PAPER

ONLINE FIRST

Training Surgeons and the Informed Consent Process

Routine Disclosure of Trainee Participation and Its Effect on Patient Willingness and Consent Rates

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Objectives: To examine patient perceptions and willingness to participate in resident education and to assess the effect on patient willingness and consent rates.

Design: Anonymous questionnaire designed to capture demographics, overall opinions of teaching programs, and willingness to consent to various scenarios of trainee participation. Descriptive and univariate analyses were performed.

Setting: Tertiary-level referral center.

Patients: Three hundred sixteen individuals scheduled for elective surgery.

Main Outcome Measures: Consent rates for various scenarios.

Results: Of the 316 patients who completed the questionnaire, most expressed overall support of resident training: 91.2% opined that their care would be equivalent to or better than that of a private hospital, 68.3% believed they derived benefit from participation, and most consented to having an intern (85.0%) or a resident (94.0%) participate in their surgical procedure. However, when given specific, realistic scenarios involving trainee participation, major variations in the consent rate were observed. Affirmative consent rates decreased from 94.0% to 18.2% as the level of resident participation increased. Patients also were more willing to consent to the participation of a senior resident (83.1%) vs a junior resident (57.6%) or an intern (54.5%). Patients overwhelmingly opined that they should be informed of the level of resident participation and that this information could change their decision of whether to consent.

Conclusions: Most patients expressed approval of teaching facilities and resident education. However, consent rates were significantly altered when more detailed information was provided and they declined with increasing levels of resident participation. Providing detailed informed consent is preferred by patients but it could adversely affect resident participation and training.

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THE CONCEPT OF A PREOPerative interaction between patient and surgeon to achieve informed consent can be traced back at least as far as ancient Greek and Byzantine sources.[1] However, only in the modern era has a formal system of performing and documenting the informed consent process been widely adopted in Western medicine.[2] The accepted standard is to provide information that "a reasonable patient" would want and would need to know to make an informed decision, but this counseling may vary widely by health care professional, setting, and type of surgical procedure.[3] The informed consent process is further complicated in the setting of a teaching hospital. The foundation of surgical training in the United States,[4] adapted from the German model by Osler and Halsted, is a system of graded responsibilities and independence. Currently, no widely accepted guidelines or

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policies exist for providing information regarding the role of surgical trainees to the patient during the informed consent process. It is not uncommon to have little to no relevant discussion regarding the role of the trainee or to have this issue addressed only by vague blanket statements in the written consent form.

Table 1. Demographics of 316 Respondents[a]

Characteristic	Value
Age, mean (SD), y	46 (16)
Sex	
Male	120 (38.0)
Female	196 (62.0)
Status	
Active duty military	56 (17.7)
Retired military	82 (25.9)
Dependent family member	178 (56.3)
Highest educational level	
High school diploma or lower	88 (27.8)
Any college or higher	228 (72.2)
Any prior surgical procedure	259 (82.0)
Prior surgical procedure at MAHS	145 (45.9)
Degree of difficulty of the planned procedure	
Simple	136 (43.0)
Intermediate	123 (38.9)
Complex	57 (18.0)

Abbreviation: MAHS, Madigan Army Health System.
[a]Data are given as number (percentage) unless otherwise indicated. Percentages may not total 100 because of rounding.

Several recent studies[5-7] have pointed out the paucity of information typically provided to the patient regarding trainee participation; those studies call for this information to become a standard and universal component of informed consent. However, the specifics of such a policy and their potential effect on the patient and the trainee remain unknown. The purpose of this study was to examine the general understanding of and willingness to participate in the surgical education process among a group of patients scheduled for a surgical procedure. Also, we sought to analyze the potential effect on patient consent rates of providing specific and detailed information regarding possible resident participation in the surgical procedure and to identify any patient factors that influence the decision of whether or not to consent.

METHODS

This study was conducted at a tertiary-level US Army hospital and referral center. In addition to containing a busy surgical service, this facility serves as 1 of 6 major Army teaching centers for graduate medical education. The residency in general surgery is a 6-year training program (including a research year), with a total of 5 interns (postgraduate year [PGY]–1) and 16 residents (PGY 2 through PGY 6). This program follows the standard US paradigm of increasing levels of responsibility and decreasing levels of direct supervision over time. Because our institution is a military training program, all graduating residents are expected not only to be able to begin the independent practice of surgery but to be fully prepared to deploy to remote areas or combat zones and to provide a full range of care in challenging conditions with little to no direct assistance or supervision.

The study population consisted of all patients who were scheduled for an elective surgical procedure and who had arrived at the general surgical clinic for their final preoperative evaluation. Only adult patients (18 years or older) with adequate English-language skills to read and to complete the survey instrument were included. Patients who were unable to provide their own informed consent due to mental or physical disability were excluded. The survey was anonymous and voluntary; individual responses were not available to any of the treating physicians or nurses. At the completion of the patient accrual phase, all completed surveys were collected and their data entered into a computerized spreadsheet.

The survey instrument was 2 pages long and started with basic questions concerning patient demographics. Next was a series of questions regarding the patient's understanding of our teaching hospital status, his or her planned surgical procedure, and his or her comfort level pertaining to receiving care at a teaching facility in general. Prior to the next set of questions, definitions for terms such as *teaching hospital*, *medical student*, *intern*, *resident*, and *staff surgeon* were provided. The final section presented the patient with 9 specific scenarios for his or her surgical procedure, with escalating levels of trainee participation and training level (ie, PGY level), along with corresponding decreases in the level of staff surgeon participation. These were created to represent real and common scenarios of resident and staff level of participation at a teaching hospital. They ranged from a surgical procedure performed solely by a staff surgeon with others merely observing to junior residents performing the procedure with the aid of a senior resident without direct staff presence. We concluded the survey with questions aimed at assessing to what extent patients expect to be informed regarding the involvement of trainees, who should be held responsible for surgical complications, and whether they believe that societal and/or personal benefit accrues from allowing residents to take part in their care.

A summary score of "patient willingness" was created by summing the number of scenarios (out of 9) in which the respondent answered affirmatively to questions regarding trainee participation, with possible scores ranging from 0 to 9. Respondents scoring in the lowest 25th percentile were categorized as being "highly unwilling." Initial exploratory descriptive data analysis was performed to characterize the study population demographics and the responses to each question. Univariate analysis using the χ^2 test for categorical data and the *t* test, the 1-way analysis of variance, or the Mann-Whitney test for continuous data was performed to compare responses between groups categorized by demographics such as sex, military status, age group, and type of surgical procedure. Multivariate logistic regression models were created to identify characteristics associated with the highly unwilling group. All data analysis was performed using Predictive Analysis Software, version 18.0 (SPSS Inc, Chicago, Illinois).

RESULTS

DEMOGRAPHICS AND PATIENT PREFERENCES

Five hundred surveys were distributed, of which 316 were completed and returned (response rate, 63.2%). The overall demographics of the study population are shown in **Table 1**. Most patients indicated no preference for a type of facility (teaching vs private). Among those with a preference, more preferred a teaching hospital for overall care (24.9% vs 8.8%) and for minor surgical procedures (28.2% vs 12.0%), with equivalent results (24.7% vs 26.6%) for major surgical procedures. A total of 91.2% of those with a preference opined that their care in a teaching hospital would be equivalent to or better than that of a private hospital. Patients overwhelmingly preferred to be informed regarding resident

participation in their surgical procedure, regardless of whether they were undergoing a minor (87.5%) or a major (95.7%) procedure. Also, 92.2% opined that they also should be informed if this was the first time the trainee was performing a particular procedure; more than half (55.0%) stated that this information would make them less likely to consent.

GENERAL WILLINGNESS TO PARTICIPATE IN TRAINING

Most respondents demonstrated overall understanding and support of teaching and surgical trainee education. Most (78.9%) already knew that our institution is a teaching facility before their clinic visit and supported the concept of trainee participation in their surgical procedure. A total of 94.0% stated that they would consent to the involvement of a surgical resident; this decreased to 85.0% for surgical intern involvement and 79.9% for medical student involvement. Most respondents (68.3%) perceived a personal benefit from participating in resident training (68.3%), and almost all (87.4%) believed that their participation would benefit other patients.

RESPONSE TO SPECIFIC TRAINING SCENARIOS

When given specific, realistic scenarios involving trainee participation, major variations in the consent rate were observed. Consent rates declined from 95.0% for no direct resident assistance to 82.7% with a senior resident assisting, 57.6% with a junior resident, and 54.5% with an intern. The **Figure** demonstrates the marked change in consent rates with increasing levels of resident participation. The consent rate declined sharply from 57.6% with a junior resident acting as the first assistant to 25.6% and 18.2% when the resident acts as the operating surgeon with or without direct staff observation, respectively.

WILLINGNESS TO CONSENT

Respondents who had a summary score (the number of scenarios with an affirmative response) in the lowest quartile were categorized as being highly unwilling. **Table 2** shows the comparison of demographics and key survey responses between the highly unwilling group and the rest of the cohort. Respondents who were less willing to participate in trainee education were younger and, more often, women. Although experience with prior surgical procedures was equivalent between the 2 groups, a history of prior surgical procedures at our facility was significantly less prevalent among respondents in the unwilling group (35.4% vs 50.5%). Striking differences were observed between groups for the answers to questions relating to a belief that benefit would accrue from care at a teaching facility. Highly unwilling patients were significantly less likely to believe a personal benefit (46.8% vs 76.6%) or a benefit to future patients (75.7% vs 91.7%) would accrue from participating in the training of surgeons. A multivariate logistic regression model including key demographics and response to survey opinion questions was then created. Independent factors associated with the highly unwilling group were female sex (odds ratio, 2.2; 95% confidence interval, 1.1-4.4; $P=.03$), having been unaware that the facility is a teaching hospital prior to their clinic visit (2.6; 1.2-5.7; $P=.01$), and negative response to whether they believed that personal or societal benefit accrues from participating in the education of surgical trainees (4.1; 1.7-10.4; $P=.002$).

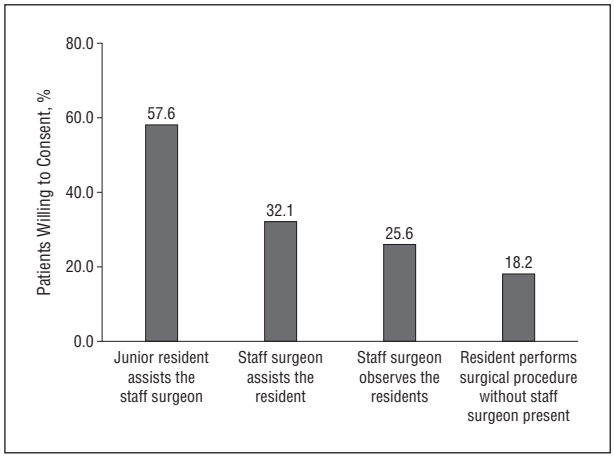

Figure. Percentage of respondents willing to consent to scenarios involving increasing levels of trainee participation, from assisting only (far left) to fully performing the procedure without the responsible staff surgeon present in the operating room (far right).

COMMENT

Although the concept of obtaining a patient's permission and assent for surgery has been noted since the earliest recorded days of medicine,[1] not until the landmark decision *Schloendorff v The Society of the New York Hospital* in 1914 did informed patient consent become legally defined. In the United States and in many parts of the world, the formerly paternalistic role of the physician dictating treatments to an obedient patient has given way to recognition of and respect for patient autonomy.[3] The modern process of informed consent entails describing to the patient the risks, the benefits, and the alternatives to a surgical procedure. This has become an ethically expected and a legally required component before any nonemergency surgical procedure.

A key component of the informed consent process is that the responsible surgeon or surgeons who will be performing the procedure are identified to the patient. Although this point is relatively straightforward in a nonteaching or a private practice setting, there have been significant controversy and debate regarding times when trainees also will be participating in a surgical procedure. The term *ghost surgery* was originally coined to describe the practice of allowing someone other than the responsible surgeon to perform the procedure; it subsequently has been applied to the practice of allowing trainees to perform procedures without specific patient consent.[8,9] In a detailed investigation in the state of New York, the Lifflander Report found that this practice was ex-

Table 2. Demographics of Respondents Categorized as Highly Unwilling to Consent to Trainee Involvement Compared With the Rest of the Cohort[a]

Variable	Highly Unwilling Group (n=82)	Remainder of the Respondents (n=218)	*P* Value
Age, mean (SD), y	41 (14)	47 (17)	<.001
Sex			.02
Male	22 (26.8)	92 (42.2)	
Female	60 (73.2)	126 (57.8)	
Active duty military	18 (22.0)	35 (16.1)	.30
Retired or family member	64 (78.0)	183 (83.9)	
Highest educational level			.09
High school diploma or lower	29 (35.4)	54 (24.8)	
Any college or higher	53 (64.6)	164 (75.2)	
Any prior surgical procedure	64 (78.0)	181 (83.0)	.44
Prior surgical procedure at MAHS	29 (35.4)	110 (50.5)	.03
Degree of difficulty of the planned procedure			.48
Simple	32 (39.0)	98 (45.0)	
Inermediate to complex	50 (61.0)	120 (55.0)	
Whether patient knew that MAHS is a teaching hospital			.004
Yes	55 (67.1)	192 (83.1)	
No	27 (32.9)	39 (16.9)	
Whether patient believes a personal benefit will accrue from participating			<.001
Yes	36 (46.8)	154 (76.6)	
No	41 (53.2)	47 (23.4)	
Whether patient believes a societal benefit will accrue from participating			.001
Yes	56 (75.7)	187 (91.7)	
No	18 (24.3)	17 (8.3)	

Abbreviation: MAHS, Madigan Army Health System.
[a]Data are given as number (percentage) unless otherwise indicated; excluded 16 patients who did not answer all 9 of the scenario-based questions.

tremely common in teaching hospitals and that no consent or a general consent to allow "such assistants as he [the attending surgeon] shall select" was obtained.[8] This report generated proposed legislation dictating that detailed information regarding the role of trainees must be provided as part of informed consent. Attending surgeons countered with the argument that informed consent must only include the "responsible" surgeon who will provide supervision and oversight. The proposed legislation was subsequently defeated; to this day, it remains common practice to provide little to no information regarding the role of trainees during the informed consent process. In agreement with other published studies,[6,10-13] our results demonstrated that most patients (87.5%-95.7%) would prefer to be given more information regarding the role of trainees in their medical and surgical care.

In contrast to the finding of overwhelming patient preference for information regarding trainee participation, the available data indicates that this information is rarely volunteered or provided by counseling physicians. Trainees themselves have frequently not volunteered this information, particularly in the setting of obtaining consent for an invasive procedure.[11,14] In a detailed interview of 30 attending surgeons in an academic hospital, Knifed et al[5] found that most (83%) did not volunteer information regarding trainee participation during the informed consent process. They also demonstrated the willingness of attending surgeons to allow active trainee participation, with 87% allowing residents to operate while the attending surgeon was not adequately dressed and washed for surgery but was present and 77% allowing residents to operate when their attending surgeon was not present in the operating room. In our study, these 2 common situations of minimal resident supervision were associated with the lowest consent rates, with only 25.6% and 18.2% of patients indicating a willingness to consent to these respective scenarios. Many previous studies[5,6,9,15,16] of this issue have concluded with arguments for routine and detailed disclosure of information regarding trainee participation during the informed consent process but they provide no data estimating the potential effect of such a policy on consent rates. Our results raise significant concerns regarding the effect of such a policy on resident education and, in particular, the effect on allowing increased levels of autonomy to trainees.

The purpose of this survey was not only to clarify patient preferences but also to attempt to quantify the potential adverse effects of implementing requirements for detailed informed consent. We found that the vast majority of patients would prefer to be given detailed information regarding trainee participation and that this information could change their likelihood to consent. Of concern, we also found that providing this information had the striking effect of decreasing the willingness to consent to having trainees participate, with many scenarios demonstrating a less than 50% affirmative consent rate. It becomes obvious that an unintended consequence of such policies may be harm to surgical education and diminishment of the expertise of graduating surgical trainees.

In a prior study[7] of 199 patients in an emergency department setting, providing additional information re-

garding the trainees' level of experience increased unwillingness to be treated by medical students from 17% to 28% and from 8% to 13% for interns. Our study similarly demonstrated the adverse effects on consent rates of providing detailed resident participation information and demonstrated decreased patient willingness to allow more junior trainees to participate in their care. Of interest, our consent rates for trainee participation (18.2%) were significantly lower than those reported in a previous study.[7] This likely reflects increased apprehension when preparing to undergo a surgical procedure compared with a routine examination in an emergency department or a clinic setting. It also emphasizes the potential for a disproportionately adverse effect on consent rates for surgical specialties. Another interesting finding of our study is the difference between results obtained when asking generalized questions regarding support for the medical education process and/or resident participation compared with more specific and individually relevant questions. When we posed generally worded questions regarding overall support for resident participation, most patients responded affirmatively. The markedly lower consent rates when additional and specific information was given regarding how the trainee will be participating highlights the need to carefully evaluate not only the results of this and other studies but also the exact wording of the questions and response choices.

Although this and other studies[11,17] have found decreased consent rates when additional information regarding trainee participation is provided, it is unclear whether these effects could be counterbalanced by educating patients regarding the positive aspects of care in a teaching setting. Our results suggest that patient understanding and perceptions may significantly affect their attitude toward surgical education. Patients who had been unaware that our facility is a teaching hospital and those who did not believe personal and/or societal benefit would accrue from allowing resident participation in their care were much more likely to be among those highly unwilling to consent. Patient education pertaining to these factors may represent a high-yield target for improving patient understanding and willingness to allow full trainee participation.

In conclusion, our findings confirm those of other series, namely, that patients routinely would prefer to be informed regarding details of trainee participation in their care, and that this information would significantly affect their willingness to consent. This is the first study, to our knowledge, that has quantified the effect on consent rates of providing detailed descriptions of resident participation. Although most patients express an overall willingness to participate in surgical education, wide variations can be observed in the actual consent rates for specific training situations. This decreased willingness to consent and the potential effect on training programs must be considered when discussing policy initiatives aimed at improving informed consent. Several factors regarding patient understanding of training programs and their appreciation of the benefits of participation appear to be linked to willingness to consent; these factors could represent targets for educational efforts. Although we cannot make specific recommendations regarding the appropriateness and the proper level of disclosure regarding resident participation in surgery based on our results and our review of the literature, we believe that broad calls for routine mandated disclosure should be carefully planned and analyzed prior to implementation to avoid any adverse effects on surgical training.

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Informed Consent, Trainees, and the Cost of Full Disclosure

Informed consent is the process of communication between a patient and a physician that results in the patient's authorization or agreement to undergo a specific medical intervention. As a shared decision, it is a critical component in the relationship between surgeons and their patients. Central to informed consent is the idea of autonomy, whereby patients make their own decisions after the physician has detailed the nature of the treatment, its possible alternatives, and its potential risks and benefits. As part of this discussion, it seems obvious that patients would want the extent of involvement of surgical trainees during a surgical procedure to be disclosed, but current ethical and legal requirements for informed consent for care by trainees have not been well elucidated. According to the American Medical Association, the physician is obligated to disclose and to discuss the patient's diagnosis; the nature and purpose of the proposed procedure; and the associated risks and potential benefits of the procedure, its possible alternatives, and of foregoing the procedure. To my knowledge, no specific requirement or guidance exists regarding disclosure of the extent of participation of surgical trainees.

In their article in this issue of the *Archives*, Porta and colleagues[1] provide an interesting study regarding the effect of surgical trainee involvement on patient consent rates. Using an anonymous survey administered to patients scheduled for elective surgical procedures, the authors set out to answer 2 questions: Do patients want to know more about trainee involvement in their surgical procedures? and, Would this information affect patients' decisions of whether to consent? Not surprisingly, patients provided affirmative responses to both questions. The authors then demonstrate how consent rates are adversely affected by the full disclosure of trainee participation, although they do not discuss in depth the implication of these findings. With current discussions regarding mandatory disclosure of the amount of sleep surgeons have had the night before surgery[2] and increasing calls to maximize patient safety, the consent process and level of disclosure of trainee involvement will become a more prominent issue because it lies at the core of the surgeon-patient relationship. How will we address the idea that full disclosure may damage this important relationship?

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