequently, it seems appropriate to inform the patient as to what additional risks may be presented by anesthesia.

Opinions on how that is best achieved and recorded vary across institutions and the country – including whether there should be a surgical consent form with a section on consent for anesthesia, or a separate anesthesia consent form.

By using a separate anesthesia consent form, some anesthesiologists believe that they are best placed to explain the risk of anesthesia, as opposed to leaving it to surgical colleagues who

a) may not obtain consent for all applicable modes of anesthesia in these circumstances (e.g. a regional block for ankle surgery, as opposed to general anesthesia , in a patient with asthma) and/or

b) may not fully appreciate and have the knowledge and expertise of anesthesia to fully explain the varying risk/benefit profiles of each circumstance and the alternatives (e.g. the risk of airway compromise in a patient with recent upper respiratory tract infection).

In other words, the process of consent has not been adequately completed - which may compromise *autonomy*.

In other cases, consent for anesthesia is contained within the same form as that giving consent to a procedure or intervention, and is obtained by another physician (e.g. surgeon). The anesthesiologist may provide information at the time of anesthesia evaluation, but does not seek a separate written agreement to anesthesia. They may instead engage in a verbal confirmation of consent, but there is no objective record that this consent has been requested, given or understood.

Given the diversity of practice, departments and institutions can review the arguments for these varying viewpoints and make a considered decision on which stance will best meet the needs of their patient population.

Some institutions have chosen a compromise in constructing a printed document detailing the risks of anesthesia, and ensuring its distribution at the time of an initial outpatient surgical clinic appointment. That practice allows the patient to review the risks with opportunity for a subsequent detailed discussion with their anesthesiologist if they have concerns. It also promotes a more considered appreciation of risk with better factual recall than that achieved in clinic interviews, where the problem of limited retention of information has been well described[3-5].

How much detail do I need to go into in describing possible risks?

This question often arises in reference to the likelihood of adverse outcome and the duty of care of the physician in advising the patient of that risk. Clearly, the principles of *autonomy* and *non-maleficence* argue that one cannot simply decide not to tell the patient anything. Denying them the right to a fully informed decision compromises patient autonomy and risks doing them harm, as the patient may very well decide not to proceed with anesthesia or the procedure were he or she adequately informed in sufficient detail.

On the other hand, simply listing an exhaustive list of unlikely complications does not protect the anesthesiologist from legal consequences should an unlikely event materialize, and risks doing the patient harm in both inducing unnecessary degrees of stress (e.g. the ASA 1 status 23 year old male who is being seen for knee arthroscopy being told he may die or have a stroke) or indeed harm (the same 23 year patient deciding not to proceed with surgery after being scared by listing a risk of death under anesthesia, and thereby suffering unnecessary pain and knee dysfunction from a meniscal fragment)

The degree to which disclosure is pursued in any consent process has been previously held to three standards.
Firstly, that of the medical community or 'the reasonable physician' – where what is said corresponds to what the majority of physicians within a community would disclose.
Critics of this approach suggest that it creates an incentive whereby such groups of physicians may collectively limit what is said, in order to redefine the standard protectively – a step which, rather than being in the best interests of the patient, seeks instead to serve the medical community.
A second alternative is to pursue the standard of 'the reasonable patient' i.e. how much information would the physician need to present to the average person in the community, in order to help them appreciate the balance of risks and benefits associated with a procedure, before deciding to accept or refuse that procedure.
A more recent third standard – with a more exacting application of the 'reasonable patient' principle - is the acknowledgement of 'subjective patient values'. This requires that the physician must disclose those elements of risk or benefit which have particular significance to what they know of that individual patient (e.g. risks of brachial plexus damage to a concert pianist).
Not surprisingly, the second and third standards enjoy more favor within legal jurisprudence.

Central to all of these processes of disclosure is the honest judgment of the physician in determining how much information is truly understood – and indeed desired. All the barriers to communication described above have to be accounted for, in any valid consent process. However, O'Neill has stated that "Genuine consent is apparent where patients can *control* the amount of information they receive, and what they allow to be done."[2] Following this principle, the physician should offer careful open-ended questions in determining what a patient would like to know, and in how much detail. However, an inadequate exploration of the patient's wishes in this regard, risks subjective interpretation by the physician in deciding what the patient is comfortable with.

<u>If a surgeon has obtained consent for a procedure, does that cover my anesthetic plan..?</u>

As discussed above, opinions on this topic vary. However, most feel that the simple signing of a surgical consent form does not relieve the anesthesiologist of the need to offer some information on the risks and benefits of anesthesia in adequate detail, and with documentation thereof in the medical record. Again, the ethical principle at stake is preservation of *autonomy* in decision making regarding one's healthcare. That requires a comprehensive and accurate description of the risks associated with <u>both</u> surgery and anesthesia. Anesthesiologists rarely accompany surgeons to clinic to check the veracity of such information. However, there may be opportunity for a coordinated pre-anesthesia clinic visit to facilitate assessment and allow a more thorough discussion of risk.
While it is unlikely and impractical that patients would consent to surgery yet refuse anesthesia, there may more accurately be opportunities for choice in the mode of anesthesia, and a patient should be allowed to be involved in this decision.

However, as also mentioned above, it is unlikely that the constrained timescale for discussion on the morning of surgery allows for an adequately considered appreciation of the risks involved.
Construction and distribution of informational leaflets for anesthesia in various settings would support reproducibly consistent standards of information transfer, as well as empower patients to ask remaining questions prior to their arrival for surgery.

When is it appropriate to seek surrogate consent?

Preservation of the patient's autonomy of decision making in the management of their body and health is a fundamental principle guiding physicians and care providers within our society. However, there are circumstances in which it is appropriate to ask selected others to make such decisions on the behalf of the patient.
e.g.

1. Status as a minor, where limited experience of life and mortality, as well as immature cognitive skills either limit perception of risk, or induce an unreasonable degree of fear. Both may seriously compromise decision making. In this circumstance parents are widely perceived to be valid decision makers for their child. Some thought should be given to involving the child in discussions of care, as the child matures - together with consideration of those social and cultural factors that affect the family as a whole. (See the question on '...discussion with the child' below).
2. Cognitive impairment as a consequence of acute and/or chronic disease. If it is an acute circumstance, consideration should be given to comparison of the anticipated time till recovery of independent decision making, and the time scale necessary for safe care. It should not be a consequence of a desire for efficiency.
   If the cognitive impairment is chronic with less likelihood of functional improvement, social work and psychiatry should be consulted with regards to assisting the family with creation of a power of attorney for healthcare, to facilitate repetitive and recurrent decisions.
3. Cognitive impairment as a consequence of medical treatment of an acute and serious disease process e.g. sedation to facilitate mechanical ventilation for respiratory failure. While this is really a subset of the previous category, the transient but potentially profound nature of sedation can confuse the issue. In some cases this has unfortunately stimulated discussion with surrogates; a more satisfactory alternative would have been to wait for a sedation break, and consult the patient once the effects of the sedation have waned.

This is not an exhaustive list of conditions and several more permutations of disease and circumstance can arise.
In these circumstances, the ethical principle of *substituted judgment* comes into force – where a family member (or appointed representative) is asked to make a decision based on their knowledge of the wishes and attitudes of the patient, as opposed to their own personal point of view. Invoking substituted judgment can be challenging, and family members may need

reminding that their decisions should be based on the patient's wishes - especially when limitations or cessation of treatment are being considered.
Individual states may have laws that designate levels of authority given to family members, and physicians should consult Risk Management within your institution to determine whether these are in force in your practice area, before talking to families regarding consent. For example, there is often a listed order of precedence afforded to spouses, then adult children, then parents, then siblings etc. Sibling decisions may also require a majority or unanimous vote depending on the decision at hand, and it's best to know what constitutes a valid decision before engaging in such discussions. Any ambiguity or conflict should provoke a discussion with the institutional Ethics Consult service and Risk Management, at the earliest opportunity.

Management of any situation where surrogate decision-making is required should consider the following questions:

- How acute is the need to make a decision?
- What is the likelihood of a return of cognitive function?
- What time period is estimated for that to occur by?
- What will be the consequences to *the patient* of inaction and waiting?

The answers to these questions should be recorded in the patients chart to support and guide subsequent directions of care, and the discussion revisited whenever there is a material change in the patient's medical condition.

Should the anesthesiologist have any discussion with the child?

As mentioned above, emotional and psychological states – including immaturity – can be a barrier to a rational perception of risk and benefit. That is often used to explain why children are not included in a consent process. However, this should not mean that they are incapable of participating in a process of assent to treatment – and there should be a distinction between such assent and the consent required[6]. While this concept has arisen mostly in the field of research, good faith efforts should be made to involve children in explanations of risk and benefit of procedures, alongside their parents – the emphasis placed on such efforts increasing with age of the child. Due consideration should be paid to family culture and experience, however, and the physician would be well-advised to structure involvement of the child in a preliminary discussion with parents beforehand.

What if there's no family or relatives?

In considering this question, two situations frequently arise.
a. Elective or non-urgent interventions. Once more, this may vary by local statute, but the fundamental ethical principle again is that of substituted judgment. That judgment may not be informed by previous knowledge in the absence of family members. However, a court appointed guardian takes the stance of what 'a reasonable person' may decide to do – aided by whatever verifiable information they can derive on previous stated values and wishes from the patient's friends, physicians, and associates. The usual stance taken is one of conservative decision making, while collating what information is available.

b. Urgent or emergent interventions

Physicians can justifiably make a case for intervention without consent when patients are unable to give their own consent, in circumstances where a delay of medical care risks harm to the patient – usually disability or death. This is usually a situation fueled by urgent need, and while good faith attempts should be made to contact either families or legal guardians where they exist, those attempts should not inhibit proceeding with treatment if the alternative is one of real harm. Physicians should record the circumstances and their justification in the chart, for subsequent appraisal and discussion, if required. This also applies to the pre-anesthesia evaluation.

Is there such a thing as two physician consent..?

One of the enduring mythologies of practice, at both the attending and trainee level, is that a patient's consent form signed by two physicians supposedly suffices to support a decision to proceed without consent of patient, their family, or legally appointed representatives. It is difficult to know where and when this mistaken belief originated. However, it should be made clear to all that there is no current legal or ethical justification for such a step, which breaches the principles of *autonomy*, *non-maleficence or beneficence*.

The only ethical alternative in emergent circumstances is as described above – a note justifying intervention by describing the risks of inaction, written in the chart (and preferably by an attending physician).

What if the patient has taken and/or received any medications?

This question is also relevant to patients with substance abuse disorders. Where there is any suspicion of acute intoxication and confounding of decision making – whether self-administered or iatrogenic – physicians should consider the preceding questions around acuity of need for decision-making alongside the timescale for return to competent autonomous decision making. This may involve the exercise of very careful judgment around those patients routinely using such drugs as anxiolytics or analgesics, in determining whether there is any loss of competency. If there is concern around the capacity for rational decision-making, and the time scale permits, generally it is better to defer procedural treatment and anesthesia for another time.

If there is urgent need to proceed, then surrogate decision making may be required.

Careful documentation is required in every circumstance, and it may be appropriate to seek a second opinion from colleagues (e.g. psychiatry) where there is ambiguity or uncertainty on the effect of chronically consumed medications.

Is there an optimal time to explain things to patients? If so, when..?

There is a well-established body of literature detailing the limited comprehension and poor quality of information transfer during a single patient-physician conversation[3,4,7]. Those limitations get worse the closer such a conversation occurs to the time of procedure or intervention.

Some argue the point that unless the patient has been seen and consented in a pre-anesthesia clinic, most elective patients will present on the day of a procedure which they have been told

they require, and have already committed themselves to. There is an expressed concern that further counseling on risk at this stage is unlikely to be adequately appreciated, unlikely to change the patient's mind, and may add to their level of stress.
This has been likened to offering prenuptial agreements while walking down the aisle to the marriage altar, or broadcasting risks of flying while passengers are boarding a plane. It raises concerns that the principle of *nonmaleficence* in medical practice is being compromised (i.e. doing no harm, which in this case is additional stress and anxiety), for the sake of 'legal protection' of the practitioner.
The efficient limitation of *non-maleficence* and maximal *beneficence* would arise from an opportunity for adequate comprehension of information, with time afforded for processing and asking of questions. That may require either repetition, or the use of written aids delivered before an interview.
However a conversation *many weeks* in advance of a procedure risks errors of recall, and the optimal period for accurate recollection may vary considerably between patients. Written sources of information to supplement and facilitate a conversation is some measure of protection against that variability, and may assist in the understanding and processing of information regarding the risks, benefits and alternatives discussed.

How do I ensure that a patient remembers what I have said to them on risks?
See the discussion on optimal timing of explanation above. Due consideration should also be given to the modifying effects of pharmacological agents on memory e.g. timing of sedation.

My patient has a loose tooth – but I warned them of the risk of dental damage. Am I still liable..?
This is more a legal question than an ethical one; however, as mentioned previously, simply describing a possible consequence does not make its occurrence a justifiable one. A patient with a demonstrably difficult airway may credibly be at risk of dental damage, and explanation of that increased risk would satisfy one's ethical duty of care. A patient who sustains dental damage as a result of poor technique has sustained harm that breaches that duty of care and which compromises the ethical principle of non-maleficence. No amount of prior explanation releases the physician from liability in cases of gross negligence.
However, careful documentation of all preoperative discussions (including the identification of broken or carious teeth) is a supportive foundation to good clinical practice.

DN(A)R and anesthesia consent – who should be involved in that discussion..?
This is a subject which is well explored in existing recommendations from the American Society of Anesthesiologists, and the reader is strongly advised to acquaint himself or herself with the concept of required reconsideration.[8].
Nonetheless, if a 'Do not (Attempt) Resuscitation' order exists, the patient (or legally authorized representatives), the surgeon and the anesthesiologist should engage in a discussion around the patient's wishes in the event of acute deterioration or cardiac arrest. This discussion should

be convened with enough notice to allow meaningful participation by all concerned, in advance of the anticipated procedure.
In what is ideally a *goal oriented discussion*, attention should be given to the risk factors and outcomes for perioperative cardiac arrest and their variation from those arising from cardiac arrest in other circumstances[9]. In other words, there may be very real differences between the ability to successfully intervene and consequent outcomes that may persuade a change in decision making for the perioperative period.
However, it ultimately remains the patient's decision - and both the American College of Surgeons and the ASA independently state that forced rescindment of a DN(A)R (as a condition of surgery) is not ethically tenable. To insist on such rescindment compromises patients *autonomy*, and may actually induce harm *(non-maleficence)* by rendering them in a physical state they have previously decided would be worse than death, as well as the stress of feeling that their decision making ability has been compromised.

The best advice for ethical care is to explore what the patient fears as a consequence of cardiac arrest - and discuss what levels of care (and possible intervention) would support successful surgery and anesthesia, while avoiding the feared outcome.
It's important to the validity of any discussion that this NOT be seen as an 'all or nothing decision' – in other words, consequent to their discussion with the anesthesiologist and surgeon, the patient may wish to

a) only consider certain components of resuscitation care (e.g. no chest compressions but cardioversion is okay) - although care must be taken to ensure understanding of the limitations
b) let the clinical team decide the scale of intervention, based upon the patients predefined goals (e.g. 'if I'm not recovered in 5 minutes, stop resuscitation, because I do not wish to risk ending up in a vegetative state')
c) suspend the DN(A)R order completely.

A key component of such discussions is that if a DN(A)R order is modified (irrespective of the form that modification takes), the duration of such modification needs to be specified ahead of time, with clear documentation in the chart as to when the modification comes into force, and when it terminates.

If a patient remains decided upon maintaining the instruction of DN(A)R in the perioperative period, any providers who feel that their individual ethics inhibit their involvement in such cases still have an ethical responsibility to find another anesthesiologist to assume care of the patient.
As with many such policies, all concerned benefit from discussion well in advance of actual need, avoiding precipitate or unnecessarily hurried discussion.

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