

INFORMED CONSENT SUBSTITUTES: A DECISION MAKING FLOW CHART

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Members of a VA ethics committee
describe the tool they developed to address clinician
confusion surrounding informed consent policies.

When, due to physical or mental illness, patients lack the capacity to make informed decisions or communicate their wishes regarding medical treatment, clinicians are faced with the quandary of identifying appropriate surrogate decision makers. Yet, many clinicians find the intricacies and ethical dilemmas surrounding informed consent, capacity, and surrogate decisions mystifying—especially when such factors as durable powers of attorney (DPOA) for health care, guardianships, advance directives (AD), “do not resuscitate” (DNR) orders, and conflicting wishes of patients’ family members or recommendations of staff are introduced into the process.

A 1996 study found that medical staff at a nursing home facility

were able to identify only 65% of those patients who lacked medical decision making capacity. Worse, when they did correctly identify patients who lacked capacity, no clinician followed through by identifying an appropriate surrogate decision maker.¹ In 1998, Wenger and Lieberman administered a test on general ethical issues to 102 surgeons. The mean score was 73%—but dropped to 58% when only the questions dealing specifically with informed consent were considered.²

Moreover, as potential surrogate decision makers, the general public shows no particular proficiency in making important health care decisions on behalf of loved ones. A 1998 study surveyed 250 legal surrogates of patients with terminal conditions. When surrogates were asked to predict the patient’s treatment wishes in different scenarios, they made incorrect predictions 34% of the time.³ Similarly, in 2001, when Ditto and colleagues asked the patient-selected surrogate decision makers of 401 older adult outpatients to predict their loved ones’

preferences for differing life sustaining treatments in several illness scenarios, surrogates made inaccurate predictions 30% of the time. And accuracy wasn’t improved when surrogates were given the opportunity to read the patient’s AD before making their predictions.⁴

The patient ethics committee at the VA Pittsburgh Healthcare System (VAPHS), Pittsburgh, PA has been approached by a number of clinicians who find themselves in a maze of confusion when confronted with problems regarding informed consent and capacity. To address the problem and, thereby, better serve its patients’ interests, the committee created a flow chart, a “front-line” device designed to guide clinicians through applicable VA policies quickly and easily. In this article, we explain the development of this informed consent flow chart. But first, we take a closer look at the nature of clinicians’ confusion and the VA’s guidelines for determining patient capacity, identifying appropriate patient surrogates, and fulfilling documentation requirements.

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DETERMINING CAPACITY

At first glance, the principle behind surrogate decision making seems relatively straightforward: If a patient lacks decision making capacity, identify the appropriate surrogate to make decisions on the patient's behalf. In practice, however, it's hardly clear-cut, and it's that first step—determining whether the patient has capacity—that clinicians appear to have the most difficulty grasping.

The National Ethics Committee (NEC), part of the VA's National Center for Ethics in Health Care, conducted a 2004 study of clinicians and ethics committee chairs and found 10 common myths that clinicians hold about decision making capacity. For example, one commonly held but false perception was that patients who make decisions against medical advice must lack medical decision making capacity, or conversely, that there is no need to assess capacity in patients who agree with or accept medical advice.⁵ The NEC also cited confusion between the terms decision making "capacity" and "competency." They found that many clinicians believed the two definitions to be the same.⁵

Competency is a legal term referring to a person's mental ability to understand the general effect of a transaction or document. Adults are presumed to be competent to make a wide variety of personal decisions, and this presumption can be overridden only in a court of law.⁶ Capacity, on the other hand, refers to a clinician's assessment of the person's ability to make decisions within a specific context. When capacity is at issue in a health care setting, it would likely be the capacity to make medical decisions that was being

questioned. Although clinicians lack the legal authority to declare a patient incompetent, they can and should make determinations regarding the patient's capacity to make medical decisions and, if indicated, take appropriate steps to identify a surrogate.

- Communication—the patient is able to make a clear choice and communicate it to the clinician.

Remember that capacity isn't all or nothing. Patients can have the capacity to make medical decisions but not to handle their finances or to make other decisions.

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Unfortunately, there is no absolute standard for determining decision making capacity. It is an informed judgment based on clinical evidence.⁷ Nevertheless, many states, health care institutions, professional societies, and educational textbooks have guidelines that delineate what capacity assessment should entail.

In the VA health care system, the National Center for Ethics in Health Care assists in developing, interpreting, and implementing ethics guidelines and policies. Comprised of a multidisciplinary staff, this center has defined medical decision making capacity using the following guidelines^{8,9}:

- Understanding—the patient understands the nature and complexity of his or her medical condition.
- Appreciation—the patient comprehends the nature of both the disease and the proposed treatment as well as the risks associated with each.
- Reasoning—the patient has the ability to compare the proposed treatment with alternatives and weigh all treatment options.

Neither age nor diagnosis are paramount factors in determining capacity, as even patients with dementia may still retain the capacity to make medical decisions, particularly in the early stages of the disease. The same is true for patients with a mental illness.⁵ Severe mental illness, such as schizophrenia, certainly affects thought processes, but the degree of impairment differs considerably among individuals. Although clinicians retain responsibility for determining capacity, consultation with mental health staff is often helpful. In the case of suspected dementia, cognitive testing by a psychologist can be a tremendous help to the clinician assessing capacity.

VHA Handbook 1004.1 details the policies, requirements, and obligations of health care staff dealing with informed consent or surrogate decision making issues in the VA. It also covers atypical informed consent situations and such special circumstances as HIV testing, in which a different set of procedures is followed.¹⁰ The handbook should be reviewed by VA clinicians on a regular basis.

Continued on next page

INFORMED CONSENT SUBSTITUTES

Continued from previous page

According to the handbook, if a patient lacks the capacity to make medical decisions, an appropriate surrogate must be identified and contacted to consent to medical procedures.¹⁰ This means that treatment teams are required to make a reasonable inquiry to identify the proper surrogate and obtain consent from this designated person. There are, of course, relatively uncommon situations—for example, when a patient arrives in an emergency department unaccompanied and unconscious. With the approval of the chief of staff, medical care may be provided without patient or surrogate consent when the following three conditions are met: (1) the patient is unable to give consent; (2) immediate medical care is necessary to preserve life or prevent serious injury to the patient or others; and (3) the patient has no surrogate or the treating clinician determines that waiting to obtain consent from a surrogate would increase the risk of harm to the patient or others.¹⁰

Even if the patient lacks capacity, it's important to consider his or her wishes throughout this entire process. In the case of a patient legally declared incompetent, or one who lacks decision making capacity, the clinician must still attempt to obtain the patient's assent for treatment. In cases in which a patient without capacity refuses the proposed treatment through words or actions after the surrogate properly consents to the treatment, the clinician should refer the matter to the hospital's ethics committee for consultation.¹⁰

Finally, it's critical that clinicians recognize the surrogate's right to decline treatment—even if that treatment could be life saving—to the same extent that they would

recognize the right of a patient with capacity to decline treatment. If, however, a clinician feels that a surrogate is acting against the best interests of a patient or in conflict with the patient's previously expressed desires, he or she should consult the hospital's ethics committee for further guidance.¹⁰

IDENTIFYING THE CORRECT SURROGATE

Determining the appropriate surrogate decision maker opens another Pandora's box of potential mistakes, misunderstandings, and pitfalls. State laws vary regarding the priority of surrogate decision makers. For example, a legal guardian supersedes a spouse in New York, but in Georgia a spouse supersedes a legal guardian.¹¹

VA policy simplifies matters for clinicians by delineating its own order of priority for surrogate decision makers, which takes prece-

and may not include provisions for health care decisions.

The VA assigns second priority to a court-appointed guardian—except when the guardianship order takes effect after the health care agent is designated. In such cases, the court-ordered guardian supersedes the health care agent. Again, the clinician must examine the appointment letters to ensure that the guardian was granted the specific power to make health care decisions.¹⁰

If the patient has neither a health care agent nor a guardian, the patient's next of kin (NOK) are given third priority in the following order: spouse, adult child, parent, adult sibling, grandparent, and adult grandchild. ("Adult" refers to an individual over age 18.) In addition, if multiple NOK are identified at the same level of priority (for example, three siblings), no preference is given to age or order of

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dence over state laws. A health care agent has the highest priority in the VA. This could be a person previously designated in a DPOA for health care document or in an AD. It is important to clarify here that the DPOA document must provide specifically for the agent's authority to make health care decisions. This is critical, as some DPOA documents are general in nature, covering only finances or other business affairs of the patient

birth; all are considered to have equal standing in terms of surrogacy.¹⁰ Obviously, when this is the case, problems can arise due to nonagreement or to difficulty in reaching one of them. Under such circumstances, the clinician should contact all who are eligible surrogates and attempt to obtain an agreement between them as to whom will act on the patient's behalf. If a consensus can't be reached, the clinician must either

Continued on page 39

Continued from page 34

choose the surrogate he or she believes is best able to speak for the patient or seek guidance from the facility's ethics committee.¹⁰

Finally, if the patient has no NOK, VA policy allows for a "close friend" to act as a surrogate so long as there is proof that this individual has shown care and concern for the patient's welfare and is familiar with the patient's activities, health, religious beliefs, and values. This close friend must present a signed, written statement that describes specific examples of his or her relationship to the patient and a social worker must verify that the necessary requirements to designate this person as patient surrogate have been met.¹⁰

Each VA medical facility must have in place a process for identifying surrogates (that is, which staff member is responsible for finding the surrogate and what procedures that person should undergo in order to achieve that objective).¹⁰ Inquiries considered "reasonable" by the VA might include: (1) examining the patient's personal effects, medical records, and other VA records (such as benefits, compensation, and pension) and (2) contacting extended family, friends, neighbors, landlords, local police departments, the local post office, county and local community offices, or other community agencies. If after such an inquiry, the clinician is unable to locate a surrogate decision maker, consent can be obtained through a process involving approval from the clinician and the chief of service. If the case involves the withholding or withdrawal of life sustaining treatment, then further steps must be taken, including consultation with an ethics committee, chief of staff, and regional counsel.¹⁰

DOCUMENTATION ISSUES

Any time a practitioner deals with an issue of capacity or surrogate decision making, it must be documented accurately and promptly. This cannot be overstated. Clinicians are accustomed to charting when administering treatments or evaluating patients' conditions. When there are ethical concerns, however, it's critical to chart any and all contacts with the patient, the patient's NOK, guardian(s), and DPOA. In addition to risk management and legal issues, quality of patient care is also at stake.

in *VHA Handbook 1004.1*), it in no way eliminates the need for an evaluation of a patient's decision making capacity. In addition, VA policy requires practitioners to include in the medical record not simply the informed consent document but also the process by which they obtained the patient's informed consent. This documentation should, at the very least, include all patient-clinician discussions of the patient's diagnosis, prognosis, treatment, alternative treatments, and possible adverse effects of treatment. For patients

Some clinicians are under the mistaken impression that the VA Consent Form... satisfies all of the policy and ethical issues dealing with consent.

Patients are likely to encounter many clinicians during their contact with the hospital, and proper documentation of the patient's capacity status and surrogate is absolutely essential to ensure smooth, proper administration of care. And if a patient's situation should be presented before the ethics committee, legal counsel, or the chief of staff, prompt, accurate documentation can be of great assistance.

Some clinicians are under the mistaken impression that the VA Consent Form, which patients sign upon entering the VA health care system, satisfies all of the policy and ethical issues dealing with consent. Yet, while that form certainly deals with informed consent for treatment and is mandated to be used in certain situations (specified

who lack capacity, additional information, such as how a surrogate decision maker was determined, also should be included.¹⁰

THE INFORMED CONSENT FLOW CHART

To allow VAPHS clinicians to access the numerous policy guidelines in an abbreviated and convenient format, a subcommittee of the VAPHS patient ethics committee was formed to create a flow chart diagram. Making up the subcommittee were a geropsychologist, a nurse practitioner, a social worker, and an attorney. The idea of a step-by-step flow chart was based partially on a DNR flow chart developed by Ebell and Eaton in 1992.¹¹ The flow chart was configured to fit on laminated, three-fold cards measuring 4.25 by

INFORMED CONSENT SUBSTITUTES

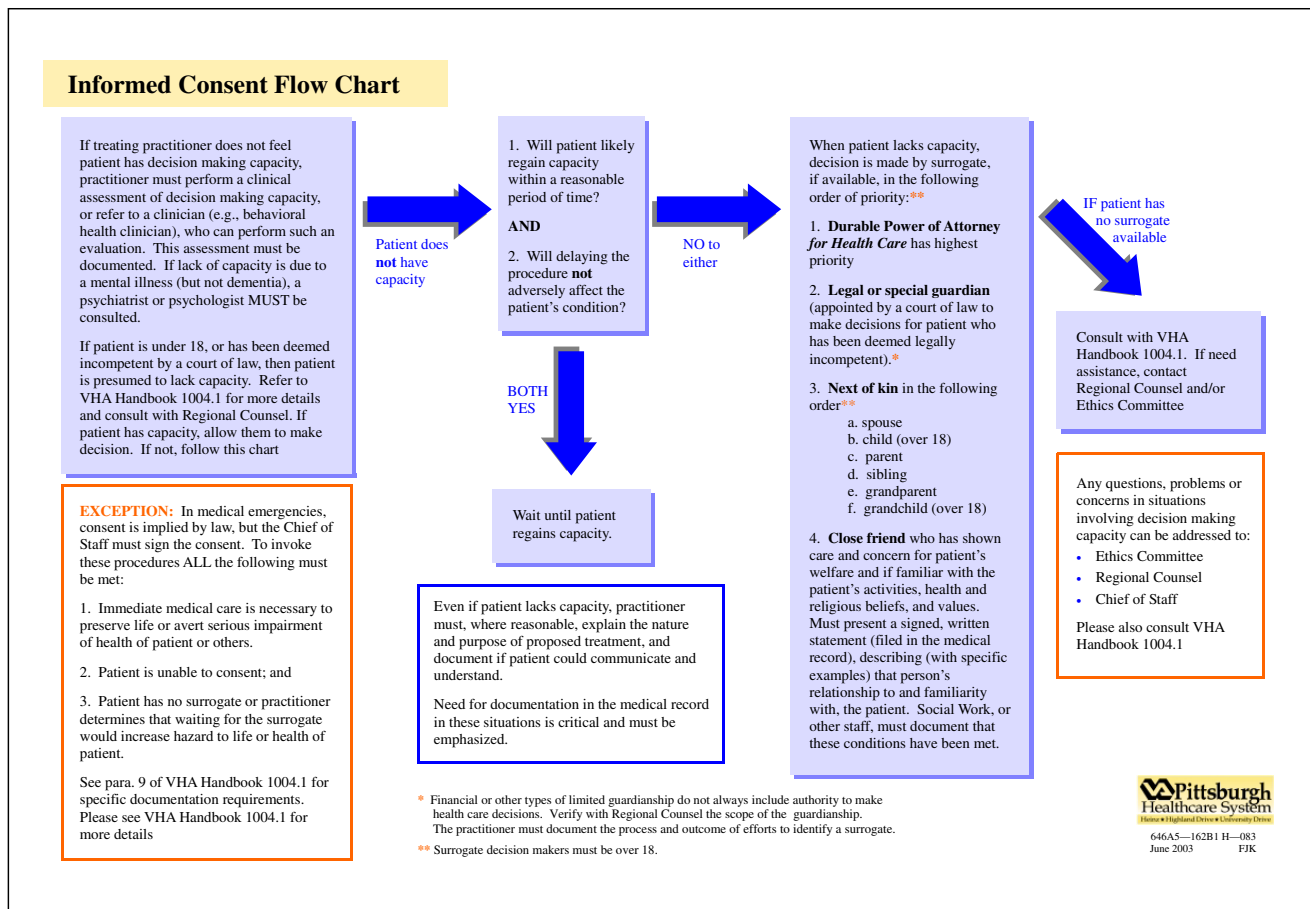


Figure. The informed consent flow chart created by a subcommittee of the VA Pittsburgh Healthcare System (VAPHS) patient ethics committee for use by clinicians at the VAPHS, Pittsburgh, PA.

3.5 in when folded—designed specifically to fit into lab coat pockets for easy access while clinicians are working in the field.

The starting point on the flow chart is the determination of decision making capacity, reminding the clinician to perform a clinical assessment of the patient's capacity or refer the patient to a qualified clinician if capacity is in question (Figure). If incapacity due to mental illness is suspected, the clinician is reminded to consult with a psychiatrist or psychologist.

If a patient is deemed to lack capacity, the flow chart prompts the clinician to consider whether the

patient will regain capacity within a reasonable period of time (as would be expected, for example, in the case of a patient recovering from surgery and under the influence of anesthesia) and whether the medical procedure in question can be delayed without adversely affecting the patient's condition. If the answer to both of these questions is "yes," then the clinician is advised to wait until the patient regains capacity before obtaining consent for the procedure. If the answer to either question is "no," the flow chart directs the clinician to the box that explains how to identify the proper surrogate deci-

sion maker. This box lists the order in which surrogates are to be prioritized.

The final box addresses situations in which there are no available surrogates and refers the clinician to *VHA Handbook 1004.1*, as well as the regional counsel or facility's ethics committee.

The reverse side of the flow chart lists relevant contact numbers for members of the patient ethics committee, as well as phone numbers for the chief of staff and the office of the regional counsel. These reference numbers are a key component of the flow chart, as it could not cover every scenario in-

volving informed consent or surrogate decision making. The chart also refers clinicians to the section of *VHA Handbook 1004.1* for specific documentation requirements and outlines procedures for invoking emergency exceptions.

The aim of the flow chart isn't to replace clinician consultation with the regional counsel, facilities' ethics committees, or similar resources. Rather, it is intended to reinforce VA policies by providing clinicians with a practical and convenient guide by which to navigate the often confusing issues that arise in situations involving informed consent and surrogate decision making. The flow chart also serves to educate staff about the resources available to them, dispel myths surrounding these issues, and increase awareness about the related ethical concerns. While the flow chart is designed to reflect VA policy, the content or format could be converted easily to reflect the policies of other private and public health care facilities.

The use of the flow chart at the VAPHS has led to greater awareness and discussion of informed consent issues, not only among clinicians but also among nonmedical staff. The ultimate goal is to transform the landscape within which these critical ethical issues are addressed from a maze of confusion and misinformation to a manageable path that will ensure the best outcomes for our patients.

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