

Intensive Care Patients' Evaluations of the Informed Consent Process

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This study examines the informed consent process from the perspective of intensive care patients. Using the largest single-method database of patient-derived information in the United States, we systematically outlined and tested several key factors that influence patient evaluations of the intensive care unit (ICU) informed consent process. Measures of information, understanding, and decision-making involvement were found to predict overall patient satisfaction and patient loyalty intentions. Specific actions supportive of ICU informed consent, such as giving patients information on advance directives, patient's rights, and organ donation, resulted in significantly higher patient evaluation scores with large effect sizes. This research suggests that the effectiveness of the informed consent process in the ICU from the patient's perspective can be measured and evaluated and that ICU patients place a high value on the elements of the informed consent process.

Keywords: Ethics, Patient satisfaction, Intensive care, Quality of healthcare, Communication, Informed consent

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This study examines the informed consent process from the perspective of intensive care patients. Using the largest single-method database of patient-derived information in the United States, we systematically outlined and tested several key factors that influence patient evaluations of the intensive care unit (ICU) informed consent process. A review of the fundamental elements of the informed consent process reveals disconnects between theory, clinical practice, and patient preferences. As an examination of the effectiveness of the current informed consent procedures in ICUs, the results are relevant to ethicists, policymakers, clinicians, and healthcare quality professionals.

What Is Informed Consent?

Cultural and social structures affect all aspects of healthcare, including intensive care and treatment decision making. Informed consent is the process through which patients or their surrogate decision maker understands and agrees to medical procedures.¹ The informed consent process fulfills 2 purposes: (1) the moral and ethical purpose of patients' maintaining their right to autonomous self-direction and freedom of choice and (2) the legal, institutional authorization obtained by satisfying rules and regulations that allow the proposed treatment to be conducted in a compliant fashion.² The latter, legal purpose often dominates because healthcare professionals

sometimes believe that the purpose of informed consent is to protect the physician or medical institution rather than the patient.³ Patients or their surrogate must be given a clear explanation of the patient's condition and any proposed treatments as well as any potential benefits and risks. In addition, patients or their surrogates should receive information on any potential problems related to recovery and the likelihood of success. Therefore, the informed consent process is not simply a legal and ethical obligation; it stands as a central factor in clinical quality by being the mechanism to help the patient arrive at a treatment decision. Achieving informed, autonomous treatment decisions is not a one-shot encounter. Rather, informed consent represents a continuous and participatory process of competence assessment, information disclosure, comprehension, and decision making (Table 1).

Informed Consent and Intensive Care

Patients' experiences in intensive care are substantially different than in general acute care, further heightening the need for, and importance of, the informed consent process. In addition to treatment decisions, ICU patients' precarious clinical situations often necessitate the difficult considerations of advance directives (eg, do not resuscitate orders), organ donation, and living wills, as well as greater involvement of family members.⁴⁻⁸ Patients' conditions, functional abilities, and prognoses can change quickly, and continuous discussion is required as patients and surrogate decision makers can change their minds with equal rapidity.⁹ Furthermore, family members may also quickly become surrogate decision makers due to heavy sedation—not just acute condition.¹⁰

Beyond illness severity and associated psychosocial burdens, psychological problems and emotional distress have been shown to arise as a direct result of the experience of treatment in the ICU.^{11,12} Patients in the ICU characterize their experiences as chaotic and unstable,

resulting in feelings of extreme instability, vulnerability, fear, prolonged inner tension, and a fragile sense of security where even trivial events create amplified emotional experiences.¹³ Furthermore, the intensive care environment is not conducive to patient comfort; ICU patients are plagued by noises that can reach a decibel level on par with an airport, causing discomfort and sleep deprivation at a clinical equivalent of sleep apnea.¹⁴⁻¹⁷ Not only do ICU patients face complex and significant treatment decisions, but the circumstances and conditions surrounding the informed consent process to help make these decisions are challenging for both patient and professional.

Patients' Perspective on Elements of Informed Consent Process

Disclosure: The first American Hospital Association Patients' Bill of Rights, along with the seminal court cases mandating the "reasonable person" standard, made informed consent a necessity for all healthcare providers and swung the pendulum from overt paternalism to explicit legal obligations to give patients information.¹⁸ Joint Commission for Accreditation of Healthcare Organizations, American Hospital Association, and other quasi-governmental regulatory agencies require that all hospitals provide patients with information on their rights before treatment.¹⁹ This includes information on patients' rights, the illness at hand, treatment options, and the inherent risks in these options, as well as nontreatment options. Katz refers to this as the "obligation for conversation," which begins the informed consent process and obligates doctors and hospitals to share more information and decision-making authority with their patients.²⁰ This approach fulfills the legal obligations but does not necessarily discharge ethical responsibilities or meet patients' needs. Fulfilling this second sense of informed consent requires thoughtful consideration of what information patients actually desire.

TABLE 1 Elements of the Informed Consent Process

Fulfilling the Ethical and Legal Purpose for Informed Consent Necessitates the Following Common Elements^{11,12}

- Competence—the ability to understand and decide
- Disclosure of information—communicating the procedure, risks, benefits, and alternatives
- Understanding—comprehension of the information
- Voluntariness—deciding while free from coercion or duress
- Decision—selection of a course of action, goal, treatment, or therapy regimen.

Fulfilling this second sense of informed consent requires thoughtful consideration of what information patients actually desire.

Many have theorized that patients' desires for information and autonomy follow a continuum, where some patients need to cede responsibility to others (paternalistic) and others need to be actively informed and involved (informative).²¹ Information provision imbues comfort to

the patient that reduces psychologic and physiologic stress.²² However, the assumption that more information is always better must be discarded as patients' desires for information varies. A certain portion of people possess a "low need for cognition" and may actually be comforted if they are relieved from the responsibilities of information seeking, information collection, and decision making.^{23,24} Fifty-five percent of low-autonomy patients opt for less information and involvement; even highly autonomous patients opt against the information-rich and involvement-heavy clinical approach at a rate of 34%.²⁵ Sometimes patients and family members who, under normal healthcare encounters, desire high volumes of information will experience information overload under the stress of the ICU situation.²⁶ Still, a preponderance of studies confirm that patients do desire information about their illness and treatment—the major question remains one of quantity and quality.

Communicating information is not limited to the illness, condition, treatment, risks, and potential benefits—patients and family benefit from learning about everything they encounter, including the basic surroundings that seem intimately familiar to the frontline staff. For example, one study significantly improved ICU patient and family satisfaction by providing information via a family information leaflet at the first visit of the family representative, including general information on the ICU and hospital, the name of the physician(s) caring for the patient, a diagram of the typical ICU room with names of all devices, and a glossary of common ICU terms.²⁷ Indeed, information provision remains just as salient for the family members, often the surrogate decision makers, as it does the patient.

Family member's evaluations of the treatment decision-making process depend not only on the frequency of communication from nurses and physicians but also on the completeness of information and emotional support received throughout the process.²⁸ Typically, physicians fail to effectively communicate information regarding the condition of patients in the ICU to family members, and more than 50% of families desired more information during their ICU experience.²⁹ According to patients and surrogates, successful informed consent experiences depend on not only frequency of information provisions but the quality of the information and *how* it is provided. Family and patient perceptions of staff and physician behavior intermingle with care, education, and communication elements, which ultimately affect evaluations.³⁰

For all these reasons, assessments of the effectiveness of the information delivery component of the informed consent process should focus on *how well* physicians and nurses kept the patient informed, thus allowing the

patient to determine their own criteria for quality instead of imposing a certain frequency or other culturally dependent value. Because family knowledge—and often involvement—is important to patients, the information given to family should also be a measure of effectiveness for this dimension of informed consent.

Understanding: Imparting information is not enough. Patients must digest this information, comprehend the issues, and react to it. Patients can react to this process in a variety of ways: (1) requests for additional information, (2) a need for greater explanation, (3) no need whatsoever for additional information or explanation, and/or (4) a desire to discuss the information in detail and assess its personal relevance. Patients respond more favorably to the informed consent process when they have many opportunities to be involved and understanding is frequently revisited.³¹

Informed consent, conceptualized as a negotiation of trust between patient and physician, means understanding that the informed consent process goes beyond merely the patient's understanding of an illness; it encompasses the physician's understanding of the patient's values, beliefs, and explanatory model.³² Once physicians truly understand a patient on this level, they can help the patient translate the medical facts into something meaningful to their situation.³³

Achieving understanding is easier said than done. The dominant model for informing patients about their illness and potential treatment deploys a barrage of future-oriented relative risk assessments and numeric probabilities.³⁴ Most people routinely misinterpret probability data, and this misinterpretation varies by culture.³⁵ Nevertheless, this is how most information is communicated by physicians and in medical brochures, despite growing evidence that indicates this is suboptimal.³⁶ One method for overcoming these inherent problems is to provide patients with a reference class, enabling them to relate the statistical information to an understandable framework—for example, instead of saying that taking a drug has a 30% to 50% chance of sexual dysfunction, stating that out of 10 patients who took the drug, 3 to 5 will experience sexual dysfunction results in a more accurate understanding and interpretation.³⁷⁻³⁹ Thus, *how* information is communicated can influence patients' judgment and decision making.⁴⁰ To assess the effectiveness of understanding, ICU patients should be asked specifically how well nurses helped them understand and how physicians handled their questions and concerns.

Decision: Decision-making preferences differ by a desire for information,⁴¹ for involvement, and for autonomy in

decision making. One recent study further highlights evidence that preferences in information-seeking and decision-making involvement are distinct; despite a near universal desire among all family members for more information, half the family members in this study of 357 patients did not wish to participate in decision making.⁴² However, there is evidence of an overlap between information giving and desired involvement that affects how patients evaluate their informed consent experience. In a recent study, 20% of patients chose an active role in decision making, and 80% chose a collaborative or a passive role; despite this overwhelming desire for passive involvement, patients still felt disempowered due to lack of information.⁴³

Increasing evidence suggests that autonomous decision making may be overrated. According to patients, participation in the decision-making process was more about being informed and feeling consulted in the treatment decision process than actually making the decision themselves.⁴⁴ Furthermore, patients from Asian and Hispanic cultures emphasize family-centered models for decision making as opposed to the individualized, patient-centered model.⁴⁵ A recent empirical study encompassing 12,680 patients from 51 hospitals in Massachusetts found that autonomy as measured by involvement in treatment decisions was valued less by patients than being treated with *respect and dignity* and *confidence and trust in providers* (ie, these aspects were more strongly associated with patients' overall evaluations of the hospital experience and their willingness to recommend).⁴⁶

Locus of control is another arm of decision-making research that asserts that people have different expectations for the amount of control they can and must assert in their life. Many are comfortable with maintaining little control over their world, whereas others feel strong needs to exert control over every facet of their life. For example, the belief that you can positively influence your own health is associated with a greater desire for information and decision-making involvement, and conversely, those who believed health was dependent on forces outside their control were less likely to desire information or involvement in decision making.⁴⁷ With healthcare encounters, in particular, many persons hold the explicit expectation that decision-making control will be in the hands of others—namely, doctors and nurses.⁴⁸ These expectations and desires for control impact healthcare experiences. Patients with high levels of internal locus of control experience acute levels of psychological distress when they perceive a lack of control over the decisions affecting their life.⁴⁹ Although age and education levels predict internal versus external locus of control, this characteristic is not stable over time, condition, and

reason for the healthcare encounter.⁵⁰ Greater complexity in ICU treatment further reduces patient and surrogate certainty and consistency in their decisions.⁵¹

Overall, almost all physicians understand the components of informed consent, but most have difficulty actualizing these components in their daily practice.⁵² For many reasons, physicians are largely unsuccessful in assessing the desired level of information and decision-making involvement patients actually want and then matching this level in service delivery.^{53,54} Sometimes, this disconnect can be quite blatant. Some physicians maintain that the informed consent process in large medical centers “represents at best a polite fiction.”⁵⁵ Despite universal recognition of informed consent as a fundamental component of all medical practice, physicians frequently make medical decisions based on what they perceive as the patient's best interest.⁵⁶ This is especially prevalent in the ICU, where physicians claim to act in the patient's “best interest” despite expressed wishes to the contrary.⁵⁷ Many physicians continue life-sustaining treatment despite patient or surrogate wishes that it be discontinued (34%), and many unilaterally withhold (83%) or withdraw (82%) life-sustaining treatment that they judge to be futile; these decisions may be made without the knowledge or consent of patients or their surrogates, and some are made over their objections.⁵⁸ Interactions with surgeons in attempting to reach a treatment decision can frustrate patients (and physicians), as surgeons have developed into well-honed, rapid decision makers—a cognitive skill necessary for successful surgery, but often detrimental to helping the patient reach a treatment decision.⁵⁹ Patients strongly desire information but do not wish to be abandoned by physicians in their utilization of that information to make decisions, instead patients want physicians to help them use the information to process and problem-solve these critical decisions.⁶⁰

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Collectively, these conflicting research findings actually concur in their conclusions. People's needs for cognition, information, engaging in information-seeking behaviors, autonomy preferences, internal versus external locus of control, and other factors that influence the

patient's desired experience in an informed consent process vary across multiple spectrums and are situationally dependent. Any patient or family member of any ethnic or cultural background may desire a position anywhere on the spectra—and these preferences can change over even short periods of time. Research and ethics philosophies converge in the conclusion that we cannot assume a particular stance, cannot avoid reassessing, and must not avoid continuous dialogue between patient, physician, and the healthcare team.

Evaluating the Ethical Effectiveness of the Elements of the Informed Consent Process

How do we know if the informed consent process is working at a healthcare facility? We can assess compliance in the legal sense through document reviews. But how can we assess success of a facility's respect of patient autonomy in the ethical and moral sense? For that assessment, the patient's perspective is required. Given the research reviewed above, it becomes readily apparent that patients themselves are in the best position to evaluate whether the informed consent process met their needs, respected their personhood, actually resulted in beneficence, and was thus effective. Patient evaluations of nursing and medical staff's provision of information, demonstration of concern, and effective communication are typically lower than the staff's evaluations of their own performances; observational studies confirm that patient evaluations more accurately reflect the broad range of staff performance.⁶¹ Evaluating the performance of an ICUs staff requires measurement and utilization of satisfaction data derived from patients and families.⁶² Table 2 matches commonly used patient-derived measures to the framework of the informed consent process. These measures have been successfully used to evaluate quality improvement clinical trials sponsored by the Critical Care Family Assistance Program and the CHEST foundation.³⁰

Variables

Ironically, although the informed consent process is intended to benefit the patient, few studies have explored the patient's evaluation of the process as it is currently practiced. The remainder of this article will discuss how to test the process, and will quantitatively test whether the patient's perspective of the informed consent process could be influenced by a myriad of factors—including an individual's age, gender, race/ethnicity, income level, and language.⁶³ We will also review how, and then quantitatively test whether, the patient's experience with informed consent can influence quality outcomes including health status and length of stay.

TABLE 2 Elements of the Informed Consent Process and Questions Measuring Patients' Evaluations of their Experience

| Disclosure of Information |
|--|
| How well the nurses kept you informed |
| How well the physician kept you informed |
| Information given to your family about your condition and treatment |
| Understanding |
| Explanations about what would happen during tests or treatments |
| How well intensive care nurses helped you understand your treatment, test, and condition |
| Physician concern for your questions and worries |
| Decision |
| Staff effort to include you in decisions about your treatment |

Age: Studies examining elderly patients' information, autonomy, and decision-making preferences have mixed results. Some studies show that these preferences do not vary by age.^{50,64-66} Other studies have found significant variation in patient desires for information, autonomy preferences, and level of involvement in decision making, with older patients possessing lower information desires and a significantly higher percentage preferring to leave decisions to the healthcare professionals.⁶⁷⁻⁶⁹ This may be rooted in social beliefs and values (ie, cohort effect). Elderly patients hold different perspectives on truth telling, patient autonomy and physician paternalism, advance directives, and the use of life support.⁷⁰⁻⁷² There is also evidence that the behaviors necessary for high levels of autonomy and participation in decision making require greater physical and mental effort. Elderly patients tend to have poor eyesight and may experience problems with written consent forms. This is not simply a problem of type size, as some elderly patients may have trouble signing their own name and could be unsure of their own ability to sign properly.⁷³ Both elderly patients and their surrogate decision makers experience greater psychological difficulty in the informed consent and treatment decision-making process because of the greater relative perceived permanence or potential finality associated with these decisions.⁷⁴

All these factors likely lead elderly patients to possess relatively lower expectations for and more favorable evaluations of information, understanding, and decision-making involvement. Previous research asserted that patient ratings of hospital care universally increased with age, but recent studies show greater variability by age

TABLE 3 Relationship to Patient Loyalty and Satisfaction

| Question | Likelihood of Your Recommending This Hospital to Others (Loyalty) | | Overall Mean Score (Patient Satisfaction) | |
|--|---|----------|---|----------|
| | <i>r</i> | <i>P</i> | <i>r</i> | <i>P</i> |
| N5. How well the nurses kept you informed | 0.65 | <.001 | 0.77 | <.001 |
| P3. How well physician kept you informed | 0.50 | <.001 | 0.68 | <.001 |
| V4. Information given your family about your condition and treatment | 0.59 | <.001 | 0.75 | <.001 |
| T3. Explanations about what would happen during tests and treatments | 0.55 | <.001 | 0.74 | <.001 |
| ICU2. How well critical care nurses helped you understand your treatment, tests, and condition | 0.53 | <.001 | 0.65 | <.001 |
| P2. Physician's concern for your questions and worries | 0.51 | <.001 | 0.68 | <.001 |
| I6. Staff effort to include you in decisions about your treatment | 0.65 | <.001 | 0.80 | <.001 |

group; specifically, the advanced elderly and baby boomers are more critical evaluators of healthcare services and provide lower ratings than other age groups—the elderly, nonelderly adults, and pediatric populations.⁷⁵

Gender: According to a recent study, men and women in the ICU had different information needs and different preferences for decision making.⁷⁶ These patients also reported receiving significantly different volumes of information. This and other studies have found that women tend to desire more information than men and therefore are comparatively less satisfied with the amount of information given by physicians and nurses.⁷⁶⁻⁷⁸ Women also tend to experience greater internal conflict in treatment decision making across a variety of illnesses.⁷⁹

Given social structures and the residue of historical imbalances, some contend that women need more explicit support in healthcare decision making, empowerment, flexible environments, personal knowledge and reflection, and emancipation from social norms.⁸⁰

Low Income: Low-income patients being treated for acute myocardial infarctions were less likely to receive key treatments for high-quality care (eg, aspirin on

admission, reperfusion, and beta-blocker therapy),⁸¹ as well as less likely to visit the physician, to comprehend and recall information, and to ask questions. Given their health needs and controlling for other factors, the poor actually use hospital services less than other populations.⁸² Poor patients may sometimes avoid visiting a physician at public clinics for financial concerns, even though the clinic in question may be free.⁸³ Furthermore, nonethnic, socioeconomic factors explain 50% of the difference in lower trust of physicians among nonwhites.⁸⁴ For instance, Medicaid patients report lower levels of trust in physicians. Medicaid patients are not “lazy” or without the traditional American work ethos; up to 56% of patients below the poverty line are working but have employers who do not provide insurance.⁸⁵ Many Medicaid patients feel socially uncomfortable or unwelcome by staff and providers whom are relatively affluent or wealthier, creating palpably uncomfortable personal interactions for both staff and patient.

Language: Non-English-speaking patients report experiencing greater difficulty with the informed consent process.⁸⁶ Patients tend to prefer providers of

TABLE 4 Multivariate Linear Regression: Patient Loyalty

| Model | Model Summary | | | | | | | | |
|----------------------------|---------------|-----------------|--------------------------|--------------------|------------------------|-------------------|-------------|-------------|---------------|
| | | | | | | Change Statistics | | | |
| | <i>R</i> | <i>R</i> Square | Adjusted <i>R</i> Square | SE of the Estimate | <i>R</i> Square Change | F Change | <i>df</i> 1 | <i>df</i> 2 | Sig. F Change |
| Likelihood of recommending | 0.747* | 0.557 | 0.557 | 13.216 | 0.557 | 60,611.515 | 7 | 336,976 | .000 |

*Predictors: (Constant) I6. Staff effort to include you in decisions about your treatment; ICU2. How well ICU/CCU nurses helped you understand your treatment, tests, and condition; P2. Physician's concern for your questions and worries; T3. Explanations about what would happen during tests and treatments; V4. Information given your family about your condition and treatment, N5. How well the nurses kept you informed; P3. How well physician kept you informed.

similar race and cultural backgrounds.^{87,88} Several studies have found that patients with different languages and cultural backgrounds than their providers were less satisfied with their care experiences.⁸⁸ One previous study using the same methodology as this study found that Spanish-speaking patients evaluated all aspects of inpatient general acute care experience higher than English-speaking patients with the exception of evaluations of courtesy.⁸⁹

Race/Ethnicity: Cultural differences complicate matters even further. Many cultures diverge from the Western model of giving honest appraisals and prognoses to the patient who is the autonomous decision maker.⁹⁰ Drastically different expectations and desires for truth telling, disclosure, and communication of hope to patients based on fundamental differences in beliefs and values regarding family, spirituality, power, and the healing relationship mean that patients from different cultural backgrounds may evaluate ICU care differently. In the ICU, patients and families are concerned about the medical technology around them, their current status and progress, comfort and pain management, being kept alive on machines indefinitely, likelihood of recovery, and coping with any changes in functional status. Attitudes toward life-sustaining technologies common to the ICU and perceptions of the medical professionals recommending for or against the technologies are often influenced by ethnicity.⁹¹ The high-technology environment and linear time orientation of the ICU pose the greatest potential for significant cultural dissonance of any healthcare encounter, along with the increased possibility of disempowerment and marginalization of ethnic and cultural minorities.⁹² Cultural backgrounds are also relevant to the informed consent process because non-Western cultures have often substantially different orientations to time; for instance, patients from non-Western cultures may not be compelled by the same sense of urgency to resolve a medical condition or issue as Westerners.^{32,93}

Research on the influence of race/ethnicity on patient perceptions of their care experience shows mixed results. Several studies have found that persons of self-identified Asian and Hispanic origins systematically evaluate their healthcare experiences lower than white individuals.⁹⁴ Black patients have provided mixed ratings—both lower and higher than whites.⁹⁴ American Indian patients who identified with the ethnic identity of being American Indian were significantly less satisfied than the general population.⁹⁵ However, a recent study with stringent methodologies for evaluating patient satisfaction found no significant differences between

TABLE 5 Comparison Between Groups: Women Versus Men

| | | N5. How Well the Nurses Kept You Informed | P3. How Well Physician Kept You Informed | V4. Information Given Your Family About Your Condition and Treatment | T3. Explanations About What Would Happen During Tests and Treatments | ICU2. How Well ICU/CCU Nurses Helped You Understand Your Treatment, Tests, and Condition | P2. Physician's Concern For Your Questions and Worries | I6. Staff Effort to Include You in Decisions About Your Treatment |
|-----------------------|------|---|--|--|--|--|--|---|
| Male | Mean | 86.38 | 85.47 | 86.77 | 85.32 | 89.01 | 86.62 | 83.86 |
| Female | Mean | 84.63 | 84.94 | 85.31 | 84.67 | 87.08 | 85.92 | 82.78 |
| t test | t | 32.21 | 9.48 | 27.27 | 12.89 | 32.31 | 13.39 | 18.38 |
| | P | .000 | .000 | .000 | .000 | .000 | .000 | .000 |
| Cohen d (effect size) | σ | 0.08 | 0.02 | 0.07 | 0.03 | 0.09 | 0.03 | 0.05 |

Intensive Care Patient's Evaluations of the Informed Consent Process

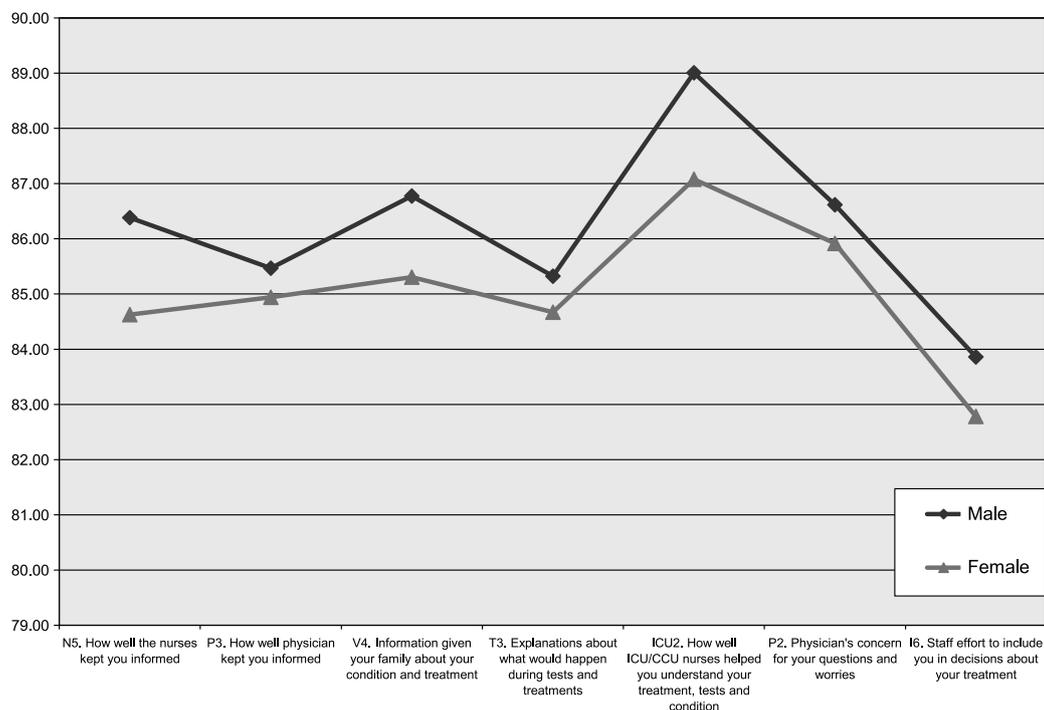


Figure 1. Gender and patient evaluations of the informed consent process.

white and nonwhite populations.⁹⁶ The concept of race/ethnicity is considered by many social scientists to be “approximate at best,” as persons of the same technical “race/ethnicity” but from different generations, geographic regions, cultural, and historical backgrounds can conceptualize their identity differently.⁹⁷

Length of Stay: Shorter stays in the ICU are characterized by greater perceived uncertainty.⁹⁸ Healthcare professionals frequently decry short stays as cutting short the opportunity to impart information and patient education. However, previous analyses using similar methodologies found that ICU patient evaluations declined as length of stay wears on.³⁰

Health Status: Health status does not affect patients’ evaluations of their healthcare experience,⁹⁹ but could ICU patients’ informed consent experience predict health status? Several studies have demonstrated that greater participation in decision making was related to reduced anxiety,¹⁰⁰ greater patient satisfaction,^{101,102} and compliance.¹⁰³ Involving patients in decision making via the informed consent process is one way to increase participation.

Hypotheses: This study had 9 hypotheses:

Hypothesis 1: ICU patients value informed consent. ICU patients value each element of the informed consent

process. Independent patient evaluations of disclosure, understanding, and involvement in decision making will be positively correlated to overall satisfaction and loyalty.

Hypothesis 2: Gender influences perceptions of the informed consent process. Women ICU patients will rate their experience with the informed consent process significantly lower than male ICU patients.

Hypothesis 3: Language influences perceptions of the informed consent process. Spanish-speaking ICU patients will rate their experience with the informed consent process significantly lower than English-speaking ICU patients.

Hypothesis 4: Race/ethnicity influences perceptions of the informed consent process. ICU patients of nonwhite race/ethnicities will rate their experience with the informed consent process significantly lower than white ICU patients.

Hypothesis 5: Socioeconomic status influences perceptions of the informed consent process. Medicaid ICU patients will rate their experience with the informed consent process significantly lower than ICU patients of other payer types.

Hypothesis 6: Age demographics influence perceptions of the informed consent process. ICU patients in the advanced elderly (>75 years) and baby boomer (40-64 years) age groups will rate their experience with the informed consent process significantly lower than ICU patients in any other age group (elderly [65-75 years], adult [18-39 years], and pediatric [<18 years]).

TABLE 6 Multivariate Linear Regression: Overall Patient Satisfaction

| Model | Model Summary | | | | | | | | |
|--------------------|---------------|----------|-------------------|--------------------|-------------------|-------------|------|---------|---------------|
| | R | R Square | Adjusted R Square | SE of the Estimate | Change Statistics | | | | |
| | | | | | R Square Change | F Change | df 1 | df 2 | Sig. F Change |
| Overall mean score | 0.931* | 0.866 | 0.866 | 5.1039 | 0.866 | 315,176.209 | 7 | 340,235 | .000 |

*Predictors: (Constant) I6. Staff effort to include you in decisions about your treatment; ICU2. How well ICU/CCU nurses helped you understand your treatment; tests and condition; P2. Physician's concern for your questions and worries; T3. Explanations about what would happen during tests and treatments; V4. Information given your family about your condition and treatment; N5. How well the nurses kept you informed; P3. How well physician kept you informed.

Hypothesis 7: ICU patients who receive information on advance directives, patient rights, and organ donation will more positively evaluate the informed consent process. ICU patients who receive information on advanced directives, patient rights, and organ donation will rate their experience with the informed consent process significantly higher than ICU patients who do not receive this information. Because this information is more relevant to ICU patients, the magnitude of this difference will be significantly greater among ICU patients compared with the difference among general acute patients.

Hypothesis 8: ICU patients' experience with informed consent will not predict health status. ICU patients' evaluations of their experience with the informed consent process will not predict physical health status.

Hypothesis 9: ICU patients with longer stays will be less favorable when evaluating the elements of the informed consent process. ICU patients' evaluations of their experience with informed consent will be negatively correlated with length of stay (ie, ratings will decline as length of stay increases).

METHODS

Data Collection

This study was a retrospective database study, drawing upon hospitalized patients' survey responses maintained in the Press Ganey national database. Press Ganey is a research firm specialized in satisfaction measurement within the healthcare industry. It collects and houses data for hospitals across the United States for the purposes of quality improvement and benchmarking.

Demographic data on hospitals were obtained from the Medicare Provider Analysis and Review (MEDPAR) dataset.¹⁰⁴ Data on teaching status (major teaching/Council of Teaching Hospitals, minor teaching, and non-teaching), case mix, adjusted length of stay, acute care beds, and bed size category are provided by MEDPAR.

All data and measures (other than those derived from MEDPAR) come from the Press Ganey Inpatient Survey. The instrument has been validated with confirmatory factor analyses, and all have Cronbach $\alpha > .89$, exceeding standards for psychometric research.¹⁰⁵ The conceptual model that forms its basis is the set of major components

TABLE 7 Gender Analysis of Variance (ANOVA)

| | | ANOVA | | | | | | |
|----------------------|--|----------------|----|-------------|-------|------|---------------------|--|
| Independent Variable | Dependent Variable | Sum of Squares | df | Mean Square | F | Sig. | Partial Eta Squared | |
| Sex | N5. How well the nurses kept you informed | 958.530 | 2 | 958.530 | 2.304 | .100 | 0.000 | |
| | P3. How well physician kept you informed | 630.502 | 2 | 630.502 | 1.451 | .234 | 0.000 | |
| | V4. Information given your family about your condition and treatment | 663.403 | 2 | 663.403 | 1.716 | .180 | 0.000 | |
| | T3. Explanations about what would happen during tests and treatments | 657.595 | 2 | 657.595 | 1.899 | .150 | 0.000 | |
| | ICU2. How well ICU/CCU nurses helped you understand your treatment, tests, and condition | 1,681.880 | 2 | 1,681.880 | 4.901 | .007 | 0.000 | |
| | P2. Physician's concern for your questions and worries | 713.934 | 2 | 713.934 | 1.860 | .156 | 0.000 | |
| | I6. Staff effort to include you in decisions about your treatment | 648.761 | 2 | 648.761 | 1.531 | .216 | 0.000 | |

ICU indicates Intensive Care Unit.

of an inpatient visit. In brief, the instrument consists of several demographic items (eg, patients' age and gender) and 49 items that ask the responding patient to rate specific aspects of inpatient care. The items are arranged into sections that correspond to the salient parts of an inpatient stay: Admission, Room, Nurses, Physicians, and Discharge. For each item, the patient is asked to provide a numeric evaluative rating of an aspect of care, such as "Speed of the admission process," rather than to express agreement or disagreement with a statement. Items are rated on a balanced 5-point, Likert-type scale ranging from very poor (1) to very good (5). Responses are converted to a 100-point scale by a linear transformation for analysis and reporting purposes.

A single wave, mail-out, mail-in method is used to reduce the tendency for patients to acquiesce to an in-person or telephone interviewer's presumed preferences, or to present oneself in a positive light. Such tendencies can bias the results of face-to-face or telephone surveys.¹⁰⁶⁻¹⁰⁸ Patients received the surveys within 3 to 15 days after discharge—well within the 6 weeks recommended by current research on reliability of patient survey responses.¹⁰⁹ The average return rate is between 25% and 30%, which is considered an acceptable range for patient surveys "cold" mailed (ie, mailed without a prior, formal agreement).¹¹⁰ This approach achieves a balance between cost and a representative sample of statistical significance.

Sample

The Inpatient Survey is used by acute care hospitals that use Press Ganey to provide patient satisfaction measurement services. These include 40% of all acute care hospitals of size over 100 beds in the United States. Simple random sampling procedures are used to determine the sample of patients to survey from each hospital. Between January 1, 2002, and November 30, 2005, 1,818 hospitals surveyed 8,359,726 patients. Within this large sample, 599 hospitals optioned to survey patients with an additional section specifically assessing the ICU experience. Only patients with an overnight stay in the ICU received this version of the survey. A total of 662,665 former ICU patients responded to the survey, representing a return rate of approximately 30%. Within this group, further self-selection occurs as hospitals must elect to survey using language-appropriate surveys versus English-only surveys and whether to ask background questions on race/ethnicity.

A total of 662,665 former ICU patients responded to the survey.

TABLE 8 Comparison Between Groups: Language of the Survey

| LANGUAGE. Language of the Survey | N5. How Well the Nurses Kept You Informed | | P3. How Well Physician Kept You Informed | | V4. Information Given Your Family About Your Condition and Treatment | | T3. Explanations About What Would Happen During Tests and Treatments | | ICU2. How Well ICU/CCU Nurses Helped You Understand Your Treatment, Tests, and Condition | | P2. Physician's Concern For Your Questions and Worries | | I6. Staff Effort to Include You in Decisions About Your Treatment | |
|--|---|---------|--|---------|--|---------|---|---------|--|---------|---|---------|---|---------|
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| English | 84.99 | 388,787 | 84.88 | 385,392 | 85.70 | 361,560 | 84.62 | 367,184 | 87.54 | 271,225 | 85.99 | 385,433 | 82.68 | 345,260 |
| Spanish | 21.39 | 86.97 | 21.63 | 88.12 | 20.27 | 87.34 | 19.24 | 86.05 | 19.95 | 88.93 | 20.30 | 88.11 | 21.67 | 86.05 |
| t test | 19.76 | 5,496 | 19.21 | 5,466 | 19.20 | 5,347 | 5,330 | 5,330 | 4,632 | 4,632 | 5,447 | 5,447 | 5,080 | 5,080 |
| P | -7.36 | .000 | -12.36 | .000 | -6.21 | .000 | -5.38 | .000 | -5.12 | .000 | -8.25 | .000 | -12.46 | .000 |
| Cohen d (effect size) | -0.10 | -0.17 | -0.09 | -0.07 | -0.08 | -0.11 | -0.18 | -0.18 | -0.18 | -0.18 | -0.18 | -0.18 | -0.18 | -0.18 |

TABLE 9 Patient Race Analysis of Variance (ANOVA)

| | | | ANOVA | | | | |
|--|----------------|--------------------------|----------------|----|-------------|-------|------|
| | | | Sum of Squares | df | Mean Square | F | Sig. |
| N5. How well the nurses kept you informed * Patient Race | Between groups | (Combined) | 1,418.92 | 5 | 283.78 | 0.520 | .761 |
| | | Linearity | 306.45 | 1 | 306.45 | 0.561 | .455 |
| | | Deviation from linearity | 1,112.47 | 4 | 278.12 | 0.509 | .729 |
| P3. How well physician kept you informed * Patient Race | Between groups | (Combined) | 4,232.27 | 5 | 846.45 | 1.207 | .307 |
| | | Linearity | 83.94 | 1 | 83.94 | 0.120 | .730 |
| | | Deviation from linearity | 4,148.33 | 4 | 1,037.08 | 1.479 | .210 |
| V4. Information given your family about your condition and treatment * Patient Race | Between groups | (Combined) | 2,644.73 | 5 | 528.95 | 1.189 | .316 |
| | | Linearity | 2.60 | 1 | 2.60 | 0.006 | .939 |
| | | Deviation from linearity | 2,642.13 | 4 | 660.53 | 1.485 | .208 |
| T3. Explanations about what would happen during tests and treatments * Patient Race | Between groups | (Combined) | 4,630.85 | 5 | 926.17 | 2.207 | .055 |
| | | Linearity | 38.40 | 1 | 38.40 | 0.092 | .763 |
| | | Deviation from linearity | 4,592.46 | 4 | 1,148.11 | 2.736 | .030 |
| P2. Physician's concern for your questions and worries * Patient Race | Between groups | (Combined) | 4,463.24 | 5 | 892.65 | 1.381 | .233 |
| | | Linearity | 1.53 | 1 | 1.53 | 0.002 | .961 |
| | | Deviation from linearity | 4,461.70 | 4 | 1,115.43 | 1.726 | .145 |
| I6. Staff effort to include you in decisions about your treatment * Patient Race | Between groups | (Combined) | 6,191.99 | 5 | 1,238.40 | 2.144 | .062 |
| | | Linearity | 1,861.96 | 1 | 1,861.96 | 3.224 | .074 |
| | | Deviation from linearity | 4,330.03 | 4 | 1,082.51 | 1.874 | .117 |

a. ICU2 (How well ICU/CCU nurses helped you understand your treatment, tests, and condition) had no within groups variance, therefore ANOVA statistics with Patient Race cannot be computed.

Limitations

The study is limited by the selection of participating facilities. Although the sample represents a broad array of hospitals, the hospitals participating in the Press Ganey national inpatient database are not a random selection of all US hospitals, nor are the patients treated by these facilities equivalent. Hospitals with fewer than 100 beds are underrepresented, whereas larger hospitals are overrepresented. In addition, the sample reflects a more complex case mix and a longer adjusted length of stay. Hospitals in the sample also differ via their strategic decision to participate in systematic patient satisfaction measurement and improvement efforts. This portends a positive bias compared with the national population. Likewise, hospitals electing to measure patients in their preferred language may receive higher rates as this may indicate a facility-wide orientation to the needs of minorities. Those asking background questions on race/ethnicity may be dedicating more resources to culturally competent care. In other words, the results presented here may represent a "best case" scenario compared with those of the national population. On the

other hand, with 32% of all US hospitals included, the Press Ganey inpatient database is the largest, most comprehensive and representative repository of patient evaluations of inpatient care available.

RESULTS

Value of the Informed Consent Process

Intensive care unit patients' evaluations of the informed consent process measures were significantly and positively correlated with patient loyalty and overall patient satisfaction with their stay. Correlations (r) ranged from 0.50 to 0.65 ($P < .001$) for loyalty and 0.65 to 0.77 ($P < .001$) for overall patient satisfaction (Table 3). Information provision, explanations of condition, tests, and treatment of patients and family; physician concern for questions; and making an effort to include patients in decision making are all care activities that relate to how well patients value because these factors all influence patients' willingness to engage in loyalty behavior and their overall satisfaction with the facility. The results of applying 6 measures of the patient's

TABLE 10 Payer Status Analysis of Variance (ANOVA)

| | | ANOVA | | | | |
|--|----------------|----------------|----|-------------|--------|------|
| | | Sum of Squares | df | Mean Square | F | Sig. |
| N5. How well the nurses kept you informed | Between groups | 152,952.58 | 13 | 11,765.58 | 26.400 | .000 |
| P3. How well physician kept you informed | Between groups | 101,982.31 | 13 | 7,844.79 | 17.385 | .000 |
| V4. Information given your family about your condition and treatment | Between groups | 134,313.80 | 13 | 10,331.83 | 25.829 | .000 |
| T3. Explanations about what would happen during tests and treatments | Between groups | 96,734.75 | 13 | 7,441.13 | 20.650 | .000 |
| ICU2. How well ICU/CCU nurses helped you understand your treatment, tests, and condition | Between groups | 105,863.31 | 12 | 8,821.94 | 23.638 | .000 |
| P2. Physician's concern for your questions and worries | Between groups | 123,149.74 | 13 | 9,473.06 | 23.841 | .000 |
| I6. Staff effort to include you in decisions about your treatment | Between groups | 116,252.47 | 13 | 8,942.50 | 19.842 | .000 |

perspective of the informed consent process into a multivariate linear regression model reveal that patients' experiences with all aspects of the informed consent process (information, understanding, and decision) collectively predict their loyalty, with $r^2 = 0.56$ [F = 60,611 (7,336,976), $P < .001$] (Table 4). Likewise, patient satisfaction was predicted by the informed consent patient evaluations, with $r^2 = 0.87$ [F = 315,176 (7,340,235), $P < .001$]. In other words, all aspects of the informed consent process account for approximately 56% of the variance in patient loyalty and 87% of the variance in patient satisfaction. This evidence indicates

that ICU patients consider the activities supporting effective informed consent of high value to them.

Gender Does not Influence Patient Evaluations

Across every measure, male ICU patients provided more favorable evaluations of each element of the informed consent process than female ICU patients with statistically significant differences ($P > .001$) (Table 5 and Figure 1). Although these differences were small (0.5-1.93), small differences can amount to larger differences in comparative performance percentile ranks, patient loyalty, and other measures of organizational success.^{10,111} The differences

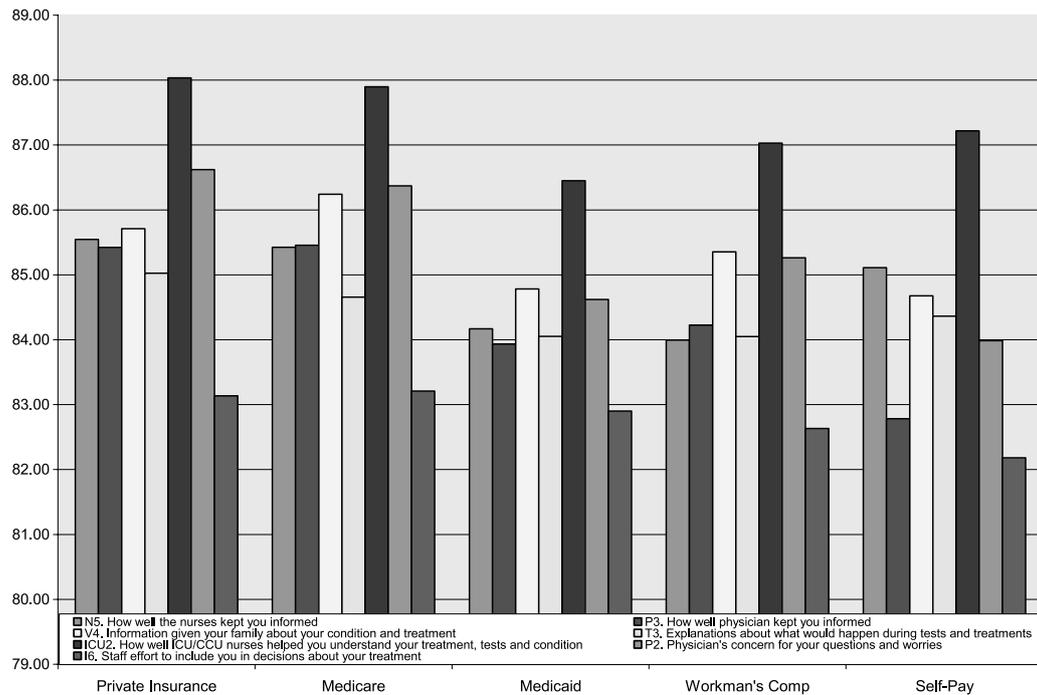


Figure 2. Payer status and patient evaluations of the elements of the informed consent process.

Intensive Care Patient's Evaluations of the Informed Consent Process

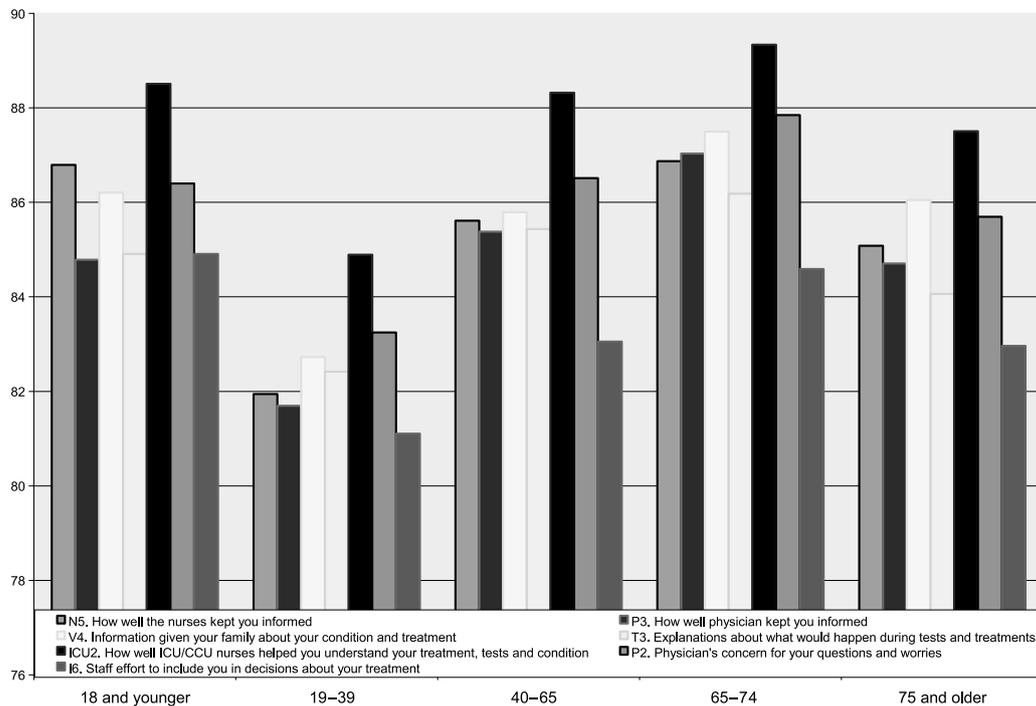


Figure 3. Age groups and patient evaluations of the informed consent process.

are not practically significant (Table 6). Furthermore, an analysis of variance (ANOVA) demonstrated that the gender variable is not a significant predictor of any measure of ICU patients' experience with the informed consent process (Table 7). Gender does not seem to be an influential factor in ICU patients' evaluations of their experience with the elements of the informed consent process.

Language

This analysis compares the group of patients who self-identified themselves as primary Spanish-language

speakers in facilities that elected to use Spanish-language surveying with primary English-speaking patients (Table 8). Spanish-language speakers responded more favorably to the elements of informed consent with statistically significant higher ratings for each measure. Analysis of effect size (-0.09σ to -0.17σ) suggest these differences to be of little practical significance and thus cannot be generalized to the healthcare system. These results are most likely due to the efforts these self-selected facilities are making to reach out to their Spanish-speaking patients.

TABLE 11 Age Analysis of Variance (ANOVA)

| | | ANOVA | | | | |
|----------------------|--|----------------|----|-------------|-------|------|
| Independent Variable | Dependent Variable | Sum of Squares | df | Mean Square | F | Sig. |
| Age | N5. How well the nurses kept you informed | 441.208 | 1 | 441.208 | 1.000 | .317 |
| | P3. How well physician kept you informed | 555.824 | 1 | 555.824 | 1.392 | .238 |
| | V4. Information given your family about your condition and treatment | 505.201 | 1 | 505.201 | 1.264 | .261 |
| | T3. Explanations about what would happen during tests and treatments | 181.170 | 1 | 181.170 | 0.503 | .478 |
| | ICU2. How well ICU/CCU nurses helped you understand your treatment, tests, and condition | 208.130 | 1 | 208.130 | 0.562 | .453 |
| | P2. Physician's concern for your questions and worries | 555.824 | 1 | 555.824 | 1.392 | .238 |
| | I6. Staff effort to include you in decisions about your treatment | 563.294 | 1 | 563.294 | 1.247 | .264 |

ICU indicates Intensive Care Unit.

TABLE 12 Comparison Between Groups: Patients Who Did and Did Not Receive Information on Advance Directives, Patient Rights, and Organ Donation

| LSUPPORT. Did Someone Explain Your Extended Life Support (Living Will) Options? (Y/N) | | N5. How Well the Nurses Kept You Informed | P3. How Well Physician Kept You Informed | V4. Information Given Your Family About Your Condition and Treatment | T3. Explanations About What Would Happen During Tests and Treatments | ICU2. How Well ICU/CCU Nurses Helped You Understand Your Treatment, Tests, and Condition | P2. Physician's Concern For Your Questions and Worries | I6. Staff Effort to Include You in Decisions About Your Treatment |
|---|------|---|--|--|--|--|--|---|
| | | | | | | | | |
| Yes | Mean | 87.15 | 87.00 | 87.65 | 86.53 | 89.59 | 87.84 | 85.19 |
| | N | 368,853 | 367,339 | 346,187 | 351,498 | 260,218 | 367,334 | 330,031 |
| | SD | 19.40 | 19.65 | 18.31 | 17.50 | 17.67 | 18.49 | 19.48 |
| No | Mean | 80.59 | 80.41 | 81.29 | 80.39 | 83.62 | 81.93 | 77.62 |
| | N | 144,380 | 144,148 | 131,557 | 135,943 | 104,087 | 144,011 | 125,282 |
| | SD | 24.52 | 24.72 | 23.45 | 22.08 | 22.68 | 23.22 | 24.92 |
| t test | t | 91.12 | 90.63 | 88.64 | 91.91 | 76.09 | 86.46 | 96.91 |
| | P | .000 | .000 | .000 | .000 | .000 | .000 | .000 |
| Cohen d (effect size) | σ | 0.27 | 0.27 | 0.27 | 0.28 | 0.26 | 0.25 | 0.30 |

| ORGAN. Did Someone Give You Information About Organ Donation? (Y/N) | | N5. How Well the Nurses Kept You Informed | P3. How Well Physician Kept You Informed | V4. Information Given Your Family About Your Condition and Treatment | T3. Explanations About What Would Happen During Tests and Treatments | ICU2. How Well ICU/CCU Nurses Helped You Understand Your Treatment, Tests, and Condition | P2. Physician's Concern For Your Questions and Worries | I6. Staff Effort to Include You in Decisions About Your Treatment |
|---|------|---|--|--|--|--|--|---|
| | | | | | | | | |
| Yes | Mean | 88.56 | 88.34 | 88.76 | 87.71 | 90.67 | 89.00 | 86.78 |
| | N | 145,262 | 145,149 | 138,446 | 139,694 | 106,362 | 145,179 | 133,017 |
| | SD | 18.49 | 18.77 | 17.62 | 16.83 | 16.77 | 17.75 | 18.51 |
| No | Mean | 83.31 | 83.17 | 83.99 | 83.01 | 86.07 | 84.42 | 80.67 |
| | N | 272,436 | 271,913 | 251,591 | 257,496 | 200,670 | 271,659 | 237,492 |
| | SD | 22.46 | 22.69 | 21.34 | 20.20 | 20.78 | 21.29 | 22.83 |
| t test | t | 80.85 | 78.64 | 74.93 | 78.24 | 66.34 | 73.78 | 88.51 |
| | P | .000 | .000 | .000 | .000 | .000 | .000 | .000 |
| Cohen d (effect size) | σ | 0.23 | 0.23 | 0.22 | 0.23 | 0.22 | 0.21 | 0.27 |

| RIGHTS. Did Someone Give You Information About the Patient's Bill of Rights? (Y/N) | | N5. How Well the Nurses Kept You Informed | P3. How Well Physician Kept You Informed | V4. Information Given Your Family About Your Condition and Treatment | T3. Explanations About What Would Happen During Tests and Treatments | ICU2. How Well ICU/CCU Nurses Helped You Understand Your Treatment, Tests, and Condition | P2. Physician's Concern for Your Questions and Worries | I6. Staff Effort to Include You in Decisions About Your Treatment |
|--|------|---|--|--|--|--|--|---|
| Yes | Mean | 87.30 | 87.11 | 87.70 | 86.62 | 89.73 | 88.00 | 85.35 |
| | N | 373,428 | 372,284 | 351,329 | 356,180 | 267,965 | 372,321 | 336,174 |
| No | SD | 19.32 | 19.66 | 18.35 | 17.47 | 17.58 | 18.44 | 19.39 |
| | Mean | 80.25 | 80.00 | 81.04 | 80.08 | 83.31 | 81.43 | 77.06 |
| | N | 144,603 | 144,020 | 131,165 | 136,110 | 102,613 | 143,851 | 124,063 |
| | SD | 24.63 | 24.72 | 23.42 | 22.16 | 22.80 | 23.27 | 25.09 |
| t test | t | 97.84 | 97.88 | 92.88 | 97.92 | 81.34 | 96.20 | 105.29 |
| | P | .000 | .000 | .000 | .000 | .000 | .000 | .000 |
| Cohen d (effect size) | σ | 0.29 | 0.29 | 0.28 | 0.30 | 0.28 | 0.28 | 0.33 |

ICU indicates Intensive Care Unit.

Race/Ethnicity

Analysis of variance by patients' self-description of race reveals that patient race is not a significant predictor of ICU patients' evaluations of the informed consent process (Table 9).

Socioeconomic Status

Using Medicaid payer status as a proxy for socioeconomic status, ANOVA by patient payer type (Medicare, Medicaid, Insurance, Self-Pay, Workers Compensation) revealed statistically significant variances (Table 10). For most measures, patients paying for healthcare through Medicare, Self-Pay, and Workers Compensation responded less favorably in evaluating their experience with the elements of the informed consent process (Figure 2).

Age

The hypothesis that ICU patients in the advanced elderly (>75 years) and baby boomer (40-64 years) age groups will rate their experience with the informed consent process significantly lower than ICU patients in any other age group (elderly [65-75 years], adult [19-39 years], and pediatric [<18 years]) was partially unsupported because the advanced elderly and the adult age groups were least satisfied with the informed consent process (Figure 3). This result differs from previous research on general acute care, where baby boomers were most critical. Perhaps younger adult patients have a different experience and care expectations than older patients; the ICU experience may be more unexpected and more threatening to their life goals. However, ANOVA does not affirm the strength of these differences (Table 11).

Advance Directives, Patient Rights, and Organ Donation Information Dramatically Improve Patient Evaluations

Table 12 examines the differences in ICU patients' evaluations of the informed consent experience based on whether they received information regarding advance directives, patient rights, and organ donation. The differences are both statistically and practically significant. Patients in the ICU that receive this information were dramatically more positive about their experience with each measure of the informed consent process than patients who did not receive this information.

Health Status Predicted by Patient Evaluations of the Informed Consent Process

Each measure of the patient's perspective of the informed consent process was weak but statistically

TABLE 13 Multivariate Linear Regression Analysis of Patient Evaluations as a Predictor of Health Status

| Model | Model Summary | | | | | | | | |
|--|-------------------|----------|-------------------|--------------------|-----------------|-----------|------|---------|---------------|
| | Change Statistics | | | | | | | | |
| | R | R Square | Adjusted R Square | SE of the Estimate | R Square Change | F Change | df 1 | df 2 | Sig. F Change |
| N5. How well the nurses kept you informed | 0.112 | 0.013 | 0 | 21.020 | 0.013 | 6,316.281 | 1 | 493,487 | .000 |
| P3. How well physician kept you informed | 0.113 | 0.013 | 0 | 21.246 | 0.013 | 6,332.927 | 1 | 49,1830 | .000 |
| V4. Information given your family about your condition and treatment | 0.113 | 0.013 | 0 | 19.975 | 0.013 | 5,910.755 | 1 | 459,074 | .000 |
| ICU2. How well ICU/CCU nurses helped you understand your treatment, tests, and condition | 0.093 | 0.009 | 0 | 19.230 | 0.009 | 2,984.153 | 1 | 340,094 | .000 |
| T3. Explanations about what would happen during tests and treatments | 0.115 | 0.013 | 0 | 18.905 | 0.013 | 6,310.898 | 1 | 467,870 | .000 |
| P2. Physician's concern for your questions and worries | 0.117 | 0.014 | 0 | 19.922 | 0.014 | 6,771.062 | 1 | 491,684 | .000 |
| I6. Staff effort to include you in decisions about your treatment | 0.124 | 0.015 | 0 | 21.178 | 0.015 | 6,781.602 | 1 | 435,856 | .000 |

ICU indicates Intensive Care Unit.

significant predictor of health status (Table 13). Patients who experience a better informed consent process according to their own evaluations are more likely to have a higher rated health status postdischarge (Figures 3 and 4).

Length of Stay and Patient Evaluations

Patients with longer stays in the ICU gave lower evaluations of the informed consent process. As length of stay increases, satisfaction with the elements of the informed consent process declines (Figure 5).

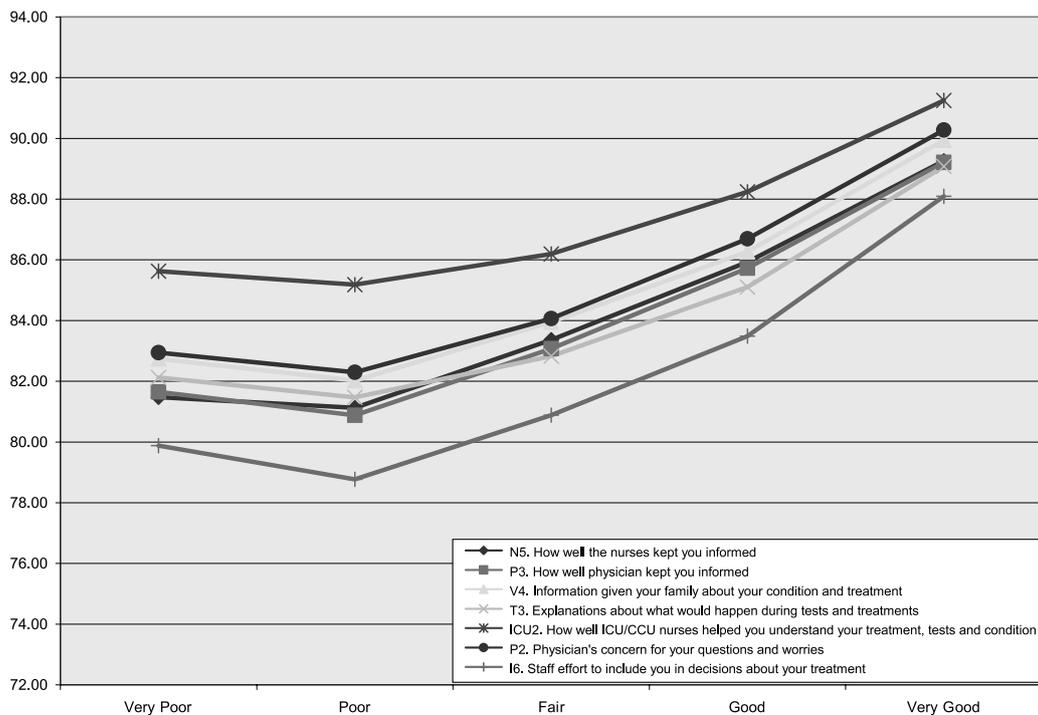


Figure 4. Health status and patient evaluations of the informed consent process.

CONCLUSION

The informed consent process is a critical component of patient's and family member's experiences in intensive care. Evaluating both the quality of care and the ethical effectiveness of the informed consent process requires the patient's perspective. Only the patients can compare what happened with their own values, beliefs, and expectations for what should happen. This study presented several findings regarding the ICU patient's perspective of their experience with the critical elements of the informed consent process.

Patients place a high value on the elements of the informed consent process. Measures of information, understanding, and decision-making involvement predict overall patient satisfaction and patient loyalty intentions. This indicates that hospital facilities, which support patients' needs, and ethically effective informed consent processes could result in better business outcomes. The finding that health status was weakly predicted by patients' evaluations of their informed consent experience indicates the potential for an even better payoff for hospital facilities—contributing to the beneficence of the patient's health. Patients whose payer status indicate lower socioeconomic status (Medicaid, Self-Pay, and Workers Compensation) reported less favorable evaluations of informed consent, indicating that these patients may be treated differently. Although differences existed between gender, age groups (19-39

years and advanced elderly), and Spanish versus English-speaking patients, the lack of substantial effect size or predictive power in these differences and the lack of any significant differences by race/ethnicity suggest that the cultural backgrounds of patients do not supersede the behaviors, actions, attitudes, and service quality of doctors and nurses in actually delivering the elements of the informed consent process. This was supported by the finding that specific actions supportive of ICU informed consent—giving patients information on advance directives, patients rights, and organ donation—lead to dramatically and significantly higher patient evaluations.

Measures of information, understanding, and decision-making involvement predict overall patient satisfaction and patient loyalty intentions.

Acknowledgments

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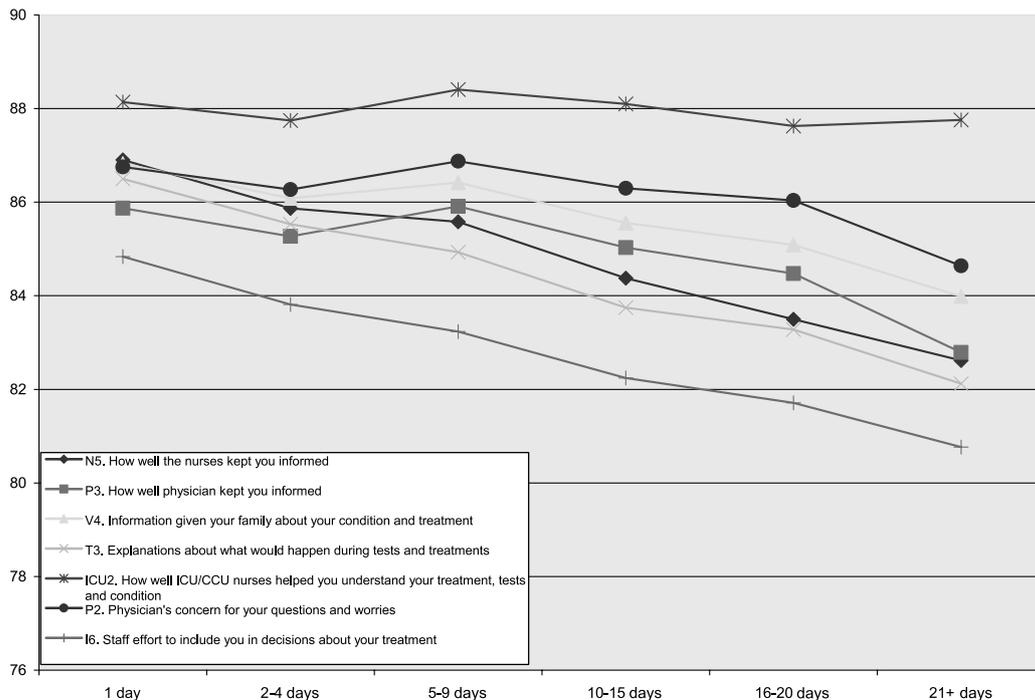


Figure 5. Length of stay and ICU patients' evaluations of the informed consent process.

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