

Informed Consent and Incompetent Medical Patients

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The mentally incapacitated patient is frequently encountered in the general medical hospital. Incapacity is the clinical state in which a patient is unable to participate in a meaningful way in medical decisions. Mentally incapacitated patients relinquish the authority, that is the competent patient's right, to choose among professionally acceptable alternative treatments. Such patients, therefore, require a surrogate decision-maker. There are certain clinical situations in which questions of incapacity are especially important to consider. In a study for the President's Commission for the Study of Ethical Problems in Medical Biomedical and Behavioral Research, the most common problem in recognizing incapacity was found with previously capable patients who became transiently incapacitated during the course of hospitalization. Questions of incapacity or the authority of surrogate decision-makers also arose with comatose, mentally retarded, mentally ill, and physically handicapped patients. While standards to determine capacity remain unclear, a practical approach is to demonstrate that a patient is able to describe the physician's view of the situation and to understand the physician's opinion as to the best intervention. When a patient is deemed to be incapacitated, the physician should turn to family members, whenever possible, to make decisions.

While much has been written about the problem of informed consent with psychiatric patients,¹⁻³ there is relatively little written about the mentally incapacitated patient in the general medical setting. Yet the mentally incapacitated patient is not a rarity in the general medical hospital. In a recent study for the President's Commission for the Study of Ethical Problems in Medical Biomedical

and Behavioral Research (PCEMR),⁴ the authors intensively observed the interaction between staff and patients on a general surgery and a cardiology service of a teaching hospital. Patients were also interviewed in depth about their understanding of their illness and treatment. It was found that questions about competency were or might have been raised in 13 of 101 cases. Despite this surprisingly large proportion of questionably competent patients, medical staff paid little attention to questions of incompetency and how it affected patients' participation in medical decision-making.

The concept of competency plays a central role in the legal and ethical doctrine of informed con-

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sent, the doctrine that allocates authority to make decisions about health care within the physician-patient relationship. Patients are presumed to be competent and thus to possess ultimate authority to choose among professionally acceptable alternative treatments or even to reject treatment altogether. However, patients who are legally incompetent because they are "mentally incapacitated" or, more properly, because they lack "decisional capacity" relinquish this authority over decision-making and require that another person (a surrogate) be appointed to make their health care decisions. Not only does the informed consent doctrine promote patient autonomy in decision-making, it also seeks to encourage that the decisions the patients do make are rational ones. If a patient's reasoning is seriously impaired, this goal of informed consent is undermined. For the physician who seeks to comply with legal and ethical mandates while still promoting a patient's best health interests, the incompetent patient can present a serious clinical problem.

This paper, based on data from the PCEMR study, describes common clinical situations involving patients with impaired decision-making capacity in the general medical hospital. Case vignettes from observations are also reviewed to highlight some of the more common problems and misconceptions in this area. Finally, some general guidelines on the assessment of incompetency and the management of decision-making with incompetent patients are suggested.

The Informed Consent Doctrine

The informed consent doctrine has evolved over the past three decades to promote society's interest in the dual values of individual autonomy and personal health. The doctrine encourages active patient participation in medical decision-making and holds physicians liable for patient injuries if they have failed to obtain valid informed consent for a diagnostic or therapeutic intervention.

The informed consent doctrine envisions that decisions about health care are to be made through the joint efforts of health care professionals and patients. Professionals contribute technical information about therapeutic possibilities—treatment options, the risks and benefits of those options, the nature and purpose of the procedures, and any other information that would be relevant to making a decision. Health care professionals also con-

tribute professional judgment and serve as advisors to patients. Patients, however, are entitled to make the final decisions. To do this, they apply their own personal values, goals, and beliefs to the technical information and advice that they receive from health care professionals and other such information that they may already have acquired. Patients ask questions, seek advice from professionals (and possibly family and friends), and then decide, or possibly decide that someone else such as a physician or a spouse should make the decision.

There are four exceptions when disclosure of information or consent is not required: the emergency, the therapeutic privilege (whereby the physician withholds information based on his belief that disclosure would be harmful to the patient), the waiver (whereby the patient elects to forego disclosure or decision-making), and incompetency.⁵ While the focus of this paper is on the incompetency exception, there frequently is overlap with the other three exceptions.

Distinguishing Legal Incompetency and Clinical Incapacity—Defining Terms

Discussion and understanding of the role that the concept of incompetency plays in health care decision-making are complicated by the vagueness of some of the terms used in the discussion and by the lack of agreement on the meaning of many of the terms.

At the outset, there is the meaning of the term *incompetency* itself. Technically, incompetency is a legal term referring to a determination by a court, that is, an adjudication that a person lacks the capacity to make a particular kind of decision. The consequence of an adjudication of incompetency is that the person adjudicated incompetent loses the legal authority to make decisions for himself. Adjudications of incompetency may be general or specific. In general incompetency the individual is globally incapacitated so that he or she is unable to make even basic decisions about everyday life. Inability to make medical decisions is only one aspect of the generally incompetent person's disability. Specific incompetency may occur, as the term suggests, regarding a specific medical decision in an individual otherwise competent to manage his or her affairs. Henceforth, the term *incompetency* will refer only to a legal state, and the terms *limited capacity* and *incapacity* will refer to the clinical state in which a patient

is unable to participate in a meaningful way in medical decisions.

Whether a person is adjudicated generally or specifically incompetent, the basis for the determination is some sort of deficiency in the person's decision-making process. The source of the deficiency may be a physical handicap (such as deafness), an intellectual deficiency (mental retardation), a mental illness, substance abuse, or a medical illness (such as delirium). There is, however, no one-to-one correspondence between any of these kinds of impairments and legal incompetency. Rather, the determining factor is the extent to which the patient's impairment affects his ability to make decisions.

Finally, there is no agreed-upon set of criteria for ascertaining whether a person lacks decision-making capacity; nor are there any accepted tests that can be administered to a patient to determine capacity. Discussion of these matters so far has been largely confined to scholarly journals; neither courts nor legislatures nor other law-making bodies seem to be aware of these issues, or if they are, they prefer to disregard them.

These difficulties make the clinician's situation, when confronted with a possibly incompetent patient, even more difficult. Legally, all patients are presumed to be competent unless otherwise adjudicated. Judges, not physicians, have the legal duty to determine incompetency. While only a few patients in general medical settings are legally adjudicated incompetent, many are limited in their capacity to make medical decisions. It is the physician's duty to recognize incapacity prior to accepting a patient's consent to or refusal of treatment because the legal validity of a consent or refusal of an incapacitated patient is questionable.

Clinical Presentations of Possibly Incapacitated Patients

The following different types of presentations provide examples of typical ways in which incapacitated patients present themselves in a university-based teaching hospital. Case vignettes illustrate some typical problems and misconceptions that arise when dealing with patients of limited capacity.

Comatose Patients

A comatose patient is the clearest example of an individual who can be considered generally inca-

pacitated. As with a severely retarded individual or a patient with a profound organic brain syndrome, there is little doubt that a comatose patient is unable to make informed decisions. In these cases, a surrogate decision-maker must be obtained. The following case vignette illustrates the appropriate use of a surrogate decision-maker for a comatose patient but also points out the limitations on the authority of a surrogate to make decisions.

Case 1: The Limits of Surrogate Consent

Mr. A. was an 89-year-old married man admitted to the hospital in a coma with a diagnosis of ischemic bowel disease. Immediate surgery was recommended, albeit hesitantly, because of his medical status. His wife was consulted, and she refused to grant permission for the surgery because she believed that her husband was terminally ill and she preferred that he die in peace. The surgeon honored her decision without argument. Unexpectedly Mr. A. improved with medical treatment alone and awoke from his coma long enough for some discussion with his wife. At that point, Mrs. A. requested that the surgeon proceed with surgery. By then, however, the surgeon viewed surgery as too risky and agreed to operate only if certain specific complications arose in the future. Mrs. A. readily agreed to this plan. Mr. A. died a short time later.

There was no difficulty in this case in assessing incapacity. Nor was there difficulty in designating a surrogate decision-maker. The case highlights an important issue, however. Although a competent patient or an appropriate surrogate decision-maker is usually entitled to refuse an intervention, rarely can either insist that an active intervention be undertaken if it is one to which the physician is opposed.⁶ In this case the surrogate went along with the physician's decision not to proceed with surgery, just as earlier the surgeon respected the surrogate's decision to refuse that intervention. If a conflict had arisen, the surrogate could have sought or been referred to another physician. Alternatively, review of the conflict before a hospital committee or a court might have been appropriate.⁶

Transient Incapacity

It is common for severely ill patients to lose full control over their mental functioning transiently. Medications that affect the central nervous system, such as narcotic analgesics, sedatives, or

hypnotics, are commonly prescribed in hospitals and may cause transient incapacity. Patients may also suffer various insults to their central nervous system as part of the disease process itself. Thus, previously capable persons may be temporarily limited in their capacity to participate in decision-making during the course of treatment. If transient incapacity is not recognized, inappropriate decision-making can result. The following case illustrates how easy it is to miss transient incapacity.

Case 2: Transient Incapacity

Mr. B., a 66-year-old man, was treated in the coronary care unit (CCU) for a myocardial infarction. He was doing well and, in part because he pressed for it, was transferred out of the unit to a regular room. The next day he experienced severe chest pains and what turned out to be a second myocardial infarction. During the acute episode, Mr. B. was alert and helpful to the physicians in assessing his condition. Because he was in severe pain, he was given a considerable amount of morphine. Three days later, while he was recovering in the coronary care unit, it was discovered that he had no memory of the events prior to the second myocardial infarction. He even forgot being transferred from the CCU back to the floor and back again to the CCU. Yet, at no time was the clinical staff aware of any compromise in Mr. B.'s mental function.

Whether the memory loss resulted from the stress of a myocardial infarction or from heavy doses of morphine, it is likely that there was a period of time when Mr. B. would not have been a fully capable decision-maker. Indeed, his loss of memory was probably instrumental in his repeated requests to be allowed to go home prematurely. Yet, as is common with so many cases in the hospital, the alteration in Mr. B.'s mental capacity was not noticed, or at least not attended to, by the treating staff.

The Mentally Retarded

Mentally retarded patients require careful assessment to determine their capacity to participate in decision-making. Such an assessment, however, should not consist simply of evaluating the patient's intelligence quotient but should consider the complexity of the decision at hand with a careful assessment of the patient's sense of personal autonomy and experience making life decisions.⁶

Case 3: Mental Retardation

Mrs. C. was a 54-year-old widow admitted to the hospital for a partial resection of the bowel. She had a previous diagnosis of mental retardation, but lived in the community with her daughter and son-in-law. Mrs. C.'s daughter functioned as a surrogate decision-maker in all matters. Indeed, although Mrs. C. was perfectly willing to be interviewed for the purposes of the study, she insisted that the interviewer discuss the matter with her daughter. Her daughter also discussed all of Mrs. C.'s medical care with the surgeon and the house staff. Mrs. C. was told only what would happen next and asked to assent. Although this approach was consistent with the patient's ordinary procedure for decision-making, it did not solve all problems. For example, Mrs. C.'s medical condition caused her surgeon to consider the possibility of a temporary colostomy. She repeatedly stated that she did not want "the bag." The surgeon promised that he would do his best and was therefore pleased when a colostomy proved unnecessary. Nonetheless, Mrs. C. complained bitterly that she had to have "the bag" and was not very cooperative. Only several days later, during an interview with her, was it learned that she had not understood anything about the potential colostomy and had used "bag" to refer to the Foley catheter about which she was now upset.

This case points out that discussion of treatment with patients serves more than just legal and ethical functions. That Mrs. C. could not give informed consent did not mean that there was no need to explain, in very simple terms, the consequences of the operation. For the mentally retarded patient with a limited ability to make decisions and to understand medical problems, a good model might be that of recent regulation concerning children's participation in research.⁷ In these cases, the surrogate decision-maker is the one to consent, and the patient is only required to "assent," ie, to agree to the procedure.

Mental Illness and Emotional Problems

Patients with psychiatric problems or diagnoses also need careful assessment of their decision-making ability, but like everyone else, should be assumed capable until proven otherwise. The mere fact of a history of a psychiatric disorder is not evidence that an individual is incompetent to

decide about medical treatment or even psychiatric treatment.⁸ Even active psychosis is not such evidence. As is always the case, the determinative issue is the patient's ability to make a specific decision, not the patient's mental health.¹

Nonetheless, a high index of suspicion of incapacity should be maintained for patients with severe psychiatric symptoms. Two patients with longstanding significant psychiatric illnesses were observed during the course of the PCEMR study, one a patient with chronic schizophrenia and the other with a bipolar affective disorder. Neither exhibited acute psychotic symptoms at the times that they were seen for their physical problems, and although neither patient seemed to understand particularly well the nature of the treatment they were receiving, there was no reason to believe that they lacked substantial capacity to understand.

A particularly thorny problem occurs when a patient's mental status interferes with his ability to make rational decisions despite maintaining full intellectual capacity. The following case illustrates this difficulty along with several other clinical problems.

Case 4: Irrational but Capable Refusal

Mr. D., a 61-year-old married man, was admitted to the coronary care unit following a cardiac arrest. During the first week in the hospital, he was intermittently disoriented and agitated, presumably from anoxic brain injury, and had to be physically restrained. The basis for his confusion was explained to his wife, and her help in reorienting him was enlisted, but all treatment decisions were made by the medical team. Despite continued hypoxia secondary to aspiration pneumonia, Mr. D.'s delirium slowly resolved. However, he remained a difficult patient to manage as he repeatedly removed his oxygen mask and began requesting discharge.

Eleven days after admission, the medical staff began trying to explain his condition to him so that they could obtain permission to perform a cardiac catheterization. The patient stated that he understood the procedure but four days later vehemently refused the catheterization or to consider future surgery. Despite vigorous attempts by his physician and his wife to convince him of the seriousness of his condition and the need for the test, Mr. D. insisted on discharge. The patient was interviewed at the time of his discharge "against

medical advice," and it was learned that his confusional syndrome had cleared and that he knew where he was and what he was doing. However, he did not demonstrate an understanding of the seriousness of his heart condition and seemed to be denying that he had had a myocardial infarction.

Although Mr. D.'s delirium had cleared at the time of discharge and there was no clear evidence of incapacity, still his demand to be discharged and his refusal of the catheterization was irrationally based on a denial of the seriousness of his illness. From the clinical point of view, such patients should be offered as much help as possible, including psychiatric consultation, to help them deal psychologically with their illness so that they are free to make rational decisions. Still it is important to note that Mr. D.'s physicians were correct in interpreting the informed consent doctrine. It is well accepted that bad judgment as such does not constitute incompetency. As frustrating as it may be to clinicians, all individuals are entitled to make bad judgments.⁶

The Physically Handicapped

Some physical difficulties may cause special problems for patients' participation in medical decision-making. For the physically handicapped, these problems may be more formal than substantive. For example, communications between physicians and deaf patients may be difficult, and blind patients are not able to read ordinary consent forms. There is an obvious need to alter the informed consent process for such patients. Blind patients must, of course, have someone read them the consent form if a consent form is used. Deaf patients may cause a more serious problem because of their difficulty in asking questions. A translator should be provided for speakers of American Sign Language or other means of establishing a dialogue should be developed. There is no reason, however, to remove the ultimate decision from the hands of the patient.

Assessing Capacity to Decide

It is probably easier to assess the capacity of individual patients to make decisions than it is to set standards for each assessment. The physician may well sympathize with former Supreme Court Justice Potter Stewart, who, wrestling with the problem of developing a standard for obscenity,

opined that he could not develop a clear rule but "I know it when I see it."⁹

It is not the physician's role to assess legal incompetency. The physician is responsible, however, for assessing a patient's capacity to provide informed consent to or refusal of treatment. A variety of standards have been proposed to help the clinician assess incapacity. Unfortunately there is no authoritative law to guide in the selection of a test.

Appelbaum and Roth¹⁰ have proposed four standards for judging capacity: (1) the ability to evidence a choice about treatment, (2) the capacity to have a factual understanding of the information that the average patient would consider material to making the health care decision in question, (3) the ability to rationally manipulate the information, and (4) the capacity to appreciate the nature of the specific situation.

While Appelbaum and Roth suggest that these standards can be arranged in an hierarchy, with the exception of "evidencing a choice," it is not clear that they can be easily ranked from less to more stringent. Rather than viewing each standard as a hierarchically arranged criterion for competency, it is probably better to view them as four components of competency. The ideally competent patient then would show ability in all of these areas; he would be able to evidence a choice, to understand factually the information disclosed to him, to manipulate the information rationally, and to apply it to his own situation.

Just how well a patient must do on each of these components is not established in law. Presumably, the nature of the clinical situation should determine how stringent the criteria for determining incapacity should be. The physician should increase the stringency of his criteria for determining decision-making capacity with the increasing riskiness or intrusiveness of the proposed intervention.⁶ High-risk interventions demand clearly capable decision-makers.

While the search for a single, simple test of incapacity may be futile, certain practical suggestions may be made. For example, a patient may be viewed as capable of making decisions if he or she is able to describe, although not necessarily to accept, the physician's view of the situation and understands the physician's opinion as to the best intervention. For example, in Case 4, Mr. D. would not be considered incapacitated if he were

able to say that his physician thought he had a heart problem requiring cardiac catheterization. That Mr. D. himself did not believe that he had a serious heart condition and would not consider the proposed procedure would not, in and of itself, constitute evidence of incapacity.

It cannot be too strongly emphasized that incapacity is a clinical state that should be assessed for each patient prior to his participation in medical decision-making. While it is tempting to consider incapacity only when patients refuse treatment or diagnostic intervention, it is equally important to consider whether a patient who consents to treatment has the capacity to do so. Such determinations can be easily made in most cases and do not impose an inordinate burden on the physician. The important issue is that clinicians consider the possibility of incapacity for each patient, not that they devote a great deal of time to its routine assessment.

As described above, patients with physical handicaps, intellectual deficits, or psychiatric illnesses should be assessed carefully for possible incapacity, even though they too must be presumed capable until proven otherwise. Patients with acute illnesses that can affect the central nervous system or who are medicated with central nervous system depressants should have their capacity assessed repeatedly over time. The most common error observed in the PCEMR study was a failure to consider that a previously fully capable patient might have become temporarily incapacitated as a result of either his treatment or his underlying illness. Finally, the possibility of incapacity should be especially carefully evaluated in patients for whom major intrusive or risky interventions are being proposed.⁶ From a practical point of view, it is more important for incapacity to be recognized prior to consent for open heart surgery than for a routine chest roentgenogram.

Decision-Making for Patients Who Are Mentally Incapacitated

When a patient does not possess the capacity to make health care decisions for himself, someone else—a surrogate—must make the decisions on his behalf. Only in an emergency, when there is not time to consult with the surrogate without seriously endangering the patient's life or health, is this authority conferred upon the attending physician. It has been customary in the medical profession to

turn to close family members when patients lacked decisional capacity, although only occasionally have positive laws recognized familial authority to make health care decisions for other family members (with the exception of minor children). The express denial to family members of the authority to make such decisions is, however, quite rare. In general, therefore, physicians should turn to family members to make decisions for patients who lack decisional capacity or whose capacity is in doubt.

There are, however, situations in which the presumption that family members should decide can be overcome. If a surrogate makes a decision known to be contrary to a patient's wishes expressed while competent, the surrogate's authority should be called into question. Similarly, a decision clearly not in the best interests of the patient, but one that favors the selfish interests of the surrogate or some other party besides the patient should not be automatically honored. Finally, a surrogate who himself lacks capacity to make decisions should not be permitted to make binding health care decisions for a patient.⁶

In cases in which the surrogate's authority is questionable, health care providers have a responsibility not merely to ignore the decision of the surrogate and substitute their own judgment, but to seek some sort of impartial review both of the surrogate's authority and of the decision. Unfortunately, in many jurisdictions the only available impartial review is the judicial system, which is often slow and expensive. Increasingly, though still almost imperceptibly, health care institutions have begun to create internal review committees to deal with such situations, a solution the PCEMR strongly endorsed.⁶

The absence of family members (or close friends) to act on behalf of incompetent patients also poses increasingly frequent and serious problems. In the absence of family, the medical custom is to administer routine medically indicated treatments and diagnostic procedures to patients who lack decisional capacity without seeking the judicial appointment of a surrogate. Where procedures involving substantial risk must be undertaken, however, a court-appointed surrogate should be sought and obtained. As a practical matter, this can be time consuming, expensive, and difficult—difficult because it is often impossible to find someone to act as the surrogate for the patient.

Conclusions

The patient of limited capacity is frequently encountered in the general medical hospital. Physicians, however, often are not aware of their patients' limitations as informed decision-makers and seen not to have a clear understanding of the informed consent doctrine and its exceptions.

This paper has tried to clarify how the informed consent doctrine is to be applied to patients with limited capacity. Its goal has not been to make physicians competent as lawyers but rather to help them better perform their clinical role. Toward this end some of the typical problems in both understanding and implementing the informed consent doctrine have been illustrated and some broad guidelines have been offered for managing decision-making with patients of limited capacity in the medical setting.

Acknowledgment

This work was supported in part by a grant from the President's Commission for the Study of Ethical Problems in Medical Biomedical and Behavioral Research (Contract No. P-1001) and by the National Institute of Mental Health (CRC Grant No. MH 30915).

References

1. Meisel A: Making mental health care decisions: Informed consent and involuntary civil commitment. *Behav Sci Law* 1983; 1:73-88
2. Roth LH: Involuntary civil commitment: The right to treatment and the right to refuse treatment. *Psychiatr Ann* 1977; 7:245-257
3. Barnhart BA, Pinkerton JL, Roth RT: Informed consent to organic behavior control. *Santa Clara Lawyer* 1977; 17:39-83
4. Lidz CW, Meisel A: Informed consent and the structure of medical care. In President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship. Government Printing Office, 1982, vol 2, pp 317-410
5. Meisel A: The "exceptions" to informed consent: Striking a balance between competing values in medical decisionmaking. *Wisconsin Law Rev* 1979; 1979:413-488
6. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship. Washington, DC, Government Printing Office, 1982
7. Department of Health and Human Services: Additional protections for children involved as subjects in research. *Federal Register* 1983; 48(March 8):9814-9820
8. *Rogers v Okin*, 478 F Supp 1342, 1361 (D. Mass. 1979)
9. *Jacobellis v Ohio*, 378 US 184 (1964) (Stewart J, concurring)
10. Appelbaum PS, Roth LH: Competency to consent to research: A psychiatric overview. *Arch Gen Psychiatry* 1982; 39:951-958