GENERAL THORACIC SURGERY

AN ENTRUSTMENT MODEL OF CONSENT FOR SURGICAL TREATMENT OF LIFE-THREATENING ILLNESS: PERSPECTIVE OF PATIENTS REQUIRING ESOPHAGECTOMY

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Objective: Consent to treatment has been extensively discussed and prescribed from the viewpoint of law, ethics, and policy experts; the viewpoint of patients is less well represented. The purpose of this study was to describe the process of decision making and consent to surgical treatment from the patients' perspective, in the context of life-threatening illness.

Methods: Face-to-face interviews with 36 patients who had recovered from esophagectomy for cancer at university hospitals in Toronto, Ontario, were analyzed by means of a qualitative analytic approach.

Results: Instead of the accepted model of informed consent and shared decision making, patients identified 6 concepts that describe their experience: (1) cultural belief in surgical cure, (2) enhancement of trust through the referral process, (3) idealization of the specialist surgeon, (4) belief in expertise rather than medical information, (5) resignation to risks of treatment, and (6) acceptance of an expert recommendation as consent to treatment. These concepts were developed into a model of entrustment that unites the narratives of all our patients.

Conclusions: There is a gap between accepted legal and ethical theories concerning consent and the patients' account of their experiences with surgical treatment of esophageal cancer. Although our findings should not be used to circumvent the ethical and legal requirements of the consent process and are limited to survivors of treatment of life-threatening disease, they support a careful reassessment of informed consent that includes the perspective of patients. (*J Thorac Cardiovasc Surg* 2000;120:264-9)

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*The surgeon said, "So, it's your decision."
I said, "I'm going to leave it in your hands."*

—Esophagectomy patient

Every day thousands of doctors help patients with decisions about medical interventions. A voluminous literature reflecting the views of philosophers, bioethicists, and legal scholars provides expert advice. Physicians learn from the literature that they are expected to help patients make "an autonomous authorization . . . of a medical intervention . . ."¹ and to "inform their patients about the nature of their condition and its expected course, about the benefits and risks of the proposed treatment, and of alternative treatment or nontreatment."² The emphasis on

autonomy is accompanied by clear warnings against physician paternalism. Some scholars have questioned the doctrine of informed consent,^{3,4} recognizing problems with the complexity of medical information,⁵ the patient's confusion and vulnerability when he or she is ill,^{6,7} ambiguity and inconsistency among legal interpretations,⁸ and lack of physician compliance.^{3,8} Legal and institutional policy requirements emphasize disclosure of risk and prognosis to prevent lawsuits. Patients may wish to leave worrying about these troublesome matters to the physician.⁷ Practitioners are caught in the middle of this unresolved issue.

The purpose of our study was to learn what patients believe about consent and decision making on the basis of their own experience. We asked postoperative patients to tell us about the values and beliefs that guided their decision making about a serious issue: surgical resection of esophageal cancer. What we found was unexpected. The patients told us that they did not experience shared decision making or informed consent as experts understand these processes. This is the patients' story, as told by them, interpreted by us, then taken back to the patients for confirmation. We present it here to encourage further discussion and clarification of the consent process for treatment of life-threatening illness.

Methods

Participants. We interviewed a convenience sample of patients who had recovered from esophagectomy for esophageal cancer. They came from urban and rural settings throughout the province of Ontario. Patients scheduled for follow-up visits with thoracic surgeons at the University of Toronto hospitals were invited by a letter from their surgeon to participate. All of these surgeons conformed to accepted standards of disclosure and informed consent before the operations. We excluded patients who had undergone an operation within 8 weeks and those who did not speak English; two eligible patients declined the invitation to participate. Participants were enrolled until no new concepts arose during analysis of successive interviews, a concept called "saturation" by qualitative researchers.⁹

Design. Interviews with patients yielded data that we analyzed and developed into a conceptual model. This process, called "grounded theory" by sociologists, is "a general methodology for developing theory that is grounded in data systematically gathered and analyzed." It is appropriately used for data that are conceptually dense and involve social processes.^{9,10} Written informed consent was obtained from participants. The study was approved by the research ethics committees of the participating institutions.

Data collection. We conducted face-to-face semi-structured interviews with each participant. A spouse or family member was often present during the interview; their comments were welcomed as part of the data. The interviewer

asked open-ended questions, followed up participants' responses, pursued themes as they arose, and sought clarification as required. The interview guide was developed with a pilot group of patients. Participants were asked what they thought and felt about their experience with decision making regarding their esophagectomy. As is common practice in qualitative research, the interview guide was modified to follow up issues emerging from the data as the study progressed. Copies of the guide are available from us on request. The interviews were audiotaped, transcribed, rendered anonymous, and kept in secure storage.

Data analysis. The analytic method, called "constant comparisons," was characterized by 3 steps: open, axial, and selective coding. During open coding, the transcripts were read and segments of text that related to a theme or idea were identified and given a conceptual label (eg, surgeon characteristics). During axial coding, similar concepts were grouped into conceptual categories that were developed further through comparisons between categories and between transcripts (eg, idealized surgeon). During selective coding, one core category emerged as the central theme of the study (entrustment), and conceptual relationships with other categories were developed. As is customary in qualitative research, data analysis began after the first interview and continued after all interviews were completed. The analysis was aided by reformatting with *The Ethnograph* computer software.¹¹

We used several techniques to verify the trustworthiness of our findings. During each interview, we summarized for participants what we thought they were saying to ensure that we clearly understood their meaning as well as their words. The primary analysis of the transcripts, conducted by D.K.M., was subjected to frequent critical discussion by both of us. At the end of the study, we conducted a group meeting with 5 study patients to clarify our comparisons between their experience and the models of consent and decision making in the literature and to confirm our choice of quotes to illustrate the patient perspectives. Patients' agreement was required to include each element in the model. On 4 occasions we presented sections of transcripts and their interpretations to an interdisciplinary group of scholars in law, philosophy, bioethics, medicine, nursing, and social science, who are members of the Consent Research Network of the University of Toronto's Joint Centre for Bioethics. Their comments were used to refine our interpretations.

Results

Our patients' sex, age, and extent of disease were typical for patients with esophageal cancer in North America¹² (Table I). Patients with recurrent cancer were included. A wide range of educational and cultural backgrounds was represented.

The concept of patient autonomy did not come up unless the interviewer raised it. When he suggested that textbooks of medicine,¹³ ethics,^{14,15} and law¹⁶ prescribe the processing of information, weighing of alternatives,

Table I. Characteristics of the patient sample (n = 36)

	No.	%*		No.	%*
Sex			Occupation		
Female	8	22	Working	7	19
Male	28	78	Temporarily off work	3	8
			Retired	26	72
Age (median 67.5 y; range 39-83 y)			Marital status		
39-49	4	11	Single	2	6
50-59	5	14	Married	27	75
60-69	16	44	Separated	2	6
70-79	9	25	Divorced	1	3
80-83	2	6	Widowed	4	11
Months postop (median 13.5 mo; range 2-168 mo)			Education		
2-6 mo	12	33	Completed grammar school	3	8
7-12 mo	6	17	Some high school	14	39
13-24 (1-2 y)	4	11	Completed high school	4	11
25-60 (2-3 y)	5	14	Some college/university	6	17
61-96 (5-8 y)	7	19	Completed college/university	5	14
Over 97 (>8 y)	2	6	Graduate/professional degree	4	11

*Percentages do not all sum to 100 because of rounding.

assessment of risks and benefits, and evaluation of advice as part of the patient's responsibility as an autonomous decision maker, our patients rejected these notions as inappropriate to their circumstances.

Entrustment emerged as the core concept uniting the narratives of all our patients. Trust developed as the patients progressed from an initial state of profound vulnerability and distress to a feeling of confidence that the surgeon would make good decisions on their behalf and care for them with a high level of competence and fidelity to their trust. The conceptual model of entrustment that we developed from patients' descriptions of their experience contains 6 elements, illustrated here by verbatim quotes from patient interviews:

Cultural belief in surgical cure. Nearly all of the patients in our study came to their surgeon with a pre-established belief that surgery is required for cure (*"It's cancer; it has to be cut out."*). Support for this belief consisted of anecdotes from friends or family members with cancer in whom nonsurgical treatment seemed to destroy the quality of their residual lives, leading to a degrading death. In contrast, the patients knew of others who were alive and well after surgical treatment.

We asked: "Can you remember what made you think that you had to have surgery?"

Patient: *Oh, it was the diagnosis of . . . a malignancy. The faster you get at that the better. In my case that's the way it turned out.*

Enhancement of trust through the referral process. Patients described a series of visits to various physicians for tests and advice. Typically, symptoms led them to seek help from their family physician, who

indicated that something was seriously wrong and referred them to a local specialist, usually a gastroenterologist or a general surgeon. After a number of tests the local specialist diagnosed esophageal cancer, indicated that a difficult and complicated surgical operation might be necessary, and recommended referral to a specialist surgeon at a university teaching hospital. Patients recalled that presentation of the opportunity for them to choose among alternative treatments undermined their confidence that their doctors *"knew what they were doing."* The stepwise process of referral reinforced the patients' conviction that the problem was very serious and raised their expectations that the next physician at each stage could provide a higher level of skilled help. Our patients experienced at least two referrals before seeing their specialist surgeon. According to the patients, the referring physician recommended the specialist surgeon highly. Patients came to understand that their specialist surgeon embodied the highest available level of skill and expertise.

[The local surgeon] said, *"This is a malignancy, we're sure of that. It requires surgery and it's something I don't really think I should do in [local hospital]. I think you should go to [big city] for it."* When I got down here, the first nurse I spoke to said, *"You got the best one [surgeon]."*

Idealization of the specialist surgeon. All of the patients recounted forming deeply respectful conceptions of their surgeon's character and competence early in the relationship, despite a relatively short period of interpersonal contact. Patients idealized the surgeon, emphasizing positive attributes and minimizing shortcomings.

P: *He's very fast, very good. He's always there.*

Q: What made you think he was very good?

P: *Oh, his manner. (What about his manner?) He's excellent. He's always there. He makes you think that he's only there for you, while at the same time, you know damn well that he's got a stopwatch in his hand. He . . . make(s) the patient feel very good that way.*

Belief in expertise rather than medical information. Patients considered themselves unqualified to process the diagnostic and prognostic information presented to them. Regardless of their level of education or career success, they felt incapable of making suggestions or decisions about their care because they lacked expertise and felt psychologically debilitated by anxiety and fear.

I did not have a clue what they were talking about. It would not have made any difference to me. He knows what he is doing; let him go ahead and do it . . . I can't say "No, I don't think you should do it that way."

As patients proceeded through the referral process to their specialist surgeon, their anxiety and sense of responsibility for making frightening decisions diminished, replaced by trust in the expert consultant.

Resignation to risks of treatment. Patients expressed the view that analyzing risks was irrelevant to their decision. They had to accept the risk and burdens of surgical treatment to escape a miserable death.

I knew that the percentage survival varied between 10% and 50% . . . It was . . . a moot point in the sense that not to get surgery would mean that you would proceed to the level where the odds are 0%. So did I agonize? There was no agonization . . . either you go forward or you fall down . . . to do nothing was to die.

Acceptance of an expert recommendation as consent to treatment. Patients did not perceive themselves to be making an informed decision; they viewed themselves as accepting an expert recommendation. They acknowledged two possible courses: (1) refuse surgical treatment, deteriorate, suffer, and die, or (2) accept surgical treatment. Since the first option was unthinkable, their only question was whether they met the qualifications for an operation.

The patients described themselves as relieved, encouraged, and hopeful when the surgeon recommended an operation. They felt "in control" of the decision process based on trust rather than information.

P: *I didn't know what to do. I just had to go along . . .*

Q: Did you feel out of control?

P: *No. Never.*

Wife: *He basically trusted what they said. (To P) Didn't you?*

P: *Yes, everything they said. You have to . . . what's the sense of going through it if you're going to be worried? I wasn't worried in the least when I went through the operation.*

Discussion

The patients in our study universally described their trust in the competence and willingness of their surgeons to make good treatment decisions on their behalf and to care for them with vigilance. Trust has been defined as the "reliance on others' competence and willingness to look after rather than harm things one cares about which are entrusted to their care"¹⁷; trust provides an "alternative to vigilance and rational calculation of risks, benefits, and alternatives."¹⁸ Across the range of characteristics of our patients' age, sex, level of education, experience with medical care, and outcome of surgical treatment, the patients consistently described the same experience of trust in similar language.

Gastroenterologist and *New England Journal of Medicine* editor Franz Ingelfinger eloquently described a personal experience that reflects the same feelings our patients recalled. Ingelfinger reported how "confused and emotionally distraught" he and his multi-physician family felt when they were expected to make decisions about his own esophageal cancer.

Quote available in print only

Our study extends and deepens the discourse opened by earlier empirical research into patients' views about decision making and consent. The experience of entrustment that our patients described helps explain why Robinson's cardiac surgical patients "yielded . . . decision making to experts,"¹⁹ ignoring or forgetting²⁰ his audiotaped preoperative discussions about risk. In questionnaire-based studies that used hypothetical illnesses of varying severity to assess decision making, the majority of patients thought they would delegate decision making to their doctors; more serious hypothetical illness prompted greater delegation.²¹⁻²³ A

*From Ingelfinger FJ. Arrogance. *N Engl J Med* 1980;303:1507-11. Copyright © 1980 Massachusetts Medical Society. All rights reserved.

study of relatively asymptomatic outpatients in hypertension clinics using structured questions and Likert scale responses found that these patients defer to their physicians for most decisions, especially about initial treatment, but may prefer a more active role after having experience with the medication.²⁴ Our study subjects were more seriously ill and our questions opened; ideas and feelings such as idealization and entrustment emerged that are outside the scope of conventional questionnaires and scales.

Using qualitative methodology to evaluate patients' views about decision making, Lidz and associates²⁵ interviewed and observed surgical and cardiology patients in a university hospital. They concluded that the legal model of informed consent failed "to deal with the realities of medical decision making." Barriers to incorporating the legal model into practice included the extended time course of decision-making processes and the tendency to disclose risks after the patient is emotionally committed to treatment. Rather than test a pre-established model, we used the qualitative analytic approach to develop an explanatory description of the patients' experience. The resulting entrustment model may help reconcile legal theory and medical practice in a patient-centered direction.

The legal model of consent^{5,16} places heavy emphasis on disclosure of risk. For the patients in our study, entrustment was the meaningful process; they signed the consent form to satisfy requirements of the hospitals in which they received their care. The standard bioethics model defines informed consent as "the autonomous authorization of a procedure by an individual patient" and views enabling and protecting individual autonomous choice as "the benchmark of moral adequacy."¹ But the reasonable, autonomous persons envisioned in the cool analytic atmosphere of an ethics seminar or judge's chamber are not the vulnerable "sick human beings" we encountered, whose feelings are well described in Sherlock's insightful analysis of "the case of Mrs. B."⁷ Our patients delegated responsibility for assessing medical information and making treatment decisions to their physicians and surgeons. This exercise of "second order autonomy,"²⁶ that is, making an autonomous choice to delegate decision-making authority to a collective such as one's church or military organization, may logically be applied to the physician-patient relationship.^{26,27}

Katz²⁸ argues that the legal doctrine of informed consent "was not designed as a medical blueprint for interactions between doctors and patients" but was intended as a prod to physicians to fashion a "doctrine that is responsive to the realities of medical practice." Katz recommends that *physicians* "attend to the task of giving

meaning to the requirement of informed consent . . . because it is they who work in the trenches." Our data suggest that the perspectives of sick patients should be included in thoughtful reconsideration of informed consent for serious illnesses like esophageal cancer. As we attend to the task of developing a responsive and realistic approach to informed consent, we can be guided by the viewpoint and needs of those in the trenches with us: patients who are anxiously entering treatment. This is the viewpoint encountered daily by physicians and surgeons, as they work in the gap between legal theory and their clinical estimate of the patients' needs and avidity for medical information.

Limitations. A limitation of this study is that the findings describe the experience of patients who elected to accept major surgery for life-threatening disease; our study participants may have felt more vulnerable, passive, and restricted in their choices than other patients. In general, the selection bias introduced by interviewing patients who have survived treatment and chosen to participate in a study can distort assessment of the decision-making process, especially if treatment failures are excluded.²⁹ However, our sample includes several patients whose treatment was not successful. Some knew their esophagectomies were palliative because unresectable metastases were found at the time of the operation. Some had recurrent cancer causing severe symptoms at the time of their interview. Remarkably, all of these patients reaffirmed the entrustment model, irrespective of the outcome of treatment. Patients with esophageal cancer who did not follow the pathway to surgery and patients with less-threatening disease may hold different views.

In summary, we developed a conceptual model of entrustment from the perspective of patients undergoing surgical treatment for esophageal cancer that captures their experience with decision making and consent. The model contains 6 elements: (1) cultural belief in surgical cure; (2) enhancement of trust through the referral process; (3) idealization of the specialist surgeon; (4) belief in expertise rather than medical information; (5) resignation to risks of treatment; and (6) acceptance of an expert recommendation as consent to treatment. Our model of entrustment should not be construed as subversive to the moral and legal requirement for communication between physicians and patients about the risks of failure, disappointment, or harm from treatment. The need for this respectful conversation³ remains undiminished by our findings. Further development of legal, ethical, and policy frameworks for decision making and consent should include reflective analysis of patients' experience. An effective response to Katz's challenge requires articulation and further

analysis of the viewpoint of physicians and surgeons, as well as exploration of the patients' perspective in a wider range of illnesses and treatments.

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REFERENCES

1. Beauchamp TL, Childress JF. In: Principles of biomedical ethics. 4th ed. New York: Oxford University Press; 1994. p. 142-57.
2. Jonsen AR. In: The birth of bioethics. New York: Oxford University Press; 1998. p. 355.
3. Katz J. In: The silent world of doctor and patient. New York: Free Press; 1984.
4. Veatch RM. Abandoning informed consent. *Hastings Cent Rep* 1995;25:5-12.
5. Dickens BM. Informed consent. In: Downey J, Caulfield T, editors. Canadian health law and policy. Toronto: Butterworth; 1999. p. 117-41.
6. Ingelfinger FJ. Arrogance. *N Engl J Med* 1980;303:1507-11.
7. Sherlock R. Reasonable men and sick human beings. *Am J Med* 1986;80:2-4.
8. White WD. Informed consent: ambiguity in theory and practice. *J Health Polit Policy Law* 1983;8:99-119.
9. Strauss A, Corbin J. Basics of qualitative research: grounded theory procedures and techniques. Beverly Hills: Sage; 1990. p. 188.
10. Strauss A, Corbin J. Grounded theory methodology: an overview. In: Denzin NK, Lincoln YS, editors. *Handbook of qualitative research*. Thousand Oaks: Sage Publications; 1994. p. 273-85.
11. Seidel J. *The Ethnograph*. Amherst: Qualis Research Associates; 1994.
12. Casson AG, McKneally MF. Esophageal cancer: epidemiology. In: Pearson FG, Deslauriers J, Ginsberg RJ, Hiebert CA, McKneally MF, Urschel HC, editors. *Esophageal surgery*. New York: Churchill Livingstone; 1995. p. 551-9.
13. Singer PA, Siegler M. Clinical ethics in the practice of medicine. In: Wyngaarten JB, Plum F, Bennett JC, editors. *Cecil's textbook of medicine*. 20th ed. Philadelphia: WB Saunders; 1995. p. 4-6.
14. Beauchamp TL, Childress JF. Respect for autonomy. In: *Principles of biomedical ethics*. 4th ed. New York: Oxford University Press; 1994. p. 120-88.
15. McCullough LB, Jones JW, Brody BA. Informed consent: autonomous decision making of the surgical patient. In: McCullough LB, Jones JW, Brody BA, editors. *Surgical ethics*. New York: Oxford University Press; 1998. p. 15-37.
16. Picard EI, Robertson GB. Informed consent: the doctor's duty of disclosure. In: *Legal liability of doctors and hospitals in Canada*. 3rd ed. Scarborough [ON]: Carswell; 1996. p. 109-72.
17. Baier A. Trust and antitrust. *Ethics* 1986 (January);96:231-60.
18. Baier A. Trust and its vulnerabilities. In: *Moral prejudices*. Cambridge: Harvard University Press; 1995. p. 130-51.
19. Robinson G. The treating physician's view of informed consent: observations made in a retrospective study. *Conn Med* 1986;50:818-9.
20. Robinson G, Merav A. Informed consent: recall by patients tested postoperatively. *Ann Thorac Surg* 1976;22:209-12.
21. Deber RB, Kraetschmer N, Irvine J. What role do patients wish to play in treatment decision making? *Arch Intern Med* 1996;156:1414-20.
22. Ende J, Kazis L, Ash A, Moskowitz MA. Measuring patients' desire for autonomy: decision making and information-seeking preferences among medical patients. *J Gen Intern Med* 1989;4:23-30.
23. Ende J, Kazis L, Moskowitz MA. Preferences for autonomy when patients are physicians. *J Gen Intern Med* 1990;5:506-9.
24. Strull WM, Lo B, Charles G. Do patients want to participate in medical decision making? *JAMA* 1984;252:2990-4.
25. Lidz CW, Meisel A, Osterweis M, Holden JL, Marx JH, Munetz MR. Barriers to informed consent. *Ann Intern Med* 1983;99:539-43.
26. Childress JF. *Practical reasoning in bioethics*. Bloomington: Indiana University Press; 1997. p. 60-1.
27. White BC, Zimbelman J. Abandoning informed consent: an idea whose time has not yet come. *J Med Philos* 1998;23:477-99.
28. Katz J. Reflections on informed consent: 40 years after its birth. *J Am Coll Surg* 1998;186:466-74.
29. Sackett DL. Bias in analytic research. *J Crohn Dis* 1979;32:51-63.