Attitudes, Practices, and Training on Informed Consent for Transfusions and Procedures

A Survey of Medical Students and Physicians

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Key Words: Transfusion medicine; Special topics; Education; Generalist

Am J Clin Pathol August 2015;144:315-321

DOI: 10.1309/AJCPP85EXSGZORYZ

ABSTRACT

Objectives: *While many studies have demonstrated problems with informed consent in current practice, there remains controversy on how to address this. The aim of this study was to evaluate the opinions, attitudes, practices, and training for informed consent.*

Methods: *Medical students, residents, advanced practice providers, and attending physicians at an academic institution were invited to complete a survey on informed consent for transfusions and procedures through an electronic platform.*

Results: *Most (94%, n = 304) respondents indicated previous training in informed consent, only 60% (n = 192) felt the training was adequate, and 35% (n = 92) indicated difficulties with informed consent. When asked what would aid in obtaining consent, 59% (n = 189) selected a written guideline, and 36% (n = 117) selected patient simulation.*

Conclusions: *Only 60% of respondents felt their informed consent training was adequate. Multiple areas of difficulty in obtaining proper informed consent were identified that should be addressed with focused training or written guidelines.*

For most of the history of Western medicine, paternalism was commonplace and patients had little say in their own medical care. Over the past 75 years, however, the pendulum has shifted toward a focus on patient autonomy. Seminal court cases have found physicians liable for battery for not providing patients with "facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment"[1] or negligence for failing to disclose collateral hazards that any "reasonable medical practitioner" would disclose.[2] Nearly half of the US states have subsequently shifted the focus to what a "reasonable patient"[3] would need to know to make an informed decision.[4]

While it is universally acknowledged that informed consent is a central component of patient-centered care,[5] the increasing complexity of medical options combined with the varying disclosure requirements makes the process of obtaining informed consent quite complicated. The physician must explain not only the treatment proposed but also the alternatives, benefits, risks, and the reasons for a recommendation.[6] It is also imperative that the physician make a reasonable effort to ensure that this information was comprehended and leave time for questions.[7,8] Informed consent also requires that the patient voluntarily decide, without evidence of coercion.

Despite the centrality and complexity of obtaining informed consent from patients, there is a lack of research showing what, if any, training is occurring at residency programs and medical schools on this subject. The studies that have looked specifically at consent or communication training show that few physicians receive formal training in obtaining informed consent for procedures or transfusions.[9,10] The result is that often incorrect information is provided[11] and

relevant information is omitted.[12,13] Even when the physician is capable of describing what may occur, often physicians are so pressed for time that they do not pause to verify that a patient understood the information that was communicated. For example, one study using evaluation of taped interactions showed that an assessment of the patient's understanding of the information was done only 12% of the time (n = 141) with a mean encounter time of 16 minutes.[9]

While *informed consent* should refer to an individualized[14,15] and ongoing[16] conversation between physician and patient—with the written document merely an attestation that this has taken place[5,17]—the process is often reduced to obtaining a signature on a piece of paper,[18] which often requires a reading level achieved by only a fraction of the adult US population[19] and which most patients may not even read before signing.[20] The end result is that patients often misunderstand the likely outcomes of procedures.[21,22] In fact, this critical task is often delegated to junior house staff, medical students, nurses, and even registration staff.[17]

The aim of this study is to evaluate the opinions, attitudes, practices, and existing training on informed consent for both physicians and medical students. To better understand the challenges to improving informed consent for transfusions, it was necessary to also study informed consent in general for other procedures for comparison. We hypothesized that while physician experience in obtaining consent will increase with increased level of experience, there will be no increase in the numbers who have actually received training in doing so. The data acquired could also be used as a preintervention baseline for comparison.

We ultimately wish to identify difficulties clinicians face in obtaining consent and preferences for what type of intervention might be welcomed. Personalization, for example, has been shown to be helpful, with one study finding that implementation of an individualized consent form resulted in increased participation by patients and showed better risk recall.[23] Given the potential interrelatedness of the informed consent process for transfusions and other procedures, opportunities for improvement might be identified for transfusions that are also applicable for other procedures and vice versa.

Materials and Methods

Study Design

This was a cross-sectional cohort study that took place during April 2014 at the University of Vermont, College of Medicine, and its affiliated medical center, University of Vermont Medical Center, in Burlington. Third- and fourth-year medical students, residents, advanced practice nurses (APRNs), physician assistants (PAs), and attending physicians were invited to complete a survey through an anonymous electronic platform. The survey introduction included a definition of informed consent, the nature and purpose of the study, the anonymity of the survey, and the voluntary nature of participation. Survey questions and statements inquired into the following areas: demographics, experience with and training in understanding of and obtaining informed consent, informed consent practices, challenges to obtaining consent, and attitudes regarding informed consent. Additional data beyond demographics were collected only from participants indicating they do obtain consent from patients.

Attitudes toward adequacy of prior training, importance of obtaining consent in different situations, difficulties faced in obtaining consent, and preferences for future interventions were assessed using a five-point Likert scale with responses ranging from strongly disagree to strongly agree.[24] Responses from the five-point Likert scale were subsequently condensed for "strongly disagree" and "disagree" to *disagreement* and "strongly agree" and "agree" to *agreement*. Questions asking about a specific type of prior training in informed consent were presented in a way that participants could select multiple methods of training they had already received or "none." These responses were condensed to categories of "formal" and "informal" training. Participants were considered to have received formal training if their responses included any of the following: lecture, group discussion, online module, quiz, or exam to assess competency after training or patient simulation. All other participants who otherwise had identified the other categories of training were considered to have received informal training. The number of people receiving formal training was compared with both the total group of respondents and the subset of respondents indicating that they had received any type of training. Responses that selected both "none" and also indicated additional types of training were excluded from analysis since "any training" and "no training" are mutually exclusive categories, resulting in two surveys being excluded from the study.

The study was deemed exempt by the University of Vermont Institutional Review Board and approved for distribution to medical students by the College of Medicine Research Office. The procedures followed were in accord with the ethical standards established by our institution. The secure survey platform (www.limesurvey.com) was approved for use by both offices and by the University of Vermont. Participants were informed that results would be made available upon study completion and data analysis.

Participant Selection

The inclusion criteria were third- and fourth-year medical students, resident physicians, attending physicians, and other medical staff credentialed to obtain consent (ie, PAs

DOI: 10.1309/AJCPP85EXSGZORYZ

and APRNs). To protect participant privacy and anonymity, potential respondents were not asked about their age or sex. However, there were no people younger than 18 years in any of the above programs or positions listed at the time of the survey. Questions were asked about specialty area, but the available categories included only hospital specialties that had multiple members to avoid singling out any one participant in the survey. Individuals provided consent by completing the questionnaire. Before distribution, the survey was piloted with seven attending physicians, one fellow, four residents, and three medical students. Modifications were made based on their feedback.

Statistical Analysis

Demographic data, including type of licensure, level of training, specialty, and previous informed consent–specific training, were analyzed using descriptive statistics (Excel; Microsoft, Redmond, WA). Similarly, data regarding current practices when obtaining consent for different types of procedures and attitudes regarding obtaining informed consent also used only descriptive statistics. APRNs and PAs comprised a small number of respondents and were grouped with attending physicians for these analyses given their status as licensed health care practitioners with medical staff privileges who have completed formal training.

Regulations and Policies in Effect During This Study

Vermont law regarding informed consent specifies providing patients with information about "medically significant risks."[25] The informed consent discussion must include the risks, benefits, and alternatives in a manner that allows the patient to evaluate that information unless consent is not reasonably possible.[26] Our institution requires the use of standardized forms that have areas where the clinician can fill in information as applicable. Informed consent is documented in one of two ways at our institution: (1) as part of an operative procedure informed consent form signed by the patient or (2) as a physician attestation of obtaining informed consent when ordering blood transfusions using the computer physician order entry system that cannot be left unanswered (computer hard stop). There is an online training module on informed consent available to providers that must be successfully completed every 2 years as part of their medical staff reappointment. At our institution, obtaining consent is the responsibility of the treating provider and focuses on the goal of making patients active in their own health care. Informed consent, in the detail described above, is not required for simple procedures such as venipuncture. The provider is tasked with the decision of whether a procedure constitutes significant enough risk, is invasive, or is complex, thereby necessitating full informed consent be obtained.[27]

Table 1
Distribution of Survey Responses by Level of Practice

Level of Practice	No. (%)
Third- or fourth-year medical student	68 (21)
Resident	84 (26)
Attending physician	140 (43)
APRN/PA	30 (9)

APRN, advanced practice nurse; PA, physician assistant.

Results

Demographics

In total, 1,290 people were invited to participate in the survey, and a total of 322 completed surveys were received, giving a response rate of 25%, with the largest number of responses coming from attending physicians **Table 1**.

The respondents were also asked to select the specialty with which they most identify. The results of this included identification with 32 distinct specialties **Table 2**. Medical students were counted as a unique group, even if they had already matched in a specialty.

Existing Informed Consent Training

Ninety-four percent (n = 304) of respondents indicated they had received some kind of training in informed consent, and 6% indicated they did not recall having any training **Table 3**. Of those who received some training, 72% (n = 233) specified a certain type of training. The majority (60%; n = 192) of those who received some training felt that training was adequate, 20% felt it was not, and the remaining 20% were neutral on the topic. The most commonly cited type of training was an informal conversation regardless of the level of practice of the respondent, with lectures or printed materials being the second most frequently selected. Regardless of the type of training or level of practice, a minority of responses indicated a posttraining quiz or examination to assess for competency (19% overall with 22% of medical students, 15% of residents, and 19% of attending physicians and advanced practice staff).

The level of practice was also compared with how often training occurred and how frequently consent is obtained. Interestingly, compared with residents, medical students, attending physicians, and APRNs all had a larger percentage indicating having no informed consent training (7% of attending physicians and APRNs/PAs, 6% of medical students vs 2% of residents). The frequency with which consent was obtained by the respondents varied from never to more than once each day, and this increased with increasing level of practice, where the largest number of "more than once daily" respondents were attending physicians (12% of all responses; n = 40), and the largest number of "never" respondents were

DOI: 10.1309/AJCPP85EXSGZORYZ

Table 2
Distribution of Survey Responses by Specialty

Specialty	No.
None—currently a medical student	68
Anesthesia	20
Dermatology	6
Emergency medicine	7
Family medicine	27
Internal medicine	39
Neurology	1
Neurosurgery	2
Oral and maxillofacial surgery	2
Obstetrics and gynecology	32
Orthopedics	13
Pathology	8
Pediatrics	34
Primary care/internal medicine	3
Physical medicine/rehabilitation	1
Psychiatry	6
Radiology	6
Interventional radiology	3
Surgery	24
Urology	2
Other	18
Allergy/immunology	1
Cardiology	2
Cardiothoracic surgery	1
ENT	1
Hematology	1
Nephrology	1
Oncology	3
Otolaryngology	1
Pediatric dentistry	1
Pain medicine	1
Pulmonary	1
Radiation oncology	1
Rheumatology	1
Other/not specified	2
Total	322

ENT, ear, nose, and throat.

medical students (14% of all responses; n = 45). Seventy-one percent of medical students reported obtaining consent less than yearly, with only 10% of attending physicians/APRNs/PAs and 7% of residents in this category. While 77% of residents and 75% of attending physicians/APRNs/PAs reported obtaining consent at least monthly, only 10% of medical students fell into this category.

Attitudes and Opinions

Only respondents who indicated that they presently obtained informed consent (n = 264) were asked for their attitudes and opinions as to when consent should be obtained and what (if any) difficulties they had while obtaining consent. Sixty-five percent (n = 172) indicated no difficulties obtaining informed consent. Of those who did identify difficulties, the most frequently cited was insufficient time **Table 4**. However, medical students were more likely to select knowledge-based difficulties.

All participants were asked what assistance or tools would be helpful in obtaining consent; 59% (n = 189) felt a written guideline would help, and 36% (n = 117) felt training involving a patient simulation would be helpful. These were presented as two separate questions with no free text option. Respondents could agree or disagree with each statement separately regarding whether this specific intervention would be helpful. In each demographic category, written guideline was selected more frequently than patient simulation (79% vs 63% for medical students, 57% vs 32% for residents, and 51% vs 28% for attending physicians/APRNs/PAs).

More than 90% of respondents in all categories felt it was "very important" to obtain consent for operative procedures (of all types), bedside procedures, and transfusions. With regard to emergent procedures, 64% of attending physicians and APRN/PAs felt consent was required compared with slightly less than half of medical students and residents (43% and 49%, respectively).

Finally, participants were asked how much they agreed with two statements on the purpose of informed consent: for medical/legal documentation and/or to inform the patient. Of the participants, 39% (n = 127) agreed that the primary purpose of informed consent was for medicolegal documentation, 87% (n = 281) stated that the primary purpose was to inform the patient, and 34% felt informed consent had two primary purposes and selected both options (n = 111) .

Practices in Obtaining Informed Consent

To address current practices in obtaining consent, participants who indicated they obtain informed consent were asked additional questions on the average number of minutes they spend obtaining consent for different types of procedures **Table 5**. Most respondents (69%) indicating they obtain nonemergent transfusion consent reported spending less than 5 minutes obtaining that consent, a slightly higher percentage than for emergent procedures (including emergent blood transfusions). No responses indicated spending more than 60 minutes to obtain informed consent for any type of procedure.

Discussion

Although most respondents indicated they have received some kind of informed consent training, only 60% felt their training was adequate. Compared with other studies, this study is consistent in identifying knowledge of risks and benefits as a problem and that there seems to be no standardized or consistent approach in teaching informed consent skills.

More than one-third of the respondents indicated having difficulty obtaining informed consent, and multiple areas of

DOI: 10.1309/AJCPP85EXSGZORYZ

Table 3
Previous Training in Informed Consent[a]

Training Received	% of Total (n = 322)	% of Students (n = 68)	% of Residents (n = 84)	% of Attending, APRN, or PA (n = 170)
None	6	6	2	7
Informal conversation	75	82	83	68
Printed material	50	51	45	52
Electronic material or media	30	26	31	32
Group discussion	54	38	50	37
Lecture	41	62	55	51
Online module	25	25	29	22
Posttraining quiz or exam	19	22	15	19
Patient simulation	14	9	30	8

APRN, advanced practice nurse; PA, physician assistant.
[a] Respondents were able to select more than one option.

Table 4
Difficulties and/or Barriers in Obtaining Informed Consent

Selected "Agree" or "Strongly Agree" to the Following Difficulties in Obtaining Informed Consent[a]	Medical Student[b] (n = 23), %	Resident[b] (n = 79), %	Attending and APRN/PA[b] (n = 162), %
Time	17	19	11
Ability to answer questions	39	18	7
Knowledge of how much/little to say	30	14	8
Knowledge of risks/benefits	30	13	8
Knowledge of alternatives	26	8	9
Knowledge of outcomes if treatment is declined	30	15	4

[a] Respondents were able to select more than one option, and only participants who indicated they obtain consent were asked this question set.
[b] Number (n =) includes total responses to the question, *including* responses indicating *no difficulties* obtaining consent, and percentages are a percentage of this overall number of responses indicating each type of difficulty.

Table 5
Time Spent Obtaining Informed Consent by Procedure Type

Procedure Type	Less than 5 Minutes, %	5 to 10 Minutes, %	11 to 30 Minutes, %	31 to 60 Minutes, %	No. of Responses
Transfusion	69	30	1	0	188
Bedside procedure	55	38	7	0	178
OR low risk <1 h	36	42	22	<1	134
OR high risk >1 h	13	39	45	3	118
Emergent	64	30	6	0	158

OR, operating room.

difficulty were identified. The difficulties experienced can be summarized into knowledge-based and systems-based problems. The licensed providers indicated fewer difficulties in their level of knowledge on obtaining consent, but they more often had time constraints. The medical students, on the other hand, indicated many difficulties in their fund of knowledge. They would also benefit from a written guideline but may need additional formal instruction added to the curriculum and practice sessions to help them feel more comfortable before graduation and residency. Based on the results from this study, it seems that different interventions could be recommended for the licensed clinicians and nonlicensed students. Many of the respondents were open to a written guideline to help with these difficulties, and having a set standard could also help save time and streamline the process so that it does not feel rushed to either the patient or the provider.

A recent randomized trial involving medical residents (n = 2,802) showed that compared with the usual education, a simulation-based approach to teaching communication did *not* increase the patient- and family-reported quality of communication.[28] However, in this trial, the comparison education is only defined as "usual" and not further classified, so it may be that the training was adequate to begin with. What "usual" training is occurring is difficult to determine since many programs have no consistent approach to teaching or evaluating the process of when and how consent is obtained.[10,29] Considering that more than one-third of respondents reported that a simulation-based approach would be helpful, this should be explored as a possibility for training, especially at the medical school level, where it was more frequently identified as an acceptable intervention. In a randomized controlled trial (n = 30) of senior medical students, the intervention group who received communication

DOI: 10.1309/AJCPP85EXSGZORYZ

training had simulated patients (laypersons) who recalled significantly more (41 vs 23 items, $P < .0001$).[30]

Complicating the problem is that many consent forms are written at a level above many laypeople's comprehension. Although standardized forms have been widely used in the past to try and solve some of the issues surrounding both knowledge and time constraints, even with the use of these forms, studies have shown that patients often do not understand or cannot recall the information discussed with them.[31] A retrospective analysis done in Ireland reports that only 48% to 66% of consent forms were completed to set standards at three separate centers, and following a teaching session, this went up by an average of 9%.[23] As a profession centered on teaching and lifelong learning, physicians have a duty to find a way to effectively communicate with patients, enabling their active participation in the process.

This can be difficult because patients rarely give direct feedback about communication issues, making it difficult for providers to know if they truly understand when they sign the form.[32] A physician untrained in the elements of informed consent or ways of effectively communicating this to the patient is then at a significant disadvantage and would have to rely on the consent form itself to provide this information. However, often consent forms are viewed as a means to authorize treatment or to protect caregivers from liability rather than as a means to inform the patient[33] in the true spirit of consent as a process. The ultimate goal is to make a decision that is also owned by the patient and to promote the concept of patient-centered care.[34] By doing this as physicians, we enhance the patient's control of his or her own care[35] and promote one of the central values in medicine, autonomy.[36]

There were several limitations of this study. The voluntary nature of participation meant that only those participants willing to fill out the survey were included in the data. This may represent a group with significantly different opinions and attitudes compared with the providers and students who chose not to complete the survey. In addition, the study was conducted over 1 month. More responses may have been obtained with additional time, but most responses were received in the first 2 weeks of the study, and very few additional responses were gained in the final few weeks. In addition, we did not assess the patients' understanding of consent in our study, although there has been a demonstrated need to improve patient comprehension in the existing literature. Related to this limitation, this study did not address the possible impact of various systematic improvements to the informed consent process itself, such as the use of multimedia consent programs,[37] but focused primarily on health care provider training and their perceived challenges to properly obtaining informed consent.

In summary, although most health care providers have received training in informed consent, a surprising number do not feel their training was adequate and identified a variety of challenges while obtaining informed consent. Furthermore, most felt a written guideline or additional training would be helpful. This study sets a baseline level with which a postintervention analysis could be compared. Another study exploring what interventions may aid them in spending more time obtaining consent could help focus recommendations in this area. This would likely require collaboration with hospital leadership on a committee composed of providers from all levels of practice (residents, attending physicians, PAs, and nurse practitioners) to discuss possible solutions. Something as simple as clinic schedulers blocking a few extra minutes for patients coming to discuss surgery or finding other preprocedure duties that could be taken on by ancillary staff may save time the provider can spend with the patient instead.

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Parts of this study were presented as a poster at the AABB annual meeting; October 25-28, 2014; Philadelphia, PA.

Acknowledgments: We thank Wasef Abu-Jaish MD, FACS, Assistant Professor of Surgery, and William V. Raszka Jr., MD, Professor of Pediatrics, University of Vermont Medical Center, for their assistance with survey development.

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