Feature

Informed Consent Challenges: A Mixed-Methods Study of Hospital Ethics Consultations

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ABSTRACT

Introduction: Hospital ethics committees guide healthcare workers and patients through complex consent issues. Prior research highlights gaps in consent forms and information delivery, but little is known about real-world ethics consults on consent. This study examines common challenges in consent discussions and compares patient and consult characteristics of consent-related versus other consults. Methods: De-identified ethics consult notes and patient data from Vanderbilt University Medical Center, a quaternary care academic medical center (2014–24), were analyzed. Consults were classified as consent or nonconsent related. Chi-square, Fisher's exact, and Wilcoxon rank-sum tests compared characteristics, while logistic regression assessed associations between consent themes. Results: Among 4,127 ethics consults, 137 (3.3%) were consent related. Compared to nonconsent consults, consent consults involved more adult (96.4% vs. 84.2%, $p = .005$) and female (58.4% vs. 19.0%, $p = .001$) patients and were more often low in complexity (36.5% vs. 22.8%, $p < .001$). Common issues included capacity (65.0%), surrogate decision-making (46.0%), communication barriers (38.0%), treatment timing (29.2%), goals of care (20.4%), patient refusal (19.7%), and sensitivity/invasiveness concerns (13.1%). Capacity concerns increased the odds of surrogate decision-making issues (OR = 2.97, 95% CI: 1.51–6.30). Advance directive completion was linked to older age ($p = .031$) and goals-of-care discussions (50.0% vs. 17.5%, $p = .018$). Conclusion: Consent-related consults differ in patient demographics and complexity, with capacity, surrogate decision-making, and communication barriers as key concerns. This study provides actionable insights to improve consent protocols, patient-clinician interactions, and ethical decision-making.

INTRODUCTION

Informed consent is vital to ethical clinical care, ensuring that patients understand and agree to medical decisions while also serving an ethical-legal purpose for clinicians.[1] However, components of the informed consent process fall short: consent forms are complex,[2] discussions are often not sufficiently interactive,[3] and information delivery tends not to incorporate diverse modalities.[4] Additionally, patient traits (e.g., gender, education, and health status) and the context of the surgery play a role in how scared and informed patients feel.[5] Shortcomings in the informed consent process have particular potential for harm in the setting of complex issues such as communication

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Journal of Clinical Ethics, volume 36, number 3, Fall 2025.
 https://doi.org/10.1086/736146

barriers, decision-making challenges, and conflicts between stakeholders.

When patients and their families are dissatisfied, or when healthcare workers need additional help during a particularly complex consent process, consults are often sent to the hospital ethics committee (HEC). Initially created to navigate refusal of life-sustaining treatment,[6] HECs play a critical role in clarifying uncertainties, mediating conflicts, and guiding decision-making.[7]

While prior research has elucidated shortcomings of consent forms and information delivery, less attention has been paid to the nuanced dilemmas clinicians encounter during the consent process. This study will determine whether hospital ethics consults about consent differ in patient and consult characteristics from other (nonconsent) consults. Additionally, this work aims to identify common challenges clinicians encounter during context-specific consent practices.

METHODS

Data Collection

We extracted de-identified data from the Vanderbilt Ethics Consultation Database from January 2014 to October 2024. Data were collected from ethics consultants' notes, identified as related or not related to consent (i.e., consent or nonconsent) on a REDCap drop-down menu as part of their standard process of responding to hospital ethics consult requests. Each note consists of free text describing the patient, context for the ethics consult, the consultant's impression and suggestions, and status of the ethical concern resolution. Ethics consultants may exhibit potential biases but have been trained to provide objective insight into patients' concerns to the best of their ability. For example, ethics consultants often use standardized frameworks such as principlism (i.e., respect for autonomy, beneficence, nonmaleficence, and justice) as a foundation while supplementing ethical theory with context-specific considerations for helping patients and their families elucidate their values.[8] Additionally, they may conduct interdisciplinary case reviews, seek input from diverse stakeholders, or apply structured decision-making tools to ensure fairness and consistency.[9] Along with the note free text, we collected patient demographics, hospital unit, role of the individual who requested the consult, consult duration, advance directive status, and consultant's perception of consult complexity. In cases where demographic information was not coded by the consultant, we abstracted this data from the free text of the note. Acute care settings included the emergency department, operating room, observation, step-down, and acute/critical/intensive care units. This study was approved as exempt by the study institution's institutional review board (IRB).

Reflexive Thematic Analysis

After collecting the ethics consult data regarding informed consent, we leveraged reflexive thematic analysis (RTA)—a qualitative approach well-suited for analyzing free-text data from hospital ethics consult notes since it facilitates the identification and interpretation of patterns and themes within complex, nuanced narratives.[10] In the context of ethics consult notes that typically include information about patient demographics, presenting concerns, ethical issues identified, consultant involvement, and resolution status, RTA offers a systematic yet flexible method to explore how ethical dilemmas arise and are addressed. The first step of RTA was familiarization, during which researchers immerse themselves in the data by reading and rereading the ethics consult notes to understand their content and context. The second step was coding, which involves generating initial codes that capture essential features of the text, such as common ethical concerns (e.g., consent while on mind-altering substances or inadequate translation). Two coders created a codebook, independently annotated the note free text, and discussed discrepancies, which were ultimately arbitrated by a third coder. Codes were then grouped into potential themes that reflected broader meaning across the data. Through iterative refinement, themes are defined and reviewed to accurately represent the data's complexity.

Statistical Analysis

To compare ethics consults that concerned informed consent with those that did not, we calculated descriptive statistics such as the percentages for categorical variables and median and interquartile range (IQR) for continuous variables regarding patient and consult characteristics. To compare characteristics of consent-related versus nonconsent ethics consults, chi-square and Fisher's exact tests for categorical variables and Wilcoxon rank-sum tests for continuous variables

were performed. The same methodology was applied to compare consent-related consults by advance directive completion. Associations between themes were assessed using logistic regression. We performed all statistical analyses using R statistical software version 4.3.2.

RESULTS

The total sample included 4,127 ethics consults, of which 137 (3.3%) were labeled by an ethics consultant as concerning informed consent (table 1). In the informed consent cohort, patients were most often White ($N = 53$, 38.7%) with a median age of 50 years (IQR: 30.5–65 years). Ethics consults were predominantly in the nonacute setting ($N = 83$, 60.6%). Only 16 (11.7%) patients were known to have advance directives. The four most common roles of individuals requesting ethics consults were the attending ($N = 41$, 29.9%), resident/fellow ($N = 37$, 27.0%), nurse practitioner ($N = 14$, 10.2%), and social worker or case manager ($N = 14$, 10.2%).

Compared to the consults unrelated to informed consent, informed consent cases exhibited a higher proportion of adult patients (96.4% vs. 84.2%, $p = .005$), female patients (58.4% vs. 19.0%, $p = .001$), and low-complexity consults (36.5% vs. 22.8%, $p < .001$). There were nonsignificant trends toward informed consent consults being associated with shorter median consult duration (1.5 hours [IQR = 1.0–2.0 hours] vs. 1.5 hours [IQR = 1.0–2.5 hours], $p = .059$), non-White race/ethnicity ($p = .081$), and attending/resident role of the individual requesting the consent consult ($p = .072$). Compared to nonconsent consults, consent consults were not associated with the acute care setting (28.5% vs. 33.9%,

Table 1. Patient and Consult Characteristics of Consent Versus Nonconsent Hospital Ethics Consults

Variable	Consent ($N = 137$)	Nonconsent ($N = 3,990$)	p Value
Age (years), median (IQR)	50.0 (30.5–65.0)	53.0 (32.0–66.0)	.702
Pediatric case	5 (3.6%)	423 (10.6%)	.005
Sex:			.001
Male	52 (38.0%)	902 (22.6%)	
Female	80 (58.4%)	759 (19.0%)	
Race/ethnicity:			.081
White	53 (38.7%)	1031 (25.8%)	
Black	26 (19.0%)	390 (9.8%)	
Hispanic	11 (8.0%)	82 (2.1%)	
Asian, AIAN, NHOPI	1 (0.7%)	40 (1.0%)	
Acute care setting	39 (28.5%)	1352 (33.9%)	.312
Role of individual requesting consult:			.072
Attending	41 (29.9%)	938 (23.5%)	
Resident/fellow	37 (27.0%)	994 (24.9%)	
Nurse practitioner	14 (10.2%)	478 (12.0%)	
Nurse	11 (8.0%)	343 (8.6%)	
Social worker/case manager	14 (10.2%)	720 (18.0%)	
Patient/decision maker	2 (1.5%)	34 (0.9%)	
Other	18 (13.1%)	351 (8.8%)	
Consult duration (hours), median (IQR)	1.5 (1.0–2.0)	1.5 (1.0–2.5)	.059
Advance directive	16 (11.7%)	392 (9.8%)	.264
Consult complexity:			<.001
Low	50 (36.5%)	908 (22.8%)	
Intermediate to expert	87 (63.5%)	2907 (72.9%)	

Note.—Descriptive statistics were reported as count (percent of subcategory) or median (IQR) as appropriate. Race and ethnicity were a combined metric on the ethics consult note REDCap database. Column percentages for each variable do not sum to 100% owing to missing values. One patient in the Children's Hospital was 19 years old and thus was not classified as a pediatric case.

$p = .312$) or having an advance directive (11.7% vs. 9.8%, $p = .264$).

From 95 codes (supplemental table 1), 11 themes were identified across the 137 consults. From most to least common (table 2), the themes were capacity ($N = 89$, 65.0%), surrogate decision-making ($N = 63$, 46.0%), comprehension/communication ($N = 52$, 38.0%), treatment timing/appropriateness ($N = 40$, 29.2%), goals of care/end of life ($N = 28$, 20.4%), patient refusal ($N = 27$, 19.7%), social/logistical concerns ($N = 21$, 15.3%), sensitivity/invasiveness ($N = 18$, 13.1%), healthcare team conflicts ($N = 15$, 10.9%), reproductive/pediatric concerns ($N = 12$, 8.8%), and information withholding ($N = 5$, 3.6%). Of the 89 capacity issues, 49 (55%) also involved a surrogate decision-making issue. The odds of a surrogate decision-making concern accompanying a capacity issue was 2.97 (95% CI: 1.51–6.30, $p = .004$).

Further analyses were performed to better understand the impact of advance directive completion on consent-related consult characteristics and themes (table 3). Compared to consent consult cases with no advance directive, cases with an advance directive were associated

Table 2. Representative Quotes and Counts of Informed Consent Ethics Consults by Theme

Themes	Count (Percentage)	Representative Quotes
Capacity	89 (65%)	"Patient lacks capacity to make decisions at baseline due to developmental delay but had no court-appointed conservator since turning 18."
Surrogate decision-making	63 (46%)	"There is no family or friends known who could make medical decisions on behalf of the patient."
Comprehension/communication	52 (38%)	"Team identified mother as surrogate but became concerned when she was not able to demonstrate understanding of patient's diagnosis/prognosis." "[Patient] has a sister who calls every day and a niece who calls intermittently, but [care team members] have not secured contact information for these individuals."
Treatment timing/appropriateness	40 (29%)	"There were concerns that the patient may lose her limb if she was not treated emergently."
Goals of care/end of life	28 (20%)	"[Patient] has decided to voluntarily stop eating and drinking in order to hasten his death."
Patient refusal	27 (20%)	"Currently recommended to [receive] amputation and patient requesting to leave [against medical advice]"
Social/logistical concerns	21 (15%)	"Team has also expressed serious concerns about the safety of patient's home environment specifically her roommate who appears to exploit patient's vulnerabilities."
Sensitivity/invasiveness	18 (13%)	"Patient has worsening mental status and team has found a vaginal laceration on exam that may be causing infection. Patient cannot consent for exam." "[Patient] feels he is forced into treatment."
Healthcare team conflicts	15 (11%)	"[Emergency general surgery attending] had given patient options to proceed with high risk colectomy or shift to comfort care as he held out. Patient chose surgery but various clinicians thought surgery might be futile."
Reproductive/pediatric concerns	12 (9%)	"[Patient requests] to test her fetus for Huntington's Disease. There is a history of HD on her partner's side of the family. The father of the baby has not been tested for HD. If the fetus were to be tested and found positive, it would show his disease and some think violate his and baby's privacy."'The [14yoM] patient is refusing further interventions, while his parent is requesting that he receive the surgery."
Information withholding	5 (4%)	"Son doesn't want [patient] told [about terminal melanoma diagnosis], or the word hospice used around him."

Table 3. Patient Demographics, Consult Characteristics, and Themes of Consent-Related Ethics Consults Among Cases Involving an Advance Directive Versus No Advance Directive

Variable	Advance Directive ($N = 16$)	No Advance Directive ($N = 57$)	p Value
Age (years), median (IQR)	59.5 [51.5–72.5]	37 [40–58]	.031
Pediatrics case:			<.001
Yes	0 (0%)	3 (5.3%)	
No	16 (100%)	53 (93%)	
Gender:			.822
Male	6 (37.5%)	21 (36.8%)	
Female	9 (56.3%)	36 (63.2%)	
Race/ethnicity:			.428
White	7 (43.8%)	17 (29.8%)	
Black	1 (6.3%)	12 (21.1%)	
Hispanic	1 (6.3%)	3 (5.3%)	
Asian, AIAN, NHOPI	0 (0%)	0 (0%)	
Insurance:			.296
Private	3 (18.8%)	2 (3.5%)	
Medicare	2 (12.5%)	8 (14%)	
Medicaid	3 (18.8%)	11 (19.3%)	
Other (including Tricare)	0 (0%)	2 (3.5%)	
None	0 (0%)	3 (5.3%)	
Acute care setting:			.515
Yes	6 (37.5%)	16 (28.1%)	
No	7 (43.8%)	33 (57.9%)	
Role of individual requesting consult:			.149
Attending	6 (37.5%)	16 (28.1%)	
Resident/fellow	1 (6.3%)	16 (28.1%)	
Nurse practitioner	3 (18.8%)	3 (5.3%)	
Nurse	2 (12.5%)	6 (10.5%)	
Social worker/case manager	3 (18.8%)	6 (10.5%)	
Patient/decision maker	0 (0%)	0 (0%)	
Other	1 (6.3%)	10 (17.5%)	
Consult duration (hours), median (IQR)	2.0 [2.0–3.0]	1.4 [1.0–2.1]	.239
Consult complexity:			
Low	3 (18.8%)	16 (28.1%)	.537
Intermediate to expert	13 (81.3%)	41 (71.9%)	
Theme:			
Capacity	12 (75%)	34 (59.6%)	.261
Surrogate decision-making	7 (43.8%)	26 (45.6%)	.895
Comprehension/communication	6 (37.5%)	19 (33.3%)	.756
Treatment timing/appropriateness	2 (12.5%)	16 (28.1%)	.326
Goals of care/end of life	8 (50%)	10 (17.5%)	.018
Patient refusal	3 (18.8%)	13 (22.8%)	1.000
Social/logistical concerns	5 (31.3%)	7 (12.3%)	.120
Sensitivity/invasiveness	2 (12.5%)	8 (14%)	1.000
Healthcare team conflicts	2 (12.5%)	9 (15.8%)	1.000
Reproductive/pediatric concerns	0 (0%)	7 (12.3%)	.335
Information withholding	0 (0%)	4 (7%)	.570

Note.—Descriptive statistics were reported as count (percent of subcategory) or median (IQR) as appropriate. Race and ethnicity were a combined metric on the ethics consult note REDCap database. Column percentages for each variable do not sum to 100% owing to missing values. One patient in the Children's Hospital was 19 years old and thus was not classified as a pediatric case.

with adult patients (100% vs. 93.0%) and older median age (59.5 years [IQR = 51.5–72.5 years] vs. 37.0 years [IQR = 40.0–58.0 years], $p = .031$). Additionally, advance directive completion was associated with the goals-of-care/end-of-life theme (50.0% vs. 17.5%, $p = .018$).

DISCUSSION

This study highlights the complex and multifaceted ethical challenges encountered in the informed consent process as documented in hospital ethics consult notes. Pediatric cases, female sex, and lower consult complexity were associated with consent consults. Our findings also illustrate frequently encountered concerns such as capacity, surrogate decision-making, and communication/comprehension barriers, as well as concerns that might not otherwise be captured such as sensitivity/invasiveness and information withholding. These issues underscore the need for improved practices and tailored strategies for achieving informed consent.

The prominence of capacity as a common theme is unsurprising. When patients are unable to fully understand or engage in the decision-making process, clinicians must balance respecting autonomy with beneficence. Due to high co-occurrence, potential surrogate decision-making challenges need more attention when a capacity issue is identified since it is often unclear how lack of capacity should be addressed. State laws define the hierarchy of surrogate decision makers when no designated surrogate is available. These challenges call for clearer guidelines, improved education for surrogates, and more structured approaches to surrogate engagement, especially in urgent or complex situations.

The lack of an association between advance directive completion and ethics consult type was unexpected, prompting further investigation. We hypothesized that advance directive completion might address some issues that would otherwise rise to the level of an ethics consult, which was shown to be incorrect. Interestingly, the only theme that was significantly associated with advance directive completion was the goals-of-care/end-of-life theme. This, too, was an unexpected finding: we hypothesized that goals-of-care/end-of-life issues would be covered in more depth among patients with advance directives. Given that making these choices is inherently uncertain and idiosyncratically complex, a few non–mutually exclusive explanations are possible. First, patients with advance directives may have more complex consent issues. The fact that a patient filled out an advance directive might signal that they are in worse health or have a complicated surrogate decision maker situation. Second, these patients and their families, as well as their care teams, may be more equipped/attuned to goals-of-care/end-of-life concerns because it is known that they have an advance directive. Third, following the advance directive may raise questions such as when to abide by it. These findings suggest the need to refine advanced directives and explore how the completion process affects patient understanding of their health and rights, as well as care team alignment with those preferences.

Along with capacity and surrogate decision-making challenges, communication and comprehension barriers remain a significant obstacle to informed consent. Our findings align with prior literature showing that patients often struggle with medical terminology,[11] encounter unique difficulties when speaking a different first language than the provider,[12] or cannot make decisions when overwhelmed with emotion.[13] Addressing these issues may require broader implementation of multimodal communication strategies, including visual aids, simplified forms, or live interpreters, to ensure that all patients can access and comprehend vital health information.[14]

Sensitivity and invasiveness concerns, though less frequent, exhibit a high potential to harm patients. Cases such as intimate examinations or procedures performed without clear consent highlight the importance of meticulous attention to patient comfort and understanding, ensuring that patients feel fully informed and respected. Given the potential for harm, this issue warrants earlier and more thorough discussion in clinical practice backed by policies that protect patients' rights. These findings support ongoing calls to prioritize sensitivity in all interactions, ensuring that consent discussions explicitly address the invasiveness of potential procedures.[15]

Addressing consent issues might not involve drastic changes. Our findings show that consent consults were less complex than other types of ethics consults, suggesting that simple improvements may be enough to address many of these challenges. This aligns with prior research emphasizing the role of better patient-clinician communication[16] and less complex consent forms.[17] Interventions such as diversifying information delivery modalities, enhancing access to interpreters, and improving training on consent conversations may

yield substantial improvements without significant burden.[18]

Across all types of issues, the context in which informed consent occurs must not be overlooked. Although the acute care setting was not associated with informed consent consults, emergency surgeries were found to be associated with patients feeling scared, trapped, and inadequately informed compared to elective surgeries.[19] Balancing individual patient needs with standardized consent protocols that accommodate the urgency of the situation remains a critical challenge.

Limitations

This study exhibits certain limitations. The sample may not be representative of all ethical issues regarding informed consent. Since the sample is from only one large academic medical center, informed consent issues at nonacademic hospitals that have lower case volume, are located in other regions of the country, or serve different patient populations may not be as comprehensively represented in the data. However, there is likely significant overlap of concerns across hospitals. Additionally, we do not capture consent issues that have not escalated to the level of an ethics consult. The issues captured, though, are likely to be the most serious. As with all qualitative research, findings may be influenced by researcher interpretation and may not be generalizable to all settings; however, we followed the Standards for Reporting Qualitative Research (SRQR) to enhance the transparency and rigor of our methods (supplemental table 2). Despite these limitations, this study is unique in leveraging a large corpus of documented responses to patient concerns observed in their natural hospital setting. Although ethics consultants provide their insight with potential biases, they have received training to document patients' concerns in their raw form. Without documented ethics consultations structured as conversations, surveys putting the onus solely on patients to report potentially ethical issues might fall short in capturing the same level of rich description of patients' views without bias: for example, a patient might endorse a higher level of understanding to appear informed (i.e., social desirability bias) or give higher ratings of a provider's skill in going through the consent process out of concern for negative consequences if their anonymity is compromised.

CONCLUSION

Ethics consults provide a lens into informed consent barriers that would otherwise be difficult to study. Compared to other ethics consults, consent consults differed in patient demographics and were generally less complex. While capacity, communication barriers, and surrogate decision-making dominate the landscape of ethical concerns, less common yet significant concerns such as information withholding and sensitivity/invasiveness were also identified. These findings underscore the importance of tailoring consent practices to individual patients and contexts. By identifying common consent barriers, this study provides actionable insights for improving patient-clinician interactions, consent protocols, and ethical decision-making via institutional and national policies.

FINANCIAL SUPPORT

None.

CONFLICTS OF INTEREST

No conflicting relationships exist for any author.

INSTITUTIONAL REVIEW BOARD

Approved as exempt under Vanderbilt IRB #240396.

ACKNOWLEDGMENTS

The authors thank Dr. Joseph Fanning, director of the Vanderbilt University Medical Center Clinical Ethics Consultation Services, for his insight throughout the study.

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19. Akkad et al., "Informed Consent," see note 5 above.