Informed Consent Challenges in Frail, Delirious, Demented, and Do-Not-Resuscitate Adult Patients

Jay A. Requarth, MD

ABSTRACT

Without informed consent, any invasive procedure becomes an assault. The prevailing legal and ethical standard is that the physician has a fiduciary duty to give enough information to the patient so that a reasonable person can make an informed decision to accept or refuse the proposed treatment. The patient’s frailty, delirium and/or dementia, and end-of-life concerns and expectations can make informed consent a difficult task. This review examines informed consent requirements for adults and provides communication tools to enable shared decision making while engendering patient–physician trust.

ABBREVIATIONS

DNR = do not attempt resuscitation, MOST = medical orders for scope of treatment, MPOA = medical power of attorney, POLST = physician orders for life-sustaining treatment

Although the requirement to obtain informed consent has been the law of the land in the United States since Schloendorff v Society of New York Hospital in 1914 (1), the requirements vary from state to state and are ambiguous at best. Complicating informed consent even more is that some states use a physician-based standard (ie, of what most physicians would inform the patient) whereas others use a patient-based standard (ie, what most patients would want to know) (2). The prevailing notion in both standards is that the doctor has a fiduciary duty to give the patient information so that a reasonable person can make an informed decision (3); however, obtaining informed consent can be complicated by a patient’s frailty, delirium and/or dementia, and do not attempt resuscitation (DNR) status (4).

The present article reviews informed consent and the concept of a patient’s right to choose his/her most appropriate treatment. For this to happen, patients need to be given an overview of all reasonable treatment options, some of which may include image-guided therapies. As interventional radiologists may provide increasing amounts of palliative care, specific familiarity with these issues is important.

FROM MEDICAL PATERNALISM TO SHARED DECISION MAKING

There has been a significant shift in the doctor–patient decision-making paradigm. Medical paternalism (the “doctor-knows-best” paradigm) was an accepted practice throughout most of the 20th century; however, during the past 50 years, medical paternalism has given way to patient autonomy with shared decision making (5). The Patient Self-Determination Act of 1990 established as US law that a patient’s right of self-determination was the highest standard of medical ethics—taking precedence over medical paternalism and beneficence (6). The American Medical Association adopted the following position statement on informed consent in 2006 (7):

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of
receiving at a given time and present the remainder when appropriate.

Although the previous position statement is vague with respect to “all relevant medical information,” several major court cases have specifically defined the medical information required for an informed consent. In 1994, Annas (5) succinctly described the content required for an informed consent:

With the exception of emergent procedures and the extremely rare situation where the consent process would actually cause physical or emotional harm, informed consent requires not just options, risks, and benefits, but also diagnosis and prognosis.

The American College of Radiology/Society of Interventional Radiology (SIR) practice guideline on informed consent for image-guided procedures, 2011 revision (8), states that an explanation of the procedure (why it is being proposed and how it is performed), anticipated benefits and potential risks, as well as reasonable alternatives to the procedure (including refusing the procedure), are the only necessary parts of an informed consent. The guideline does not discuss patient autonomy or the patient’s need for understanding his/her diagnosis and prognosis to fully participate in shared decision making.

REQUIREMENTS FOR INFORMED CONSENT

In general, because of the physician’s fiduciary duty to protect the weaker partner (the patient) in the informed consent contract, the physician must disclose any information that a reasonable person would find important (9). The components of informed consent are given in Table 1 (7–11). Informed consent should be a discussion that enables a reasonable patient to make appropriate decisions based on his/her own goals of care. This is not to say that physicians should not guide the patient with appropriate information; thus, this process is appropriately called shared decision making.

Depending on the state, patients may also have the right to know the performing physician’s experience and results, all diagnostic tests that may rule out a possible condition, potential risks of not undergoing treatment, and personal economic interests that may influence the physician’s judgment (12–16).

Even capable patients have the right to delegate decisions to another person (17). Although this delegate is usually a family member, it could be a friend or even the physician himself. In these cases, it is suggested that the patient formally designate a medical power of attorney (MPOA). A brief note in the patient’s chart, mentioning a witness’ name, might suffice in an urgent situation.

In the difficult situation in which the patient is not capable and does not have a designated MPOA, it is best to consult the hospital’s ethics committee because each state has different statutes and these statutes change over time. It is generally accepted that a spouse is the legal guardian; however, if the patient is not married, the medical decision making could fall to the eldest child or a majority of first-degree relatives (18).

The US Supreme Court has repeatedly ruled that people have the right to control the decisions regarding their medical treatment (19,20). Thus, if capable, the patient has the right to refuse or even discontinue treatment. The patient’s right to refuse treatment holds for guardians as well, with some notable exceptions. States and the federal government have enacted statutes to protect incapacitated adults, as they are the most vulnerable of its citizens. If the patient refuses treatment, it is suggested that the physician make a detailed note in the medical record explaining the decision.

Withholding artificial nutrition and hydration is also a special category of decision making. In most states, this decision can be made by the MPOA; however, a few states require some evidence (a witnessed verbal utterance or written document) that the patient did not want to be kept alive with tube feedings (21). Some Catholics may not want to discontinue artificial nutrition and hydration on religious grounds, but the Catholic Church has decided that a faithful Catholic has no obligation to continue forced feedings (22).

DELIURM AND DEMENTIA

All persons are competent and capable until proven otherwise (23). Competency is a legal term, and the determination of incompetence is a judicial decision. On the contrary, a physician determines capacity. Capacity usually requires the patient to understand his/her situation, proposed treatment, and risks. The capable patient must also be able to communicate his/her decision in some manner.

Some interventional radiology patients are confused because of baseline dementia and/or superimposed delirium. Determining when mild confusion interferes with capacity is difficult and best left to hospital bylaws and/or state statutes. However, if a patient has insight into
his/her situation, proposed procedure, and intended benefits and risks, and does not vacillate, he/she is probably capable of making his/her own decisions, even if the patient does not know the date, place, or President (24). Nevertheless, obtaining assent from the patient’s next of kin is a reasonable undertaking in patients with questionable capacity.

Physicians need to understand that not all dementia is equal (Table 2) (25). Dementia is a chronic acquired decline in memory and at least one other cognitive function sufficient to affect daily life. Delirium is a rapid-onset transient change in mental status that includes decreased attention, cognitive changes, and/or hallucinations resulting from physical problems. The Mini-Cog short-term memory screening test, described elsewhere (26), is an effective tool to expeditiously evaluate patients for dementia and delirium.

HOSPICE

Hospice is patient- and family-centric end-of-life care in which medical decision making aligns with patient and family goals (27). Hospice was added as a Medicare benefit in 1983 as part of the Tax Equity and Fiscal Responsibility Act (28). To activate the Medicare hospice benefit, the patient must have a life expectancy of 6 months or less as determined by a referring physician and the hospice medical director. The vast majority of hospice days (96.5%) are spent at home, where the patient may still be ambulatory (29).

Table 2: FAST Scale for Dementia (25)

<p>| | |</p>
<table>
<thead>
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<tbody>
<tr>
<td>1.</td>
<td>No difficulties</td>
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<tr>
<td>2.</td>
<td>Subjective forgetfulness</td>
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<tr>
<td>3.</td>
<td>Decreased job function</td>
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<td>4.</td>
<td>Difficulty with complex tasks</td>
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<tr>
<td>5.</td>
<td>Requires supervision with ADLs</td>
</tr>
<tr>
<td>6.</td>
<td>Impaired ADLs</td>
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<tr>
<td>a.</td>
<td>Cannot clothe themselves properly</td>
</tr>
<tr>
<td>b.</td>
<td>Unable to bathe properly</td>
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<tr>
<td>c.</td>
<td>Unable to toilet properly</td>
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<tr>
<td>d.</td>
<td>Urinary incontinence</td>
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<tr>
<td>e.</td>
<td>Fecal incontinence</td>
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<tr>
<td>7.</td>
<td>Severe impairment</td>
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<tr>
<td>a.</td>
<td>Speaks fewer than six words per day</td>
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<tr>
<td>b.</td>
<td>Speaks fewer than one word per day</td>
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<tr>
<td>c.</td>
<td>Cannot walk without assistance</td>
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<tr>
<td>d.</td>
<td>Cannot sit upright without assistance</td>
</tr>
<tr>
<td>e.</td>
<td>Lost ability to smile</td>
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Note—People progress through the FAST scale in a sequential fashion. For example, if a person bathes properly, but speaks fewer than six words per day, he/she would be staged at FAST 6b. ADL = activities of daily living; FAST = Functional Assessment Staging of Alzheimer Disease.

By law, Medicare hospice patients are not required to have DNR status, although most do. Generally, when patients elect the Medicare hospice benefit, they agree to forgo aggressive care; however, palliative procedures may still be justified. For instance, procedures such as biliary and abscess drain changes may be justified; however, the procedures should be ordered by the hospice medical director lest the patient be billed for the procedure.

THERAPEUTIC PRIVILEGE

Therapeutic privilege is the term used to describe the justifiable withholding of “bad” information because, in the physician’s opinion, the patient would be emotionally or physically harmed by the information (30). Therapeutic privilege should be used rarely, because giving disappointing information is part of a doctor’s duty and withholding such information may harm the patient. Although the patient does not have to accept the physician’s recommendations, realigning a patient’s expectations from unrealistic to realistic is an important aspect of respecting the patient’s autonomy (31).

The informed consent discussion should not be so brutal that it causes the patient to lose all hope, nor should health care providers insist that a patient confront the reality of their approaching death (32). How one tactfully negotiates between redirecting a patient’s unrealistic expectations and dashing the patient’s hope is a skill that comes only after extensive experience with its share of unsuccessful interactions.

FUTILE CARE

Although futile care may be obvious to the physician, defining futile care is difficult. Futile care can be defined as treatments that offer less than a 1% chance of success; however, futile care can also be defined as care in which a successful procedure will result in a poor quality of life. Nevertheless, some patients and their families may refuse to accept the inevitable and insist on procedures that the physician believes are futile. The physician should realize that the courts nearly always side with the patient/family when these disputes are adjudicated (33).

INFORMED CONSENT IN PATIENTS WITH DNR STATUS

Respecting the patient’s autonomy, it is important for interventional radiologists to understand the patient’s wishes regarding cardiopulmonary resuscitation before initiating any procedure. Medical orders for scope of treatment (MOST) and physician orders for life-sustaining treatment (POLST) are transportable treatment orders that detail a patient’s wishes about cardiopulmonary resuscitation (34,35). Depending on the state, MOST
and POLST take precedence over all previously executed advanced-care directives. The original copy of the MOST or POLST should be transported with the patient to any hospital, clinic, or office visit. Should the patient experience a cardiopulmonary arrest while the MOST or POLST is active, the directives on the forms should be followed before contacting the responsible physician. As noted previously, hospice patients are not required to have DNR status.

Although commonplace 25 years ago, it is no longer considered ethical to insist that a patient rescind his/her DNR status before a procedure. Because of the Patient Self-Determination Act of 1990, the American Society of Anesthesiologists, American College of Surgeons, and Association of Perioperative Registered Nurses developed the “required reconsideration” guideline that compelled surgeons and anesthesiologists to reassess a patient’s DNR status before proceeding with surgery (36–38). For patients with standing DNR orders, MOST, or POLST, these guidelines recommend that a preoperative discussion occur between the attending physician performing the procedure and the patient and his/her family. This discussion should not be delegated to a different member of the treatment team. The patient and his/her family have four possible options: (i) completely rescind the DNR status for the procedure, (ii) determine which aspects of the DNR are kept active and which are suspended, (iii) ask the physician to decide whether to proceed with resuscitation depending on the situation and the patient’s articulated goals, or (iv) continue with DNR status (39). As far as the author is aware, neither the American College of Radiology nor SIR has any guidelines about performing procedures on patients with active DNR orders, MOST, or POLST.

It is reasonable to obtain consent for periprocedural cardiopulmonary resuscitation in any patient with DNR status at the same time the procedure consent is obtained. Should a patient insist on continuing part or all of his/her DNR status during the procedure, a physician may object to participating in, or performing, a procedure on a medical basis if the patient is refusing specific therapy that would make the procedure unsafe by accepted standards of care. For example, a physician can refuse to participate in a procedure if the patient’s platelet count is less than 10,000/μL and the patient refuses blood products. A medical objection can reasonably delay a procedure, but an urgent consultation to the hospital ethics committee is recommended to mediate the dispute. A physician, nurse, or technician can refuse to participate in an emergency procedure on a patient with an active DNR status on moral grounds as long as alternative staffing is immediately available. On the basis of patient autonomy and the required reconsideration of DNR policy, there may be a day when an interventional radiologist will be obliged to let a patient die in the interventional radiology suite even if the cardiopulmonary arrest is caused by a simple tension pneumothorax or ventricular dysrhythmia.

**INFORMED CONSENT DISCUSSION TECHNIQUES**

Because interventional radiology patients are occasionally uninform as to their disease and/or prognosis, the interventional radiologist can sometimes be trapped between performing a procedure that does not align with the patient’s goals of care and performing a different procedure that aligns with the patient’s goals. These types of informed consent discussions can be extremely difficult for several reasons: (i) the patient may refuse to believe the diagnosis and prognosis information from a heretofore unknown interventional radiologist, (ii) the standard preprocedural physician–patient interaction in interventional radiology can typically be measured in minutes, and (iii) the quality-of-life and survival data for interventional radiology procedures are extremely limited. These difficult discussions may be best performed by using the six-step process taught in hospice and palliative medicine training (Table 3) (40).

**CONCLUSIONS**

Informed consent is more than just a signature on a preprinted page of legal terms. Informed consent, especially when obtained in the palliative procedural context, is the touchstone of shared decision making. Physicians must disclose all material information regarding the proposed treatment so that a reasonable patient or his/her guardian can decide whether to undergo such a procedure. Thus, informed consent requires, at a minimum, the patient’s diagnosis and the prognosis, as well as the expected risks and benefits of the proposed procedure and alternative therapies. Mentally infirm, physically frail, and end-of-life patients pose special challenges during the informed consent process. Knowing how and what to communicate during these difficult informed consent discussions may improve patient satisfaction and care.

**Table 3. Palliative Interventional Radiology Informed Consent Discussions (40)**

1. Arrange the setting (private room where both parties can sit)
2. Determine how much the patient and family know
3. Determine how much they want to know
4. Share information
   a. Align the patient’s/family’s expectations with the facts
   b. Educate the patient/family
5. Respond empathetically
6. Make a plan and/or obtain informed consent
REFERENCES

1. Schiendoff v Society of New York Hospital, 211 NY 125, 105 NE 92 (N.Y. Ct App 1914).
15. Jandre v Physicians Insurance Co of Wisconsin, 330 Wis 2d 50, 792 NW2d 558 (Wis Ct App 2010).