

# Patients' Predilections Regarding Informed Consent for Hospital Treatments

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**BACKGROUND:** Respect for patient autonomy is a core principle of American medicine. Informed consent is required for surgical procedures and blood transfusions but not for most medical treatments of hospitalized patients.

**HYPOTHESIS:** If given the option, patients want to give permission for common medical therapies during hospitalization.

**SUBJECTS:** Participants in the study were patients admitted to the medical service of a 350-bed community teaching hospital.

**METHODS:** A questionnaire comprising 4 scenarios of varying risk/benefit ratios was administered to all patients who agreed to participate.

**RESULTS:** A total of 634 patients were admitted to the medicine service between June and August 2006. Two hundred and ten patients (103 men, 107 women), with a mean age ( $\pm$  SE) of  $63.3 \pm 1.1$  years, agreed to answer the questionnaire. Of these patients, 85% wished to participate in even trivial medical decision making (ie, potassium supplementation), 92% wished to participate in treatments with moderate risk (ie, diuretic for congestive heart failure). When a risk was initially posed as less than a 5% risk of brain hemorrhage and benefits of therapy were substantially higher (eg, thrombolysis for pulmonary embolus), 93% wanted to make the decision. If the risk of brain hemorrhage was 20% or greater, 95% wanted to make the decision. Younger patients (<65 years) were more likely to prefer requiring doctors to obtain their "permission no matter what" than were older patients ( $\geq 65$  years), and older patients were more likely to waive consent across levels of risk.

**CONCLUSIONS:** Most acutely ill hospitalized medicine patients wished to participate in even the most mundane aspects of their medical decision making. Although it is not logistically feasible to obtain informed consent for every treatment of every hospitalized patient, clinicians should be aware of patients' predilections and might consider offering opportunities for patients to participate in clinical decision making, especially for therapies that carry substantial risk. *Journal of Hospital Medicine* 2008;3:6–11. © 2008 Society of Hospital Medicine.

**KEYWORDS:** ethics, informed consent, hospitalization, treatments, therapies, medications, autonomy, self-determination.

The cornerstones of American medical ethics include respect for patient autonomy and beneficence. Although informed consent is required for surgical procedures and transfusion of blood products, the overwhelming majority of medical treatments administered by physicians to hospitalized patients are given without discussing risks, benefits, and alternatives. Although patients may sign a general permission-to-treat form on admission to the hospital, informed consent for medical treatments is generally ad hoc, and there are no national standards or mandates. We hypothesized that given the choice, hospitalized patients would want to

participate in informed decision making, especially for therapies associated with substantial risks and benefits.

## METHODS

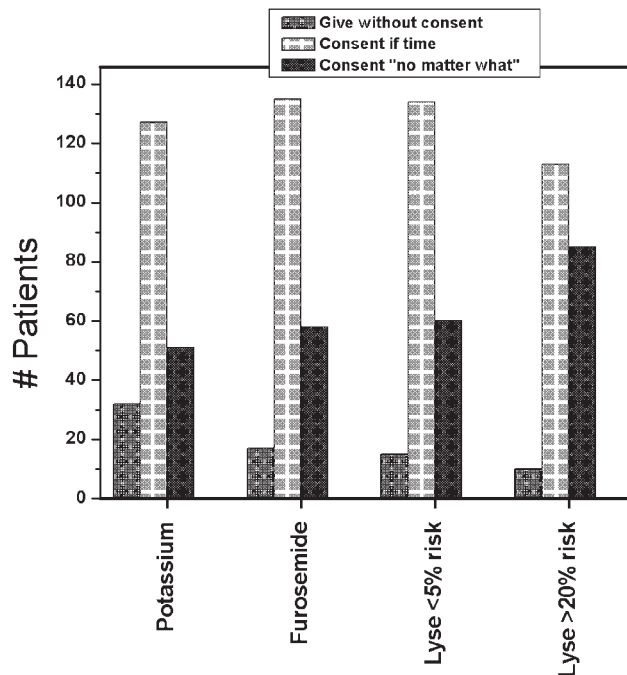
The Institutional Review Board of Bridgeport Hospital approved this study. Each day between June and August 2006, the hospital's admitting department provided investigators with a list that included names and locations of all patients admitted to the Department of Medicine inpatient service. All the patients were eligible for participation in the study. Patients were excluded if they were in a comatose state, were encephalopathic, or were judged to be severely demented. In addition, patients were assessed during the scripted intervention to ascertain whether they had the capacity to make informed decisions based on their ability: (a) to understand the presented information, (b) to consider the information in relation to their personal values, and (c) to communicate their wishes. If personnel doubted an individual's capacity in any of these 3 areas, they were not included in the study.

Study personnel read directly from the script (see Appendix) and recorded answers. Study personnel were permitted to reread questions but did not provide additional guidance beyond the questionnaire. Patients whose primary language was not English were interviewed through in-house or 3-way telephone (remote) translators.

Statistical analyses included the chi-square test to examine responses across the 3 categories of answers (ie, always consent, qualified consent, waive consent) and simple comparisons of percentages. A  $P$  value  $< .05$  was considered statistically significant.

## RESULTS

A total of 634 patients were admitted to the medicine service during the study period June-August 2006. Of these, 158 were judged to lack sufficient capacity by study personnel and were excluded from the study. Ninety-five refused to participate, and 171 were discharged before the questionnaire could be administered. Two hundred and ten patients answered the questionnaire. They ranged in age from 18 to 96 years (mean age  $\pm$  standard error,  $63.3 \pm 1.1$  years). One hundred and three (49%) were men, and 107 (51%) were women. A majority (67.5%) were white, 20% (42) were African American, and 11.9% (25) were Hispanic. Most (87.6%)



**FIGURE 1.** Distributions of answers to the 4 questions. Note that a strong majority of patients preferred to consent if sufficient time or “consent no matter what” regardless of risk. As risk increased, there were stepwise decreases in the number of patients waiving consent and, conversely, more who preferred to “consent no matter what.”

had at least a high school education, and 35% had a college-/graduate-level education. Sixty-seven percent had at least 2 comorbid conditions in addition to their principal reason for hospitalization. Their average acute physiology and chronic health care evaluation (APACHE II) score was  $7.5 \pm 0.3$  (median 7; range 0-22).

Figure 1 shows the distribution of answers to each of the 4 questions.

### Question 1: Permission for Administration of Diuretics

One hundred and ninety-three patients (92%) wished to participate in choosing whether to receive diuretics for congestive heart failure (CHF). Of these, 58 (28%) wanted their treating physicians to obtain their permission “no matter what,” even if there was an acute matter of life and death. One hundred and thirty-five (64%) wanted to be able to give permission if time allowed. Only 8% thought doctors should just give diuretics for CHF without seeking permission.

The pattern of response did not differ by sex, race, number of comorbid conditions, or primary

admission diagnosis. Age (>65 vs. <65 years) was significantly associated with predilections to waive permission for administration of diuretics (Pearson chi-square test  $P = .01$ ). For example, 36.9% of the younger patients (<65 years) wanted to be consulted under all circumstances compared with only 18.7% of the more elderly patients ( $P = .004$ ).

#### **Question 2: Permission for Potassium Replacement**

Overall, 178 patients (85%) wished to participate in decision making regarding potassium supplementation, and 51 (24%) wanted the managing physicians to obtain their permission “no matter what,” even if there was an acute matter of life and death. One hundred and twenty-seven patients (61%) responded that they would like to be able to give permission if time allowed. Only 15% thought doctors should just give potassium replacement without seeking their permission. Similar to the responses to diuretic replacement, the pattern of responses differed by age but not by sex, race, level of education, or number of comorbid conditions. Thirty-one percent of the younger patients wanted to give permission at all times compared with 17.8% of the older patients ( $P = .03$ ).

#### **Question 3: Permission for Thrombolysis of Pulmonary Embolus if Risk of Cerebral Bleed Was Less Than 5%**

If the risk of cerebral hemorrhage was less than 5%, only 15 patients (7%) thought it should be given without seeking their permission. A third of the younger patients compared with 24.5% of the elderly patients would want to be consulted for their permission at all times ( $P = .18$ ). The pattern of responses also did not differ by sex, race or level of education.

#### **Question 4: Permission for Thrombolysis of Pulmonary Embolus if Risk of Cerebral Bleed Was Greater Than 20%**

Overall, 85 patients (40.8%) would want a discussion and their permission no matter what prior to initiating high-risk thrombolysis. One hundred and thirteen patients (54%) would want to be able to give permission if time allowed. This pattern of response differed by level of education and by age. Forty-four percent of those with at least a high school education would want to give permission compared with 19% of those without a high school education ( $P = .016$ ). Four percent of those with at least a high school education would yield the need for permission at all times compared with 11.5% of those without a high school education ( $P = .09$ ).

Only 1 elderly patient (0.9%) would waive the need for permission at all times compared with 9 younger patients (8.7%;  $P = .01$ ).

## **DISCUSSION**

The principal finding of this study is that most medical patients prefer to participate in making decisions about their medical care during acute hospitalization, even for relatively low-risk treatments like potassium supplementation and administration of diuretics. Very few patients were prepared to waive consent and grant their physicians the absolute right to administer therapies such as thrombolysis, even if the risk of bleeding was estimated to be less than 5%. Whereas the elderly patients were less likely to prefer being asked to consent to treatments than were younger patients, most would want to be informed of even trivial therapies if time allowed.

In some situations older patients ( $\geq 65$  years old) were more likely than younger patients (<65 years old) to allow their physicians to make unilateral decisions regarding their health care. This could be explained by those age 65 and older having grown up when physician paternalism was more prevalent in American medicine. In the 1970s physician paternalism waned, and respect for patient autonomy emerged as the dominant physician-patient model. Patients who became adults after 1970 know only this relationship with their physician, and so it makes sense that they would be more inclined to prefer a participatory model.

These data complement and extend a series of studies we conducted with patients admitted to Bridgeport Hospital. Our data suggest that our patients wish to consent for end-of-life decisions,<sup>1,2</sup> invasive procedures,<sup>3</sup> and, now, to be apprised of medical therapies administered during hospitalization. At the same time, we have found that consent practices at many centers are not consistent with these patient predilections.<sup>1,2,4</sup> Our study suffered from having a small sample size obtained in one geographic location; so results should be generalized cautiously. Nonetheless, insofar as the expectations of patients for participation are not being met by the health care system in Connecticut (and we suspect elsewhere), clinicians, hospital administrators, and health care policy makers might consider whether more rigorous and explicit consent practices and policies are required. Another important limitation of the study was that patients included may not have entirely understood the im-

plications of their answers (ie, how cumbersome to the system and bothersome to the patient seeking consent for every therapy could become). In fact, we cannot be certain that all patients truly understood the questions, some of which were complex. Nonetheless, these results support that *considered in the abstract*, most patients prefer to consent for medical therapies. Had the implications for safety and expediency been explained in detail, it is possible that patients would have waived the need to give consent for treatments with minimal risk. The questionnaire also presents an abbreviated list of risks and benefits for each intervention, and although it refers to the formal process of informed consent in its preamble, it uses terminology (ie, “permission”) that may not reflect the complexity of informed consent. Nonetheless, our goal was to examine the degree to which patients wished to participate in their medical decision making. Notwithstanding these weaknesses of the survey instrument, the data suggest patients want to be “in the loop” whenever possible.

There are no national standards of consent for medical treatments. The Veterans’ Administration, which has led the way in many areas of patients’ rights, has a policy:

**Treatments and Procedures That Do *Not* Require Signature Consent.** Treatments and procedures that are low risk and are within broadly accepted standards of medical practice (e.g., administration of most drugs or for the performance of minor procedures such as routine X-rays) do not require signature consent. However, the informed consent process must be documented in the medical record.

Compliance with this standard (ie, consent for every new medication) is not routine in most acute care hospitals. Although some clinicians obtain formal consent for high-risk therapies (perhaps out of respect for autonomy, perhaps to reduce medical-legal liability), there are no explicit decision rules to guide clinicians regarding for which treatments they should obtain formal consent. Accordingly, some might obtain formal consent for thrombolysis for massive pulmonary embolus, and others might not. It is not clear that the consent-to-treat form signed during hospital admission would legally cover *all* medical therapies during hospitalization. The legal standard for informed consent is “what any reasonable patient would want to consent for.” Our data suggest that most “reasonable” patients wish to at least assent

and perhaps consent for much of what they receive during hospitalization. Although we have been unable to find case law predicated entirely on failure to obtain consent prior to administration of a therapy that caused a complication, it is plausible that the “reasonable patient standard” could be used in this manner. Regardless, it is impractical to require consent for the thousands of medical therapies administered each day in hospitals. Requiring consent for all therapies, if respected rigidly, would threaten the safety and efficiency of American hospitals. Naturally, a balance between respect for autonomy, that is, informed consent for the riskiest therapies, and efficiency is necessary. Explicit guidelines issued by accrediting agencies or the federal government would be helpful. The rules for consent (and/or assent) should be more explicit and less arbitrary, that is, determined independently by each clinician.

In conclusion, these data demonstrate that when considered in the abstract, that is, without explaining the logistical hurdles that it would create, inpatients wish to participate in decision making for both low- and high-risk treatments. Clinicians are faced with demands and obligations that preclude full consent for the myriad low-risk treatments administered daily to hospitalized patients. Some treatments are likely to be covered implicitly under the general consent-to-treat process and paperwork. Nonetheless, clinicians should consider explaining the principal risks and benefits of moderate-risk treatments in order to secure informed assent. Full informed consent may be most appropriate for very high-risk therapies. Patients expect and deserve frequent communication with caregivers that balances their safety with their right to self-determination.

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## APPENDIX: QUESTIONNAIRE

Good morning/afternoon/evening. My name is Dr. \_\_\_\_\_, and I am working with Dr. Constantine Manthous in a study to determine what patients want to know about their treatments during hospitalization. The research will *not* effect your



care in any way, and if it is published, your confidential medical information will be protected and will not be mentioned in any publications. In fact, the questions I will ask do not apply to your care plans but are “what ifs” to find out for what kinds of treatments patients’ want to provide permission called “informed consent.” Informed consent is when a doctor explains a treatment or procedure to the patient, including its risks, benefits, and alternatives, and asks permission before doing it. Are you feeling up to answering 4 questions that should take about 5-10 minutes? Thank you.

Again, these questions do not apply to your illness or treatments.

1. **If you had fluid on your lungs, a medicine called a diuretic could be given to make you pass more urine to help get the fluid out of the lungs. The benefits are that it can help you breathe easier. The risks are that it will make you have to urinate more often (>50%), and sometimes minerals in the blood get low and can cause the heart to beat abnormally (<1%) if enough replacement minerals aren’t given to keep up with losses in the urine. The alternative to receiving this medicine would be not to receive it, which risks continued shortness of breath, and rarely (<5%) untreated patients may need a breathing machine to help breathing.**

Which best summarizes your preference?

- a. If I needed this treatment, the doctor should give it to me without asking my permission.
  - b. If it was a question of life or death and there wasn’t enough time to talk it over, I’d want the doctor to just give it. But if there were time, I’d want the doctor to talk it over with me first to get my permission.
  - c. If I needed this treatment, I’d want the doctor to talk it over with me first to get my permission no matter what.
2. **When a diuretic is given, minerals in the blood can be lost in the urine. If the minerals in the blood get too low, the heart can have abnormal beats that are rarely (<1%) life-threatening. Doctors can give replacement minerals. The risks of replacement are minimal, and the alternative is not to give the minerals, risking abnormal heartbeats.**

Which best summarizes your preference?

- a. If I needed replacement minerals, the doctor should give it to me without needing my permission.

- b. If it was a question of life or death and there wasn’t enough time to talk it over, I’d want the doctor to just give me the minerals. But if there was time, I’d want the doctor to talk it over with me first to get my permission.
- c. If I needed replacement minerals, I’d want the doctor to talk it over with me first to get my permission no matter what.

3. **During hospitalization, sometimes blood clots can form in the legs and travel to the lungs. Very rarely (<1%), the blood clots can cause shortness of breath and the blood pressure to drop to a dangerous level. In this case there is a medicine called “tpa” that can dissolve the blood clot. It almost always dissolves the clot, improves breathlessness, and improves heart function. But there is a small risk (<5%) that it can cause serious bleeding into the brain (called a stroke).**

Which best summarizes your preference?

- a. If I needed tpa for life-threatening blood clots, the doctor should give it to me without needing my permission.
  - b. If it was a question of life or death and there wasn’t enough time to talk it over, I’d want the doctor to just give the tpa. But if there was time and I was able, I’d want the doctor to talk it over with me first to get my permission.
  - c. If I needed tpa for life-threatening blood clots, I’d want the doctor to talk it over with me first to get my permission no matter what.
4. **In the previous example, what if the serious brain bleeding from the clot-busting drug happened in more than 20% of cases, which best summarizes your preference?**
- a. If I needed this treatment, the doctor should give it to me without needing my permission.
  - b. If it was a question of life or death and there wasn’t enough time to talk it over, I’d want the doctor to just give it. But if there was time, I’d want the doctor to talk it over with me first to get my permission.
  - c. If I needed this treatment, I’d want the doctor to talk it over with me first to get my permission no matter what.

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