From the Patient’s Perspective: Is There a Need to Improve the Quality of Informed Consent for Surgery in Training Hospitals?

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Abstract

Objective: This study was performed to evaluate the presurgical informed consent process at a training hospital in Jamaica.

Methods: A postoperative survey was administered to all consecutive able and willing adult patients who underwent the presurgical informed consent process with surgical residents during a 5-week period. Information was collected on patient demographics and patients’ perception and satisfaction with the informed consent process.

Results: There were 210 surveys completed. Patients were unaware of the training status of the physician involved with their presurgical informed consent process in 48% of cases. Nineteen (9%) patients were instructed to sign a consent document without any discussion. An attempt was made to secure a signature after some discussion with the remaining 191 patients. Patients reported that details of the operation were discussed 74% of the time; potential benefits of the surgery, 72% of the time; potential morbidity, 84% of the time; potential mortality, 19% of the time; predicted postoperative course, 49% of the time; projected recovery, 26% of the time; and other treatment options, 33% of the time. Forty-five patients believed that they were instructed to sign the consent document with minimal discussion. At termination of the consent process, only 70% of the 210 patients reported that they signed the consent form voluntarily. Overall, 67% of patients thought the current informed consent process was unsatisfactory.

Conclusion: The current informed consent process in use in the surgical training program at the University Hospital of the West Indies requires improvement to meet expected ethical and legal standards.

Introduction

For medical care to be effective, patients must make important decisions about their management. Most patients do not have the requisite medical training necessary to make autonomous decisions about their care. They rely on their attending physicians to share accurate and relevant information with them that will empower them with the ability to choose from several therapeutic options and to make rational decisions about their care in their own best interest. This is the process of informed consent.

Physicians have a legal and ethical responsibility to complete this process before any physical investigations or therapeutic interventions are performed in their patients. Three criteria must be satisfied for the process of informed consent to be effective and valid: 1) capacity, 2) autonomy, and 3) disclosure. Autonomy is the second criterion for effective, valid informed consent. Anglo-American law protects the individual’s right to independent choice and freedom from unwanted intrusion on one’s liberty and self. The process of informed consent is intended to uphold this principle by requiring a capable individual to grant permission for procedures without any element of force, deceit, or coercion.

It is a delicate process that may be easily affected by patient factors such as confidence, cognition, and affect. Clinicians may introduce subtle coercion through their demeanor and body language. Situational duress may arise when patients believe that they have no choice but to accept the treatment offered by health care professionals. This may occur when patients believe that their options are limited by insurance benefits, managed health care restrictions, and even attitudes and/or opinions from health care professionals that may stifle their perceptions of alternatives.

For disclosure, the third criterion for informed consent, each patient must be furnished with sufficient relevant and updated information to enable him/her to make a decision. Although there is no clear guideline, there are two US landmark legal precedents that are instructive on the content of disclosure.

In 1960, the Kansas Supreme Court outlined information that physicians would be required to provide to their patients during the process of informed consent (Natanson v Kline, 1960). This Professional Standard of Disclosure included information on the nature and purpose of proposed treatment, potential benefits and potential risks of treatment, potential benefits and potential risks of treatment, and alternative treatments along with their risks and benefits. In the second land-
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In this setting, any patient requiring a surgical procedure was admitted to the hospital and managed by a surgical team. Each team was headed by at least one attending/consultant surgeon, who managed several surgical residents at various stages in their training. A single resident was given the responsibility to secure informed consent from the patients before any operative procedure. The decision to designate a resident to consent process was not routine during this process.

Approval was obtained from the hospital ethics committee to interview patients for this study without the knowledge of the physicians obtaining informed consent. We identified all consecutive adult patients admitted by the surgical services over 5 weeks from October 3, 2011, to November 7, 2011. Any patient who required a surgical procedure during hospitalization was considered a potential candidate for this study. Patients were excluded from this study if they were younger than age 16 years; deemed incompetent to hold a rational conversation for whatever reason (eg, confused, tracheal intubation with sedation); unable to sign their own consent form for whatever reason; or unwilling to participate in the study. Patients younger than age 16 years were excluded from this study as they were younger than the age at which they could legally give informed consent.

Any patient older than age 65 years was considered “elderly” in keeping with the definition proposed by the World Health Organization. Any patient between age 16 and 65 years was considered a “younger” patient. Permission to participate in this study was sought from any patient who met the inclusion criteria. Independent investigators interviewed the candidates using a standardized questionnaire that sought information regarding patients’ level of satisfaction with the process of informed consent and their perception of disclosure on the need for operation, details of the procedure, risks, complications, and benefits of the operation. (Postgraduate Surgical Training: Improving the Quality of the Process of Informed Consent for Surgery in Training Hospitals questionnaire available at www.fiepermanentejournal.org/files/Fall2013/AuthorQuestionnaire.pdf). Interviews were held either on the third postoperative day or on the day of discharge (whichever was first) so the patients were sufficiently recovered to allow them to reflect on the informed consent process in relation to their hospital experiences.

In this study, we used Weiser’s standardized definition of major surgery that included “any intervention occurring in a hospital operating theatre involving the incision, excision, manipulation, or suturing of tissue, usually requiring general/regional anaesthesia or profound sedation.”

This was a patient-based questionnaire study. Therefore, information on the individual physicians securing informed consent (age, sex, level of training, etc) was not recorded. Data from incomplete questionnaires were not included in the final analysis. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 12.0 (SPSS, Chicago, IL).

**Results**

During the study period, 263 consecutive patients were admitted for a range of operative procedures. After excluding 53 patients who met the exclusion criteria, there were 210 patients interviewed, including 83 men (40%) and 127 women (60%). A total of 74 minor and 136 major operations were performed. The questionnaires were completed fully by all the patients interviewed.

All patients had informed consent taken by surgical residents at different levels of training. Patients were unaware of the training status of the physician involved with their presurgical informed consent process 48% (101/210) of the time. As this was a patient-based questionnaire study, there was no accurate information on the...
They volunteered the following recommendations: consent-seeking physicians should deliberately solicit questions before consent document is signed (37%); there should be better attention to analgesia before the discussion (34%); patients should be asked whether they wish to sign a consent document voluntarily (31%); and there should be more detailed discussion before the consent document is signed (52%). More than 50% of the patients desired better disclosure in the following areas: cost of treatment in 3% of cases (n = 7); expected postoperative recovery in 11% of cases (n = 24); success rates of intended treatment in 16% of cases (n = 33); operative risk in 34% of cases (n = 72); details of the operation in 38% of cases (n = 79); and details about the operating surgeons in 52% cases (n = 109).

**Discussion**

Most postgraduate training programs mandate surgical residents to pass through a series of clinical rotations in which they actively participate in patient care. The training program at the University Hospital of the West Indies is similar, in that surgical residents are expected to secure informed consent before each procedure without specific training in this process. The findings of this study suggest that the current standard of informed consent in this setting is unsatisfactory in 67% of cases. We acknowledge that this finding is based on the patient’s subjective recall of the consent process, which could be influenced by several external factors. Nevertheless, we believe that an unsatisfactory mark in 67% of cases is indicative of a failing process that requires urgent attention.

It is a common misconception that the purpose of informed consent is to secure the patient’s signature on a written consent form to act as security if the need arises. This misconception may have been the reason that 64 patients thought that they were forced to sign a consent document without being allowed to ask questions. There is simply no excuse for the fact that patients reportedly were denied their autonomy 31% of the time. Surgical residents must be reminded that the real purpose of the informed consent process is to provide the patient with meaningful information to empower them to make proper decisions. As such, the validity of the informed consent process depends more on the quality of clinician-patient interaction than on documentation.

We cannot comment on the overall adequacy of disclosure since the study included a heterogeneous case mix and the details for each individual procedure varied widely (indications, expected benefits, morbidity, mortality, etc). However, the finding that 52% of patients desired more detailed disclosure before the consent document was signed is instructive. In the end, the patients are stakeholders in the process and their recommendations on methods to improve the process should be taken seriously. Fortuitously, the patients were able to identify specific pitfalls in the process. Although there may be inherent bias in patient perceptions based on physician-patient interaction, therapeutic outcomes, and patient-related factors, we believe that understanding patient perceptions and attitudes provided valuable insight to areas that needed improvement.

More than 50% of patients (52%) suggested increased disclosure of details about the operating surgeon. Several health professionals at our institution oppose this on the basis that the Jamaican populace is generally aware that the University Hospital of the West Indies is a teaching hospital where patients benefit by gaining access to highly trained academic physicians, experimental therapies, and cost subsidization. In turn, by virtue of their attendance, patients are expected to facilitate medical education through “implied” consent to treatment by surgical residents.

On the other hand, it is our duty as medical educators to uphold ethical principles. Regardless of their knowledge of the background of the University Hospital of the West Indies, patients do not waive their right to autonomy when they enter a teaching institution. In addition, several authorities have found that patients are more accepting of residents’ involvement if their autonomy is preserved through the process of informed consent. Even after patients are made aware of residents’ involvement, they usually remain willing to allow residents to partake in their care with appropriate supervision. Therefore, we support the divulgence of surgeon details because we believe this is in keeping with good ethics-legal practice governing patient interaction during training.

The other patient suggestions of increased disclosure on the cost of treat-
ment, expected postoperative recovery, success rates, operative risk and procedural details are reasonable. In fact, these are legal requirements in Anglo-American law and are fully supported by the Natanson,16 Canterbury,12 and Bolam18 precedents.

The study design did not allow us to determine whether there were a few individuals who repeatedly failed at the consent process. Therefore, we did not target specific physicians for remedial action. Nevertheless, we were able to take a more general approach on the basis of our results; we implemented specific changes in our practice to improve the standard of informed consent. They are described here.

Practice Changes
The five changes we implemented in practice to improve informed consent were as follows:
1. formal training on informed consent
2. introduction to the physician giving consent
3. use of a consent checklist
4. implementation of a two-stage consent process
5. aids to improve understanding and recall.

Formal Training
We introduced formal lectures on informed consent into the training curriculum to expose surgical residents to the nuances of the process. This should be done in the first training year in the hope that the surgical residents would become proficient at an early stage.

Introduction to the Physician Giving Consent
In this study, 48% of patients were unaware of the training status of the physician who discussed informed consent with them. This unfamiliarity is inappropriate because this is the primary process that secures the physician-patient relationship. We currently train our surgical residents that the first step during any consultation, inclusive of the process of informed consent, should be a clear introduction.

Use of a Consent Checklist
To ensure that the relevant information is relayed to the patients, we introduced a checklist (see Sidebar: Standard objectives of informed consent process). Anecdotal experience with local culture has shown that it is common practice for our patients to "go along with" the medical team’s suggestions because “they know best.” Therefore, we make it a point to instruct residents to avoid the temptation to truncate the process at this point and stress to these patients that they must make their own decisions after complete disclosure.

Implementation of a Two-Stage Consent Process
We firmly believe that patients should have sufficient time to process information in a comfortable environment. Additionally, there are existing data suggesting that 75% of clinical negligence solicitors (attorneys) believe that consent should be obtained 2 weeks before an elective procedure.17 Therefore, we now commence the process in the outpatient clinic as a part of a 2-step consent process, with the second step being performed at the time of elective admission for surgery. Whenever possible, Step 1 is performed by the attending surgeon, and it is stressed that it is an ongoing process that continues and strengthens at every point of physician-patient interaction.

Adequate disclosure requires the physician who is obtaining consent to have a certain level of maturity. Obviously, the physician must be sufficiently knowledgeable about the pathology and procedure for proper disclosure. Several authors suggest that only senior surgeons who can perform the operation should take consent.6,13 We believe that it is important for surgical residents to perform this duty and learn this skill during their training, although it is apparent that they require increased supervision and focused training first. Therefore, whenever possible, we now reserve the second stage of the process for ward rounds so that residents can take consent with supervision by the attending surgeon.

Aids to Improve Understanding and Recall
Several aids, including visual aids, diagrams, videos, written/printed material, and the Internet, have been used to increase patient understanding and recall.6,12 One advantage is that patients can voluntarily access this information away from the stressful hospital environment in circumstances under their control.6,35 We now encourage the surgical residents to use drawings and to document written facts on a separate sheet of paper for the patients to keep and to review on his/her own time. Although this practice is encouraged, we remain cognizant that these aids are meant to facilitate but not replace physician-patient dialogue.

The final responsibility to uphold the doctrine of informed consent is solely that of the attending surgeons. As medical educators, we must remember that we are preparing our surgical residents for independent practice in the community. As such, we must ensure that they adhere to ethical and legal guidelines when they interact with patients.

Study Limitations
There were several limitations to this study, some of which have been mentioned already. This study was a patient-based questionnaire study performed in a single institution over a limited period. Therefore, the results may not be extrapolated to other institutions.

**Standard Objectives of Informed Consent Process**

1. Explain the nature of the illness in simple lay terms
2. Explain the reason for the proposed operation and the benefit it is intended to provide
3. Discuss any available alternative treatments and compare them with the treatment you are offering
4. Explain the details of the operative procedure (illustrations and diagrams are useful)
5. Discuss success and failure rates of the operation
6. Discuss the potential complications and risks of the operation and anesthesia
7. Discuss any possible residual effects of the treatment or anesthesia
8. Discuss the anticipated in-hospital and long-term postoperative recovery period
9. Discuss the duration of hospitalization and any incapacitation that may result
10. Explain any other residual effects from the procedure
11. Explain the methods you intend to use to reduce unwanted side effects or complications in the postoperative hospitalization period
12. Encourage questions from the patient and relatives
13. Ask the patient to sign an informed consent form
14. Ask your witness to sign the informed consent form
Second, the study relies on subjective data from patients on their perceptions of the informed consent process. We are cognizant that these impressions may be affected by the in-hospital course, presence of complications, interpersonal relationships established with consent-seeking physicians, and finances. In retrospect, one method to strengthen the study would have been to correlate our results with these objective data.

Third, the study methods did not allow for accurate data collection on the physicians seeking consent. It would have been instructive to record the relationship between patients’ subjective assessment of the informed consent process and the consent-seeking physicians’ level of training, sex, age, and ethnicity. Another method to strengthen the study could have been to analyze the results of “secret shopper” surveys or observations from health care workers who may have witnessed the consent process.

Last, although independent interviewers were used to collect data, the face-to-face interview method could have influenced patients’ responses. The interviews were deliberately held on Day 3 or the day of hospital discharge to allow patients time to reflect on the consent process. Additionally, it was hoped that there would have been sufficient recovery in the way of pain control, mobilization, and return of self-sufficiency to allow patients to focus on the questions about the consent process. On the other hand, longer intervals between the informed consent process and interviews could have clouded patients’ recall of the process.

Conclusions

The current practice of informed consent in this teaching-hospital setting requires improvement to meet the ethical and legal demands of modern medicine. We have attempted to improve our practice by targeting education, increasing supervision, and creating a checklist for this process. A further study will be performed with the recommendations in effect to determine the improvement, if any, provided by these interventions.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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