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

SCHOOL OF MEDICINE VANDERBILT UNIVERSITY

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Introduction

- The informed consent process has known shortcomings: consent discussions are too complex,[1] one-sided,[2] and lacking in diverse modalities.[3]
- Hospital ethics committees (HECs) help guide healthcare workers and patients through complex issues such as consent,[4] but disparities in ethics consults may vary by patient and contextual factors.[5]
- While prior research has found gaps in consent discussions, the purpose of this study is to ethics consult notes to capture the nuanced context-specific concerns patients and clinicians encounter during the consent process.

Hypotheses

- Hospital ethics consults about consent differ in patient and consult characteristics from other (non-consent) consults.
- Analyzing consult notes for themes will highlight common consent challenges and their relative frequency.

Methods

- **Data Collection**: Extracted de-identified ethics consult notes and associated patient data from Jan 2014 to Oct 2024, labeled by ethicists as consults related or not related to consent (i.e., consent versus non-consent)
- **Statistical Analysis**: Compared consent-related consults to non-consent consults using descriptive statistics, Chi-square and Fisher's exact tests for categorical variables, and Wilcoxon rank-sum tests for continuous variables
- **Thematic Analysis**: Two coders created a codebook, independently annotated consult notes, and discussed discrepancies, which were ultimately arbitrated by a third coder. Codes were grouped into themes to identify patterns in consent ethics consults.

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Results

Table 1. Patient and Consult Characteristics of Consent versus Non-Consent Hospital Ethics Consults

Variable	Consent (N=137)	Non-Consent (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**
Basic	50 (36.5%)	908 (22.8%)	
Intermediate-Expert	87 (63.5%)	2907 (72.9%)	

Note: Column percentages for each variable do not sum to 100% due to missing values.

- Compared to non-consent consults, consent consults had:
  - Higher proportions of female and adult patients with lower case complexity
  - No association with acute care setting or having an advance directive

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

Themes	Count (%)	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 Challenges	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 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."
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 and 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."

Discussion

- The consent process should always include surrogate decision-maker designation.
- Potential surrogate decision-making challenges need more attention when a capacity issue is identified.
- Multimodal strategies (e.g., visual aids, interpreters) may mitigate medical jargon and language barriers.
- Less common themes that are potentially serious (e.g., invasiveness) need safeguards and disclosure any time they might occur.
- **Limitations**:
  - Only captures issues escalated to an ethics consult (but captures most serious concerns)
  - Potential bias in which cases trigger consults (though, ethicists are trained in being as objective as possible)
  - May not generalize to low-volume, non-academic hospitals (but likely overlaps)
- **Future Work**: Ensure that differences between consent and non-consent consults are not due to biases

Conclusion

- Compared to other ethics consults, consent consults differed in patient demographics and consult complexity.
- Capacity, surrogate decision-making, and comprehension/communication barriers were the most common consent issues.
- Only study to leverage a large corpus of ethics consults to provide actionable insights that would not otherwise be captured in their natural hospital setting

References

1. Lin GT, Mitchell MB, Hammack-Aviran C, Gao Y, Liu D, Langerman A. Content and Readability of US Procedure Consent Forms. *JAMA Intern Med*. 2024;184(2):214-216. doi:10.1001/jamainternmed.2023.6431
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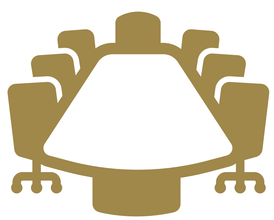
Introduction

- The informed consent process has known shortcomings:
  - Consent forms are too complex.[1]
  - Discussions are often not interactive.[2]
  - Information delivery tends to not incorporate diverse modalities.[3]



- Hospital ethics committees (HECs) help guide healthcare workers and patients through complex issues such as consent,[4] but disparities in ethics consults may vary by patient and contextual factors.[5]

- While prior research has found gaps in consent forms and information delivery, the purpose of this study is to leverage ethics consult notes to capture the nuanced context-specific concerns patients and clinicians encounter during the consent process.

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Analyzing consult notes for themes will highlight common consent challenges and their relative frequency.

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- Two coders created a codebook, independently annotated consult notes, and discussed discrepancies, which were ultimately arbitrated by a third coder.
- Codes were grouped into themes to identify patterns in consent ethics consults.
- Associations between themes were assessed using logistic regression.

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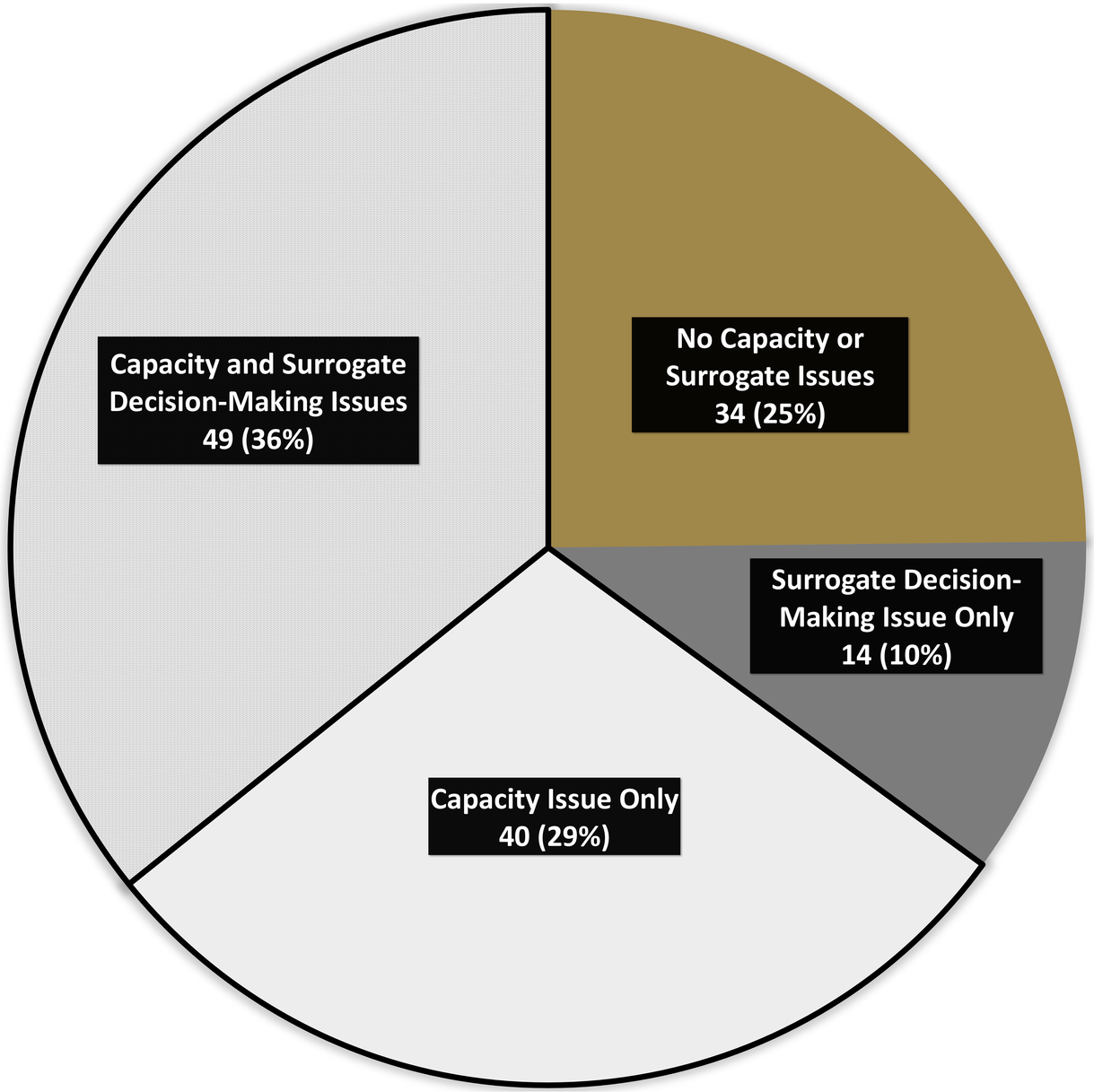
Results

- Of 89 capacity issues, 49 also involved a surrogate decision-making issue.
  - Odds of surrogate decision-making issue if capacity issue: 2.97 (95% CI: 1.51-6.30)



Discussion

- The consent process should always include surrogate decision-maker designation.
- Due to high co-occurrence, potential surrogate decision-making challenges need more attention when a capacity issue is identified.
- Multimodal strategies (e.g., visual aids, interpreters) may mitigate medical jargon and language barriers.
- Less common themes that are potentially serious (e.g., invasiveness) need safeguards and disclosure any time they might occur.
- **Limitations**:
  - Only captures issues escalated to an ethics consult (but captures most serious concerns)
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  - May not generalize to low-volume, non-academic hospitals (but likely overlaps)
- **Future Work**: Ensure that differences between consent and non-consent consults are not due to biases

Conclusion

- This is the only study to leverage a large corpus of documented ethics consults to better understand provider and patient concerns observed in their natural hospital setting.

- Compared to other ethics consults, consent consults differed in patient demographics and consult complexity.

- Capacity, surrogate decision-making, and comprehension/ communication barriers were the most common consent issues.

- Ethics consults offer a unique lens into consent challenges, providing actionable insights for institutional and national policies that would not otherwise be captured.

References

1. Lin GT, Mitchell MB, Hammack-Aviran C, Gao Y, Liu D, Langerman A. Content and Readability of US Procedure Consent Forms. *JAMA Intern Med*. 2024;184(2):214-216. doi:10.1001/jamainternmed.2023.6431

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Thank you!

Questions?

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Discussion Questions

- How do consent-related ethics consults reflect systemic gaps in informed consent, and what can be done upstream to prevent these issues?
- What strategies can improve the assessment and support of patient capacity and surrogate decision-making during the consent process?
- Why do communication barriers persist despite known interventions, and how can hospitals better ensure comprehension across diverse patient populations?
- What do the findings suggest about the limitations of advance directives, and how might their completion and use be improved?
- Why were consent consults more often low complexity, and how can simple interventions prevent these cases from escalating to ethics consults?
- How can policies and clinician training better address sensitivity, invasiveness, and emotional stress in consent conversations?
- What might explain the overrepresentation of female patients in consent consults, and how do demographic factors affect informed consent experiences?
- How can future research—such as qualitative analysis or digital tools—enhance our understanding and management of consent challenges?