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Cover Page Footnote

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ABSTRACT

Informed consent is a foundational concept in modern medicine. Despite physicians' ethical and legal obligations to obtain informed consent, no standard curriculum exists to teach residents relevant knowledge and skills. This paper presents a qualitative study of residents at one academic medical center. The authors conducted focus groups with trainees in the Departments of Internal Medicine, Emergency Medicine, and Ob/Gyn and analyzed their responses using rigorous qualitative methods. Four themes emerged: First, participants agreed that informed consent and decision-making capacity were relevant in many clinical situations. Second, participants varied widely in their understandings of consent. Third, current resident training was insufficient. Fourth, more training was needed. These results add to the growing literature that ethics education in residency is desired and useful. The findings will help educators craft instruments assessing the prevalence and degree of deficiencies related to informed consent competencies and aid in the development of a model curriculum.

KEY WORDS: Informed consent, Decision-making capacity, Curriculum development, Needs Assessment

Informed about Informed Consent: A Qualitative Study of Ethics Education

by

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INTRODUCTION

Informed consent is a foundational concept in modern medicine (O'Neill, 2003). It exhorts physicians to engage in a process of discussion with patients that typically include at least three elements: disclosure, medical decision-making capacity, and voluntariness. Disclosure involves the physician providing a patient with the information necessary to make an informed decision and includes the nature and purpose of the intervention, as well as its risks, benefits, and alternatives (del Carmen & Joffe, 2005). Capacity is the patient's ability to make decisions and is comprised of four decisional abilities: expressing a choice, understanding, appreciation, and reasoning. The degree of performance needed for these abilities depends the magnitude of the consequences of the decision (Appelbaum, 2007). Voluntariness requires that the patient be free from coercion or undue influence (del Carmen & Joffe, 2005).

Informed consent discussions exist within the broader framework of shared decision-making, in which physicians facilitate patients in making choices in line with their values (National Bioethics Advisory Commission, 2002). This approach satisfies physicians' ethical obligations both to respect patient autonomy and to promote patient welfare by ensuring that patients have the necessary information to freely make choices most consonant with their treatment goals (National Bioethics Advisory Commission, 2002).

Despite widespread agreement that informed consent is essential for ethical practice, the extent to which physicians actually hold high-quality informed consent discussions has been inconsistent (Hall, Prochazka, & Fink, 2012). Practitioners may overemphasize the administrative and legal aspects of patients' signatures on a form (Childers, Lipsett, & Pawlik, 2009; Grady, 2015). They may face structural or systemic obstacles that limit their opportunities to engage patients (Grady, 2015). When they do conduct fuller discussions, they may provide inadequate information (Faden, Becker, Lewis, Freeman, & Faden, 1981). And patients may fail to fully grasp the information that they are provided (Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009).

In graduate medical education, although some individual institutions have at times attempted to implement ethics curricula, there remains no generally accepted method of training residents to obtain informed consent (Childers et al., 2009; Wayne, Muir, & DaRosa, 2004). In one study of gynecologic surgeons, only 13% of respondents reported undergoing a standard curriculum for obtaining informed consent, while 96% indicated that they were trained solely through observation (Abed, Rogers, Helitzer, & Warner, 2007). A survey of general surgery residency program directors revealed that an overwhelming majority (85%) of program directors favored a surgical residency ethics curriculum, with nearly all (94%) believing that informed consent should be an included topic. However, no programs had established a formal curriculum, and 28% had no scheduled ethics-related activities whatsoever (Downing, Way, & Caniano, 1997). Likewise, a survey of Canadian internal medicine residency program directors showed wide variation in training residents to obtain informed consent, ranging from no teaching (6%) to informal mentoring (38%) to formal training using case studies (56%) (McClellan & Card, 2004).

The development of a standardized graduate medical curriculum could help to address the relative lack of formal training in obtaining informed consent and thereby correct the deficiencies exhibited by practicing physicians (Carrese & Sugarman, 2006). The present research thus describes an exploratory qualitative study aimed at identifying educational needs among resident physicians as a first step toward developing such a curriculum. Using focus groups and rigorous qualitative methods, we assessed trainees in the Departments of Internal Medicine, Emergency Medicine, and Obstetrics and Gynecology at one academic medical institution about their knowledge, experiences, and training around issues of informed consent and decision-making capacity. Their responses gave rise to common themes that can inform subsequent curricular development.

METHODS

SAMPLE

We contacted a convenience sample of residency program directors in the Departments of Anesthesiology, Emergency Medicine (EM), Internal Medicine (IM), Obstetrics and Gynecology (Ob/Gyn), and Surgery at the Perelman School of Medicine at the University of Pennsylvania. In the initial recruitment process, we provided a brief explanation of the investigation and requested a meeting with resident volunteers. We received responses from three departments—IM, EM, and Ob/Gyn—and scheduled focus groups with trainees in those departments.

PROCEDURE

Participants in each department were interviewed in a focus group setting led primarily by R.Z. At the beginning of each session, we provided a brief description of the study and obtained verbal consent for participation, including consent to be audio-recorded and de-identified. We also gave participants copies of the focus group questions. Each session was roughly an hour in duration. No financial incentive was offered for study participation. The University of Pennsylvania Institutional Review Board deemed the study exempt from review.

The focus groups were semi-structured. Questions were open-ended, and participants were allowed to respond to the group leaders and to each other. The questions examined three domains. First, we asked residents about their current knowledge, as well as what training they had received about informed consent or decision-making capacity. Second, we asked about the relevance of consent or capacity to their daily practice and prompted them for examples or clinical situations. Third, we asked about their educational needs with respect to learning about consent or capacity, in terms of both content and modality. The full list of questions is available as Appendix 1.

ANALYSIS

We transcribed the interview recordings and analyzed the texts using qualitative content analysis. In this well-established qualitative data analysis method, texts are read and coded with an eye toward identifying key themes. Themes are categorized and then further organized into

sub-themes that fit under broader themes (LeCompte & Schensul, 1999). Codes are short descriptors of a key theme labeling each text excerpt's main idea. Qualitative coding in content analysis simplifies and organizes textual data and allows for subsequent manipulation, categorization, and reorganization (LeCompte & Schensul, 1999).

In this study, key themes and codes were defined inductively from the data; that is, they were based on topics raised by focus group participants themselves. The texts were independently coded using QDA Miner Lite v2.0.1 (Provalis Research, Montreal, Canada) by R.Z. and J.K.N., who then met to resolve any discrepancies and achieve coding consensus. Interrater reliability was calculated using R v3.4.1 (R Foundation, International).

RESULTS

Four IM senior residents and one IM attending physician, eight EM senior residents, and one Ob/Gyn senior resident and one Ob/Gyn fellow participated. Mezzich's extension of kappa was used to assess interrater reliability. Mezzich's kappa is applicable when each text excerpt can have multiple codes (Eccleston, Werneke, Armon, Stephenson, & MacFaul, 2001; Mezzich, Kraemer, Worthington, & Coffman, 1981). Kappa in this study was 0.87 ($p < 0.001$, standard error = 0.027); kappa greater than 0.80 is conventionally considered almost perfect (Landis & Koch, 1977; McHugh, 2012).

Four primary themes emerged from the interviews: First, participants agreed that informed consent and decision-making capacity were broadly relevant, and issues around those topics frequently arose in the course of clinical care. Second, participants varied widely in their understandings of consent and capacity. Third, current resident training was insufficient. Fourth, more training was needed. For each theme below, we provide a summary of participants' responses and illustrative emblematic quotes.

CONSENT AND CAPACITY ARE BROADLY RELEVANT

Issues concerning consent and capacity arose in a variety of situations. Very often, interpersonal conflict provoked questions, whether that conflict occurred between members of the care team, between clinicians and patients and patients' families, or between patients and their families. Conflict frequently manifested as refusal of care or requests to be discharged against medical advice.

IM attending: "A lot of times where this comes up is when the patients or their families disagree with the trajectory of whatever the physicians are recommending, and so then we stop—and I think we should stop earlier than that, but sometimes we'll be like...this person is agreeable to whatever...and then we hit a point where the patient isn't agreeable and then we finally take a step back and [ask] does he actually have capacity to decide that?"

IM resident 3: "[The MICU is the place] you're most often dealing with a surrogate decision-maker. And then there's also...most likely to be disagreement between the physician team and the family or the patient about what the appropriate treatment course should be or goals of care should be."

IM resident 4: “We have a patient who has minimal mental status but expresses they're in pain...like in the MICU, the patient will say, “No, stop stop stop,” those sorts of mumblings, but...you're not able to carry on a conversation...They don't have capacity. But then the family members are more aggressive in their approach.”

IM resident 2: “A lot of the times when we do get psych involved [to assess decision-making capacity]...it's nurse-driven. Everyone else is doing a little CYA [cover your ass], and if there's that much resistance among your team members, then you feel obligated to call psych, even if it's not a complex case.”

IM attending: “AMA discharge is also the place where it comes up. It's like, well does this person really understand what's going to happen if they leave before we dialyze them?”

Relatedly, difficulty with interpersonal communication was a trigger. Residents had reservations when they could not adequately engage patients in care discussions or if there were clear barriers to understanding.

ED resident 3: “I tend to use as non-medical terms as possible because I think a lot of people don't have any idea what we're actually talking about.”

ED resident 5: “We have these standardized forms that we ask people to read and would go over. However, some people can't read. We're consenting [some people] using a translator phone and having them sign a form in English.”

ED resident 6: “It's tough because...a lot of our patients are just, yes, okay, I understand, uh-huh, uh-huh, and then they retain nothing and have no idea what's going on. They just kind of go with God and what you say, so it's hard to gauge them. I don't know what's appropriate.”

ED resident 5: “[A] 65-year-old COPD person comes in, in a flare, who's on biPAP, and you're trying to get consent and talk to them, and to understand their capacity through a biPAP machine. And they're there, and they can't talk at all, and they're bobbing their head and you're like, are they saying yes or are they just bobbing their head [from the biPAP]?”

Residents were also concerned when they perceived patients' decision-making capacity to be compromised. Sometimes, they observed that the patient was frankly impaired in her ability to choose, understand, appreciate, or reason. Other times, they were aware that the medical problems in question often impaired mental faculties, as in the case of liver disease, geriatrics, intellectual disability, delirium, addiction, or mental illness. Furthermore, when stakes were high, such as in the intensive care unit, at the end of life, acute emergencies, and cancer, residents were more sensitive to consent and capacity.

Residents struggled with ethical challenges pertaining to consent. They wondered about the proper level of disclosure, the use of therapeutic privilege, and the balance between

paternalism and patient autonomy. They lamented the seeming arbitrariness of different clinicians conducting informed consent discussions in vastly different ways.

VARIATION IN CURRENT KNOWLEDGE

Residents varied widely in their knowledge about informed consent and decision-making capacity. Some simply stated that they could not readily define those concepts. Many focused on the disclosure aspect of consent, particularly in describing an intervention's risks, benefits, and alternatives. Others commented on the administrative act of signing a form. Residents' understanding of the relationship between consent and capacity ranged from the two ideas being totally distinct to partially overlapping to capacity being an element of consent. Some believed capacity only to be relevant when patients withheld consent. And a few alluded to the notion of blanket consent, in which a patient at the outset of a care episode could consent in advance to all interventions and procedures undertaken during that episode.

Ob/Gyn resident: "We never really speak in terms of the definition of truly providing, of giving, or obtaining informed consent. We simply are taught...the gestalt of it. And it becomes more of a feeling—I couldn't say what made me question whether the patient could give consent other than that she was not consistent in the way she stated her views or her understanding."

Ob/Gyn fellow: "I don't know if I can define it, to be honest with you. I think it's very complex."

ED resident 1: "Consent is something you're asking for, whereas capacity is something that [patients] either have or do not have, so a patient can give consent for a procedure, for medical care in general, but that decision is based on whether or not they have the capacity to make decisions. And so I think sometimes a person can't consent if they don't have capacity to be able to make that decision in the first place."

IM resident 2: "We're taught that consent and capacity are two separate assessments...Consent is for this particular situation: can you reason through the risks and benefits of this intervention."

IM resident 1: "If you don't have capacity, you can't give consent, but there are often times that we need to determine capacity outside from a situation we're getting consent. Right? Like leaving AMA."

Ob/Gyn resident: "We have this blanket consent form that people sign when [they] come into the labor and delivery floor...It covers every single thing that we might do to take care of you, from the placement of an IV to the performing of an emergency C-section and everything in between that. And where we will attempt to obtain verbal consent for every single thing in between that, sometimes wind and weather don't permit that discussion."

CURRENT TRAINING IS INSUFFICIENT

Residents stated that they had no formal curriculum to teach them about consent and capacity and that there was very little training overall. Most teaching was done at the individual level, either by direct supervision or passive observation of supervisors or peers.

IM resident 1: “[There is] very little [teaching], and it's attending-specific...It's not clear what the gold standard of deciding informed consent is, because every attending, I think, has different things that they use to decide informed consent, in my experience.”

EM resident 1: “I don't think there's anything built into our curriculum, specifically...On a case-by-case basis with attendings, you get bits of knowledge...but never anything that is truly focused in the curriculum.”

EM resident 2: “A lot of what I have learned is just observing other people doing it and deciding what I like and what I don't like and trying to incorporate my own style of things.”

EM resident 2: “Some people will go in and [say], ‘This is the procedure that we'll be doing, here are some risks...You can read them on your own,’ and then just have people sign them. Some people...explain the procedure in detail...why we're doing the procedure and the benefits to the patient, and then they explain...the risks in a little bit more detail, which I personally like.”

EM resident 1: “Some seniors or attendings...choose a more paternalistic way of going about a procedure or getting consent, and then there are others who choose a much more shared decision-making type model.”

Ob/Gyn resident: “It's all experiential...based on when you have patients. Then you, on an as-needed basis, discuss with your colleagues, discuss with your attendings...There's no formal teaching of any kind.”

Ob/Gyn resident: “Somebody would go in with you and watch them consent one person. From then on, you would [do it yourself]. I was always blown away that people would just say, ‘This is a blood transfusion consent form in the event that you need blood. Sign here.’ And I didn't like that...It's all just scattered, it's all based on this apprenticeship model.”

IM resident 4: “One of the places we did get something formal was one of our standardized patient interviews for the interns. It's more focused on the patient interaction, but the actual clinical scenario is getting consent for a blood transfusion. So it's kind of a weird situation because you go, you do the interaction, [but] you don't get taught beforehand how to do blood consent, and you don't get feedback back afterwards... You get more feedback about the interpersonal thing.”

MORE TRAINING IS NEEDED

Residents indicated that they would like more teaching on consent and capacity. They believed that additional knowledge about basic concepts and how to apply those concepts to clinical situations would be helpful. They also desired improved supervision on how to conduct an effective informed consent discussion and assess a patient's decision-making capacity. They felt that multiple didactic modalities could be deployed, including lectures, case discussions, and simulations.

EM resident 5: "I would even go back to the very basics. Like not take for granted the fact that we know what consent and capacity means."

EM resident 5: "Go over the general consent process and how to determine if somebody has the capacity to make their own decision....Because right now, I'm just making stuff up."

IM resident 3: "From an internist's perspective, we should be able to understand if someone has capacity to make decisions, and we should be trained on a structured way to do that...We're most interested in making sure our patients understand what we're doing to them...Do they have capacity to make good decisions? Do they actually understand what we're trying to do? Do they buy into what we're trying to do? And have we evaluated that in a reasonable way?"

IM resident 4: "I think that's where you're going to get the most buy-in, especially from teaching residents, if you touch on those ethical boundaries. People really care about that stuff. We talk about it when we're at home. Those are the issues that are really hot button for people."

DISCUSSION

Despite encountering informed consent and decision-making capacity in a wide variety of clinical scenarios, residents had several misconceptions about these topics. They shared misgivings about their current level of training in managing both routine and challenging situations. Furthermore, they expressed significant moral distress about instances in which interventions were performed or withheld despite a questionable consent process or capacity determination. They were also concerned about unfairness due to seemingly arbitrary differences among providers. Ultimately, they were united in wanting more education to address these issues.

This study was limited by its small sample size restricted to one institution. We relied on a convenience sample, so those training directors who responded may have overrepresented the level of interest in consent and capacity education. No quantitative data were collected during the focus groups.

Nevertheless, it is clear from the literature that many in residency education share the concerns raised by our participants (McClean & Card, 2004; Wayne et al., 2004). Indeed, numerous calls have been issued over the last two decades for increased education in ethics broadly and informed consent in particular (Carrese & Sugarman, 2006; Helft, Eckles, &

Torbeck, 2009; Huntley, Shields, & Stallworthy, 1998). Moreover, the Accreditation Council for Graduate Medical Education (ACGME) Milestones Project has identified informed consent as an essential competency in residency training, usually under the rubrics of professionalism, ethics, or communication (Accreditation Council for Graduate Medical Education & American Board of Emergency Medicine, 2015; Accreditation Council for Graduate Medical Education & American Board of Internal Medicine, 2015; Accreditation Council for Graduate Medical Education, American Board of Obstetrics and Gynecology, & American College of Obstetrics and Gynecology, 2015).

Some institutions have begun to implement curricula aimed at addressing these issues. Gisondi and colleagues (2004) describe the use of patient simulations to replicate common ethical dilemmas in emergency medicine. Three of their five scenarios involved informed consent or decision-making capacity as a central topic: withdrawal of care at the end of life, do-not-attempt-resuscitation orders, and patient reluctance to give consent for a blood transfusion. McLaughlin et al. (2002) propose a three-year model EM residency simulation curriculum that includes scenarios addressing interpersonal and communication skills and professionalism. Wayne et al. (2004) describe a three-year internal medicine ethics curriculum developed in response to a survey-based needs assessment that included lectures, Grand Rounds, small-group discussions, and case conferences. McClean and Card (2004) devised a written examination and objective structured clinical examination to assess IM residents' competency in obtaining informed consent. Encouragingly, when these types of efforts have tended to be effective, producing increased resident satisfaction and improved knowledge and skills (Carrese & Sugarman, 2006; Helft et al., 2009).

Trainees, educators, and accrediting bodies recognize that the skills and knowledge underlying effective informed consent and assessment of decision-making capacity are an essential yet underappreciated component of graduate medical education. We join a growing trend that supports increased attention to residency ethics education. Moving forward, additional quantitative research investigating the prevalence and degree of the deficiencies we identify will be useful in characterizing the level of need. Additionally, we plan to cultivate a national network of educators to develop and share informed consent teaching materials and resources.

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APPENDIX 1. FOCUS GROUP QUESTIONS

CURRENT STATE OF KNOWLEDGE AND TRAINING

- What do you know about informed consent or medical decision-making capacity? How did you learn about these topics?
- What (if any) training did you have in medical school concerning informed consent or medical decision-making capacity?
- What (if any) training have you had in your residency concerning informed consent or medical decision-making capacity?

EDUCATIONAL NEEDS IN TERMS OF SPECIFIC CLINICAL ENCOUNTERS

- In what situations do you encounter issues of informed consent or decision-making capacity?
- What patients or in what clinical scenarios raised questions for you about informed consent or decision-making capacity? What were those questions? What do you wish you had known about these topics at the time?
- In what situations have you felt uncomfortable about a patient's ability to consent to (or refuse) treatment? What was uncomfortable about those situations? How were they resolved? What would have made you more comfortable about those situations?
- What difficult cases have you encountered in which informed consent or decision-making capacity played a role? What was difficult about those cases? How were they resolved? What knowledge or skills would have made it easier to resolve those cases?

GENERAL EDUCATIONAL NEEDS

- What (if any) training would you like to have in your residency concerning informed consent or decision-making capacity?
- What would you need to know about informed consent and decision-making capacity in order to be comfortable making clinical judgments about these issues? As a resident? As an attending?

SPECIFIC EDUCATIONAL NEEDS

- What is most useful for you to know regarding informed consent or decision-making capacity?
- Is it most useful to focus on the communication of the nature and risks/benefits of medical interventions (provision of information), patient's ability to make healthcare decisions (decision-making capacity), or removal of obstacles to independent choice (voluntariness)?
- What aspects of [provision of information/decision-making capacity/voluntariness] do you wish you knew more about?

IMPLEMENTATION

- What do you think would be the most effective way to teach about informed consent and decision-making capacity? Didactic lectures? Case examples? Role-play or simulation? Bedside teaching?
- How would you teach the topic to residents? To medical students?