

Beyond consent—improving understanding in surgical patients

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Abstract

BACKGROUND: Little is known of the actual understanding that underlies patient choices with regard to their surgical treatment. This review explores current knowledge of patient understanding and techniques that may be used to improve this understanding.

METHODS: MEDLINE and PubMed were searched using the terms “patient understanding,” “patient comprehension,” “consent,” “video,” “multimedia,” “patient information leaflet,” “internet,” “test-feedback,” “extended discussion,” “shared decision making,” and “decision aid.” All retrieved peer-reviewed studies were included in the review.

RESULTS: Understanding in surgical patients is poor. There is little evidence to support the use of information leaflets, although multimedia appears to be effective in improving patient understanding. The internet is not used effectively as an aid to consent by health care providers. Patients with lower educational levels may gain most from additional interventions. Improving patient understanding does not impact on their satisfaction with the treatment they have received but may reduce periprocedural anxiety.

CONCLUSIONS: There is a need for greater awareness of patients’ information needs, and novel approaches that may enhance decision making through improved understanding are required.

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Doctors, in building relationships with their patients, seek to gain their confidence and trust. Critical to maintaining this relationship is the recognition by the doctor that the autonomy of the patient should be respected and promoted. This concept underlies the consent process practiced by surgeons daily when engaging their patients in treatment decisions. Patients consenting to intervention should have a reasonable understanding of the nature of the options avail-

able to them, along with the potential risks and outcomes of each option.

Consent, as we know it, owes its origins to a landmark ruling in the United States in 1914.¹ The plaintiff, Mary Schloendorff, was admitted to New York Hospital for assessment of a fibroid tumor and agreed to examination under ether, but did not consent to excision of the tumor. At examination, the physician found the tumor to be malignant and proceeded to remove it. The court found that performing surgery without permission constituted medical battery and Justice Benjamin Cardozo concluded that “every human being of adult years and sound mind has a right to determine what shall be done with his body.” A succession of legal cases led to a shift toward a patient-based standard of

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information and the evolution of “informed consent,” in which the doctor, when making a treatment decision, has a “duty to disclose to the patient all the facts which affect his rights and interests, and of the surgical risk, hazard and danger, if any.”^{2,3} This trend toward a patient-based standard of information and emphasis on the preservation of the patients’ autonomy has been mirrored in other jurisdictions^{4–6} and forms the basis of consent as we know it today.

The consent process is designed to protect the patient for whom intervention is planned by ensuring that the correct decision is made for the individual. Furthermore, the well-informed patient may be better equipped to guard against medical error, thus enhancing their own individual safety.⁷ Although obtaining consent is required to meet legal and ethical obligations, the process also should be embedded in the development of a positive professional relationship between the doctor and patient. In practice, patients frequently do not perceive the process this way, seeing it as an overwhelming bureaucratic hurdle that leaves them feeling disempowered.^{8–10}

The consent process ends with a signature that documents agreement and should indicate that the patient and doctor have discussed and agreed upon a particular course of action.¹¹ Signing the consent form, however, frequently is seen as an act in itself, an obligatory hurdle, often overseen by a junior member of the medical team whose knowledge of the key issues may be poor.¹² Furthermore, patients frequently sign the form without reading it and often do not understand the procedure for which they have offered consent.^{13,14} Although consent before intervention is mandatory, little is known about the actual level of comprehension that underlies patient consent. Here, we report the current knowledge of understanding in patients consenting to surgical intervention, and review the outcomes of strategies designed to improve this understanding.

Methods

A literature search was performed using the MEDLINE and PubMed databases to identify articles reporting assessment of understanding in patients consenting to surgical intervention. The following medical subject headings (MeSH) headings were used: “patient understanding,” “patient comprehension,” and “consent.” The search was expanded using the “Related articles” function in PubMed and through cross-references from retrieved articles. All retrieved articles in English reporting understanding in surgical patients were reviewed.

A second search was performed to identify articles reporting interventions designed to improve understanding in patients consenting to surgical intervention. The original search was expanded using the following free text: “video,” “multimedia,” “patient information leaflet,” “internet,” “test-feedback,” “extended discussion,” “shared decision making,” and “decision aid.” The search was again ex-

panded using the “Related articles” function in PubMed and through cross-references from retrieved articles. All retrieved publication types in English were reviewed.

Understanding in Surgical Patients

In routine clinical practice, patient understanding often is presumed and rarely formally assessed. Braddock et al^{15,16} developed a model to assess 9 key elements of the informed decision-making process and analyzed taped doctor–patient discussions. They found that an assessment of patient understanding is rarely performed and that most decisions fail to meet the criteria for informed decision making.

Studies designed to formally assess understanding have shown that patients frequently are poorly informed. In a study of 200 patients undergoing laparoscopic cholecystectomy to whom written and oral information had been given preoperatively, understanding was assessed by a questionnaire 5 days after surgery.¹⁷ Although 84% of patients were satisfied with the information and believed that they were well informed, only 51% showed a satisfactory knowledge of the procedure and only 30% could list a potential complication. Similarly, poor understanding of the basic information required for consent has been shown in patients undergoing coronary artery bypass grafting, carotid surgery, lower-limb bypass, hip arthroplasty, and varicose vein surgery.^{12,18–21} Mishra et al¹⁸ developed and validated a questionnaire to assess understanding in 41 patients who had consented to surgical myocardial revascularization and found significant deficiencies in key areas such as understanding of options, potential outcomes, and morbidity/mortality risks.

In a study of 32 patients undergoing vascular surgery (femoral popliteal bypass or carotid surgery), patients (n = 9) exposed to standard consent had a mean correct response rate of only 48% on a questionnaire assessing knowledge of potential risks and complications of their surgery.¹⁹ Patients (n = 46) undergoing lower-limb joint replacement surgery were shown in a questionnaire study to have a reasonable understanding of their surgery, but a poor understanding of aspects of postoperative recovery and potential complications (recall for specific complications, 37%–61%).²⁰ The out-patient consultation has been shown to have minimal impact on patients’ misconceptions of the risks varicose veins pose to their health, the unrealistic expectations they hold for varicose vein surgery, or the poor understanding they have of the risks associated with surgery (only a quarter of patients could list any potential complication after the consent process).²¹ In a large population-based study of more than 2,000 patients undergoing surgery for breast cancer, Fagerlin et al²² showed in a postoperative questionnaire that half of patients correctly identified survival after breast-conserving surgery (with radiation treatment) to be the same as after mastectomy, however, less than one fifth of patients knew that the local recurrence rate for the pro-

cedures differed. This finding occurred in the context of 50% of women indicating that their decision was greatly influenced by the desire to reduce disease recurrence.

In a study of patients after open abdominal aortic aneurysm repair, interviews performed using qualitative techniques revealed a number of key themes: patients did not appreciate their options, believed they were not adequately informed, and differed in the information they desired.²³ In a separate study, 18% of patients undergoing aneurysm surgery indicated that they would not have had surgery had they fully understood the recovery process involved.²⁴

Even when patients appear to have reasonable comprehension at the time of giving consent, their understanding has been shown to diminish over time, suggesting perhaps that their comprehension may not have been as complete as it appeared. Six months after joint replacement more than 60% of patients have been shown to be unable to recall either the potential risks or benefits of their surgery.²⁵ It is notable that poor understanding in surgical patients occurs despite a strongly expressed desire by patients to be informed of all potential risks.¹²

In preparing patients for surgery it should be remembered that patients' information needs are frequently greater than we anticipate and their priorities are often at odds with what we believe to be important.^{26–29} Surgeons, for example, although recognizing their patients' need for disease-specific information, have been shown to underestimate their need for information relating to the surgery and the perioperative period.²⁶ After a diagnosis of cancer, patients' priorities shift to knowledge of disease spread and information regarding chances of cure.^{30,31} In patients undergoing colorectal surgery the relative importance that surgeons place on various outcomes such as permanent stoma and incontinence is often not matched by their patients.³² Furthermore, surgeon's choices frequently may be at odds with their patient's inherent and perhaps unrecognized true preference.³³ For example, patients express a stronger desire to avoid chemotherapy than to avoid permanent stoma, whereas doctors express the opposite view.³³

Multimedia decision aids (incorporating patient values into evidence-based data) and trade-off techniques may be used to assess and quantify the relative importance patients place on different outcomes, ultimately facilitating them in making decisions that are true to their inherent preferences.^{32–35} For example, patients undergoing colorectal surgery strongly express a desire to avoid a stoma, with 65% willing to trade a mean of 34% of their life expectancy to avoid this outcome.³⁶

Improving Patient Understanding

A number of tools have been assessed as adjuncts to decision making and consent with a view to improving patient understanding.

Table 1 Randomized controlled trials assessing the role of patient information leaflets as an adjunct to consent

Study	Patients, n	Surgery	Score* %	Significant improvement
Stanley et al ¹⁹ †	32	Vascular	59%	No
Ashraff et al ³⁷	110	Orthopedic	NA	Yes
Langdon et al ³⁸	126	Orthopedic	48%	Yes
Brown et al ³⁹	50	Otologic	51%	No
Mauffrey et al ⁴⁰	53	Orthopedic	96%	Yes

NA = not available.

*Score achieved in patients exposed to information leaflet, expressed as a percentage of the maximum attainable score.

†Patients were randomized into 4 groups: routine information only, added verbal information, added written information, and added written and verbal information.

Patient information leaflets

Information leaflets frequently are used as an adjunct to consent in surgical patients. However, their efficacy in improving patient understanding has been formally reported in only 10 articles, of which just 5 were randomized controlled studies that compared understanding or recall in patients who received written information with that in patients exposed to standard verbal consent^{19,37–40} (Table 1). Leaflets were written information, 1 to 2 pages in length, outlining details of the proposed surgery and recovery, along with potential complications and outcomes.^{37,38} In 2 studies, the leaflet was a written summary of risk,^{39,40} whereas in another study the content of the consent leaflet was not specified.¹⁹ Three of the 5 randomized studies showed a significant improvement in recall among patients who received an information leaflet.^{37,38,40} Even allowing for this improvement, scores for knowledge were generally low, reflecting overall poor recall of information. In one study, although overall significance was reached ($P = .0044$), there was no significant difference between the groups in 6 of the 8 knowledge areas examined.³⁸ In another study scores were worse for the information leaflet group.³⁹ In 1 of the 3 randomized studies that showed a benefit, recall of surgical risk was 96% in the information leaflet group (vs 72% in the verbal consent group).⁴⁰ The high scores achieved reflected the format of assessment used in which recall was assessed using a questionnaire asking patients if they remembered being told about specific complications, to which they answered "yes" or "no." The value of this type of prompted assessment is unclear, and as the authors acknowledged, this was a pure test of recall and not comprehension.

Some nonrandomized studies have shown significantly improved recall in patients exposed to information leaflets^{41,42} whereas others have failed to show a benefit.²⁰ The addition of illustrations to written information leaflets may not enhance patient understanding further.⁴³

Patients who receive leaflets may perceive the information they receive to be of higher quality than those who do not,⁴⁴ but objective assessment of their content has shown

that leaflets frequently do not contain the basic information necessary for informed consent.⁴⁵ Furthermore, evaluation of the readability of leaflets (eg, using readability scores and Plain English Campaign criteria) has shown that they frequently are difficult to read and therefore not accessible to much of their target population.^{46–49} The questionable benefit of even well-designed information leaflets has been noted in critical reviews of their use in other areas such as patient education in screening programs.⁵⁰

Multimedia interventions

Learning may be more complete with simultaneous auditory and visual delivery and comprehension can be enhanced when information is conveyed in multiple forms.⁵¹

Multimedia interventions use a combination of interactive computer programs, videos, and animation, often organized into chapters, some of which may be mandatory whereas others may be tailored to a person's information-seeking preference.

We identified 16 studies reporting the use of multimedia as an adjunct to consent in surgical patients. Nine studies evaluated the use of multimedia education in a randomized fashion^{52–60} (Table 2). In all studies the use of multimedia was associated with a significant improvement in patient recall as assessed by questionnaire. Among patients exposed to multimedia education the average score for understanding ranged from 59% to 82%, when expressed as a percentage of the maximum score attainable (Table 2). The mean improvement in knowledge score (per study) in patients exposed to multimedia was 13.6%, when compared with patients who received standard consent. In 8 of the 9 studies, the assessment of patient understanding was determined by completion of a knowledge questionnaire, but in 1 study this evaluation was subjective and based on patients' self-reported comprehension.⁵² In the latter study the authors acknowledged that this subjective improvement may be misleading because patients who have been exposed to additional information in a nonblinded fashion may believe they are better informed, and as a result may be more likely to overestimate their understanding. One study used

different questionnaires to evaluate recall in the control and multimedia groups,⁵⁵ whereas in another the education level was significantly higher in the group exposed to multimedia.⁵⁴ Rossi et al⁵⁹ repeated their questionnaire at the 1-month follow-up evaluation and found a persistent significant difference between the groups with respect to understanding. Rossi et al⁵⁹ also showed that patients exposed to standard consent are more likely to choose the option "Do not remember hearing this information." Danino et al⁵⁷ showed an overall improvement in comprehension after multimedia education in patients undergoing breast reduction or abdominoplasty, but did not find any benefit with respect to understanding of potential complications. A separate nonrandomized evaluation of preoperative multimedia education in surgical oncology patients found a high degree of satisfaction among patients, but those who had adverse outcomes showed poor recollection of key messages with respect to complications.⁶¹

In nonsurgical patients multimedia interventions have been shown to lead to improved patient understanding when compared with standard consent.⁶² However, in clinical trial participants multimedia has been shown to be of limited value in improving understanding. A recent Cochrane review concluded that there is no evidence that such interventions enhance understanding in this particular patient group.^{63,64}

Patient decision aids

Any of the earlier-described instruments may be used not only to improve patient understanding, but also to facilitate decision making. Decision aids contain detailed evidence-based information pertaining to medical conditions and their treatment that can be delivered to patients using any of the earlier-described or other formats, but in an individualized manner, to facilitate informed choice making.

Decision aids ultimately should help patients to make health care choices that reflect their true treatment preference by helping them recognize the relative importance and value they place on the treatment options and their potential risks and outcomes. Furthermore, they should provide struc-

Table 2 Randomized controlled trials assessing the role of multimedia interventions as an adjunct to consent

Study	Patients	Surgery	Educational	Control	Assessment	Score*	P
Bollschweiler et al ⁵²	76	Cholecystectomy	MM	Standard	Subjective	NA	<.0001
Stergiopoulou et al ⁵³	60	Cholecystectomy	MM	Standard	Objective	NA	<.001
Wilhelm et al ⁵⁴	212	Cholecystectomy	MM	Standard	Objective	66 vs 59%	<.001
Eggers et al ⁵⁵	40	Gastric banding	MM	Standard	Objective	NA	<.05
Luck et al ⁵⁶	150	Colonoscopy	Video	Standard	Objective	82 vs 69%	.0001
Danino et al ⁵⁷	80	Esthetic	CD ROM	Standard	Objective	72 vs 55%	<.001
Keulers et al ⁵⁸	113	Carpal tunnel	MM	Standard	Objective	59 vs 51%	.001
Rossi et al ⁵⁹	48	Ankle fracture	Video	Standard	Objective	78 vs 55%	.0002
Rossi et al ⁶⁰	150	Arthroscopy	Video	Standard	Objective	79 vs 65%	.00001

MM = multimedia; standard = standard verbal consent; NA = not available.

*Educational intervention versus control. Expressed as a percentage of the maximum attainable score.

tured guidance on decision making.⁶⁵ Decision aids are particularly suited to scenarios in which the choice of treatment should be based on the patient's preference (eg, mastectomy vs breast-conserving surgery for early stage breast cancer). Although widely used, there are few reports on the use of decision aids in patients undergoing surgical treatments. Whelan et al⁶⁶ used a "decision board" (written and visual information organized into 4 sections that patients reviewed with their surgeon) in patients with stage I or II breast cancer faced with the choice of mastectomy or breast-conserving surgery. A total of 201 patients were randomized to either the use of a decision board or to usual practice. The information on the board was based on a systematic review of the relevant literature and also on patient information needs that were identified during focus group discussions with women with breast cancer. Patients were encouraged to ask questions and also were given a version of the board to review at home. Patients exposed to the decision board had significantly higher knowledge scores, lower decisional conflict, and higher satisfaction with their decision.

The internet

A recent study showed that approximately one third of patients undergoing routine surgical procedures search the internet spontaneously for additional information despite receiving an information leaflet. In almost one third of these patients the information obtained was a source of worry or confusion.⁶⁷ Surgical information on the internet is frequently of poor quality and may not improve with time.⁶⁸ An evaluation, using a 34-item checklist, of web sites providing information on vasectomy showed a median score (expressed as a percentage of the maximum attainable score) of 14 (range, 0–29) in 2,002 versus 16 (range, 2–35) in 1999.⁶⁸ More recently, an assessment of 49 UK-based web sites providing information on varicose vein treatment found that only 43% of sites discussed all treatment options, complications were usually inadequately discussed, and only 56% discussed cutaneous nerve damage after surgery.⁶⁹

Government-supported web sites have been developed worldwide in an attempt to provide authoritative sources of high-quality web-based medical information (eg, National Health Service [NHS] Direct Online in the United Kingdom; Healthfinder in the United States).⁷⁰ Specialty (non-governmental) organizations also have responded in an attempt to provide reliable up-to-date information to both providers and patients. The British Orthopedic Association recently endorsed a web site (<http://www.orthoconsent.com>) that provides standardized information and consent forms and is accessible to patients and health care professionals.⁷¹ The web site was developed with legal and ethical guidance and in conjunction with the Department of Health in the United Kingdom. Furthermore, individual health care institutions can provide reliable information to both patients and providers. Many decision aids are now available on the internet.⁷⁰ For example, the Ottawa Health Research Insti-

tute web site (<http://decisionaid.ohri.ca>) provides decision aids on more than 100 health topics and provides quality ratings according to International Patient Decision Aids Standards (IPDAS) guidelines. The widespread use of such interactive decision support applications remains limited, however, with the barriers to their uptake remaining unclear.⁷⁰ These reports aside, there is a paucity of scientific analysis on the use of the internet as an adjunct to consent and its role continues to evolve.

Structured informed consent platforms

A structured conversation at the time of obtaining consent may help patients to feel more involved in decision making and improve their attitude toward the process as a whole.^{72,73} Structured consent also allows for standardization of processes and enhanced record keeping, which may protect the physician and ultimately benefit the patient. Automated structured consent tools (eg, iMedconsent, Dialogue Medical Atlanta, GA) are computer-based packages that are widely used in the United States that allow a structured computer-based interview that includes procedure-specific information and also provides a record of consent including a signature. The impact such systems have on patient understanding is unclear.

Repeat back

Using this technique, patients are encouraged to repeat what they have taken from the consent discussion and deficiencies are thus identified so that further discussion aiming to improve understanding can be undertaken. A recent randomized study showed a modest but significant improvement in understanding (71.4% vs 68.2%) in patients exposed to a computer-based consent program (iMedconsent) followed by "repeat back," versus those exposed to the computer program alone.⁷⁴

Comments

Appropriately assisting informed decision making by patients is a professional obligation of the surgeon.⁷⁵ Facilitating patients in shared decision making may help them make choices in keeping with their preferences and values, particularly when the evidence or clinical scenario do not clearly point to a particular treatment option.⁷⁶

Our review of the available literature suggests that surgical patients are often poorly informed about their condition and treatment, and are ill-equipped to make autonomous decisions affecting their care. Furthermore, surgeons' appreciation of their patients' information needs appear to be poor and methodologies to improve and assess this understanding are rarely used.

Although widely used, there is little objective evidence to show that information leaflets contribute significantly to patients' understanding during the consent process.

Our review suggests, however, that multimedia education is effective in improving knowledge in patients undergoing surgical treatment. Multimedia interventions have the advantage of delivering large amounts of information that can be reviewed and re-reviewed. As they become more sophisticated multimedia interventions may allow greater interaction and cater more for individual patient needs. However, these tools can be time consuming and expensive to produce. Repeat back is a simple intervention that appears to improve patient understanding, however, this technique warrants further evaluation in different clinical scenarios. Decision aids can help patients in decision making by allowing probabilistic information to be related to patients' values. The evidence to support the use of decision aids in selected clinical scenarios is clear, but the uptake and evaluation of these tools for surgical patients has been relatively limited. Concerns as to the quality of decision aids exist, particularly with respect to the sources of information used and biases in their presentation. Published criteria should be used to guide the development of new decision aids, or the evaluation of existing aids.⁷⁷ At present, the internet remains an underused resource and logic would suggest that much of the information needed for consent could be internet-based to allow remote access.

In working toward improved patient understanding, deficiencies and inconsistencies in information conveyed to patients should first be addressed. Variability exists in the information conveyed to patients for commonly performed procedures for which the risks and outcomes are clearly understood (eg, abdominal aortic aneurysm surgery and treatment of prostate cancer).^{78,79} During the consultation, it should be remembered that patients frequently are overwhelmed when faced with complex information requiring a decision. Information should be conveyed in as objective a fashion as possible, avoiding framing choices within a certain context but at the same time achieving a balance with information originating from the surgeon's own experience and knowledge.⁸⁰ Effective communication, awareness of the patient's information needs, and awareness of factors that may impact on their understanding are essential. Older age and factors that impact on language understanding such as education and ethnic origin may impact on understanding and treatment decision making,⁸¹⁻⁸³ whereas patients with lower levels of education may gain most when initiatives such as multimedia are used as an adjunct to consent.^{52,54,59,60} Furthermore, the patient's role during decision making impacts on information exchange and ultimately influences the appropriateness of the choice made for the particular patient.⁸⁴ Patients who achieve their desired role are more likely to be satisfied with their treatment choices⁸⁵ and experience long-term quality-of-life benefits.⁸⁶ The informed decision model developed by Braddock et al¹⁵ provides a method of assessing the quality of in-

formed decision making during consultations. Effective consultations discuss the patient's role in decision making, explore the impact of the decision for the patient, discuss the nature of the clinical issue and decision, discuss the options and their relative pros and cons, discuss the uncertainties regarding the alternatives, and include an assessment of the patient's understanding.^{15,16} In orthopedic patients it has been shown that only 57% of consultations meet the minimum requirements for informed decision making set out in these guidelines.¹⁶ Allowing sufficient time during the consultation is a prerequisite, with one study suggesting that comprehension is maximized when the consent process takes between 15 and 30 minutes.⁸³ Finally, it is noteworthy that patients frequently do not raise their concerns during the consultation,⁸⁷ and efforts should be made to encourage patients in this regard. After their review, an opportunity for further discussion may allow engagement oriented around individual needs that facilitates increased transfer of knowledge and improved understanding.⁶³ Ancillary medical staff can play a vital role in this regard during both the initial review and during subsequent discussion when needed,⁸⁸ and thus ultimately reduce the burden on the surgeon.

The introduction of measures designed to improve patient understanding and decision making must be accompanied by an assessment of their efficacy. Measuring patients' understanding and the quality of decision making is difficult and there is currently no accepted standardized means of formally assessing understanding. In most of the studies we identified, the assessment of patient understanding was based on recall of information. Recall does not indicate comprehension, but may be a necessary prerequisite. Furthermore, immediate assessment of knowledge after exposure to educational material may in part reflect learning rather than true understanding.⁶³ True understanding may be assessed by asking patients to explain their understanding, or for example their condition and the treatment options, while at the same time encouraging patients to ask questions and engage in discussion.⁸⁰ Such an assessment cannot easily be included in automated multimedia presentations and requires direct interaction with trained members of the surgical team. Although interaction with a professional may give an indication of patient understanding, there is no universal scale on which comprehension can be assessed objectively. This area has been minimally investigated and requires further evaluation. The patient's knowledge, levels of decisional conflict, and ability to participate in decision making appear to be the best available measures of the efficacy of interventions designed to improve patient understanding.

Interestingly, strategies that effectively improve patient understanding may not impact on their satisfaction with their treatment. Nonrandomized studies have shown high levels (>80%) of patient satisfaction with the information they have received during consent despite objective assessment showing their recall of this information to be poor.^{17,89} A study in patients undergoing cardiac surgery showed that

patients given detailed written information preoperatively were more satisfied with the information they received than those who were given standard information alone.⁹⁰ Of the 9 randomized trials we identified that assessed multimedia intervention as an aid to consent,^{55,58,60} four also assessed patient satisfaction and, although all showed improved recall with multimedia, in only 1 study was this associated with improved satisfaction.⁵⁵

It has been postulated that supplying patients with detailed information regarding procedure risk may cause an increase in perioperative anxiety, but the data that exist (one randomized trial) suggest that this is not the case.⁹¹ Other investigators have argued that empowering patients by supplying them with additional information actually may reduce anxiety. The effect of multimedia interventions on patient anxiety was assessed in 5 of the 9 randomized trials we identified.^{52,53,55–57} In 3 studies^{53,56,57} improved recall was associated with significantly reduced anxiety. One of these studies showed reduced anxiety in patients undergoing colonoscopy who had been exposed to video information.⁵⁶ This finding is in contrast to that of a more recent randomized study that showed no reduction in anxiety in patients exposed to an information video before colonoscopy.⁹² Taken together, these results show that although decision aids and other interventions may improve patients' knowledge, they have little impact on their satisfaction levels, and may not ameliorate anxiety.

Conclusions

Understanding in patients undergoing surgical treatment is poor. Awareness of methodologies such as the informed decision making model may help surgeons to structure and appraise their consultations. Surgeons should have greater awareness of patient factors that may impact on understanding such as age and education. Those with lower levels of education, and those whose initial understanding is poorest, may stand to gain the most from additional educational measures such as multimedia tools at the time of decision making and obtaining consent. The information given to patients to assist them in decision making varies greatly in both content and quality and often is ineffective. Specialty organizations may have a role to play in providing guidelines and supplying evidence-based standardized material that may help improve the overall quality of information available to patients. Such information could readily be modified to meet the needs of individual institutions. In modern productivity-focused health care systems, the pressure on specialists to minimize the time they spend with patients is insidious and difficult to resist. Ensuring that patients are adequately informed in making treatment choices is more challenging for the surgeon than it may appear, and remains an important ethical challenge for the profession.

References

- Schloendorff v Society of New York Hospital 211 N.Y. 125,105 (N.E. 92 1914).
- Canterbury v. Spence 464 F.2d 772 (District of Columbia Court of Appeal 1972).
- Salgo v Leland Stanford Jr University Board of Trustees. 317 P2d 170. (California District Court of Appeal 1957).
- Smith v Tunbridge Wells Health Authority 5 Med LR 334 (1994).
- Chester v Afshar. UKHL;41 (2004).
- Geoghegan v Harris. 31R 536 (2000).
- Benjamin DM. Reducing medication errors and increasing patient safety: case studies in clinical pharmacology. *J Clin Pharmacol* 2003; 43:768–83.
- Akkad A, Jackson C, Kenyon S, et al. Patients' perceptions of written consent: questionnaire study. *BMJ* 2006;333:528.
- Akkad A, Jackson C, Kenyon S, et al. Informed consent for elective and emergency surgery: questionnaire study. *Br J Obstet Gynaecol* 2004;111:1133–8.
- Habiba M, Jackson C, Akkad A, et al. Women's accounts of consenting to surgery: is consent a quality problem? *Qual Saf Health Care* 2004;13:422–7.
- Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent, and simple consent. *Ann Intern Med* 2004;140:54–9.
- Larobina ME, Merry CJ, Negri JC, et al. Is informed consent in cardiac surgery and percutaneous coronary intervention achievable? *Aust N Z J Surg* 2007;77:530–4.
- Lavelle-Jones C, Byrne DJ, Rice P, et al. Factors affecting quality of informed consent. *BMJ* 1993;306:885–90.
- McCormack D, Evoy D, Mulcahy D, et al. An evaluation of patients' comprehension of orthopaedic terminology: implications for informed consent. *J R Coll Surg Edinb* 1997;42:33–5.
- Braddock CH 3rd, Edwards KA, Hasenberg NM, et al. Informed decision making in outpatient practice: time to get back to basics. *JAMA* 1999;282:2313–20.
- Braddock C 3rd, Hudak PL, Feldman JJ, et al. "Surgery is certainly one good option": quality and time-efficiency of informed decision-making in surgery. *J Bone Joint Surg Am* 2008;90:1830–8.
- Kriwanek S, Armbruster C, Beckerhinn P, et al. Patients' assessment and recall of surgical information after laparoscopic cholecystectomy. *Dig Surg* 1998;15:669–73.
- Mishra PK, Ozalp F, Gardner RS, et al. Informed consent in cardiac surgery: is it truly informed? *J Cardiovasc Med [Hagerstown]* 2006; 7:675–81.
- Stanley BM, Walters DJ, Maddern GJ. Informed consent: how much information is enough? *Aust N Z J Surg* 1998;68:788–91.
- Turner P, Williams C. Informed consent: patients listen and read, but what information do they retain? *N Z Med J* 2002;115:U218.
- Dillon MF, Carr CJ, Feeley TM, et al. Impact of the informed consent process on patients' understanding of varicose veins and their treatment. *Ir J Med Sci* 2005;174:23–7.
- Fagerlin A, Lakhani I, Lantz PM, et al. An informed decision? Breast cancer patients and their knowledge about treatment. *Patient Educ Couns* 2006;64:303–12.
- Berman L, Curry L, Gusberg R, et al. Informed consent for abdominal aortic aneurysm repair: the patient's perspective. *J Vasc Surg* 2008; 48:296–302.
- Williamson WK, Nicoloff AD, Taylor LM Jr, et al. Functional outcome after open repair of abdominal aortic aneurysm. *J Vasc Surg* 2001;33:913–20.
- Hutson MM, Blaha JD. Patients' recall of preoperative instruction for informed consent for an operation. *J Bone Joint Surg Am* 1991;73: 160–2.
- Keulers BJ, Scheltinga MR, Houterman S, et al. Surgeons underestimate their patients' desire for preoperative information. *World J Surg* 2008;32:964–70.

27. Montgomery AA, Fahey T. How do patients' treatment preferences compare with those of clinicians? *Qual Health Care* 2001;10(Suppl 1):i39-43.
28. Elstein AS, Chapman GB, Knight SJ. Patients' values and clinical substituted judgments: the case of localized prostate cancer. *Health Psychol* 2005;24(Suppl):S85-92.
29. Devereaux PJ, Anderson DR, Gardner MJ, et al. Differences between perspectives of physicians and patients on anticoagulation in patients with atrial fibrillation: observational study. *BMJ* 2001;323:1218-22.
30. Degner LF, Kristjanson LJ, Bowman D, et al. Information needs and decisional preferences in women with breast cancer. *JAMA* 1997;277:1485-92.
31. Davison BJ, Degner LF, Morgan TR. Information and decision-making preferences of men with prostate cancer. *Oncol Nurs Forum* 1995;22:1401-8.
32. Masya LM, Young JM, Solomon MJ, et al. Preferences for outcomes of treatment for rectal cancer: patient and clinician utilities and their application in an interactive computer-based decision aid. *Dis Colon Rectum* 2009;52:1994-2002.
33. Solomon MJ, Pager CK, Keshava A, et al. What do patients want? Patient preferences and surrogate decision making in the treatment of colorectal cancer. *Dis Colon Rectum* 2003;46:1351-7.
34. Bossema ER, Marijnen CA, Baas-Thijssen MC, et al. Evaluation of the treatment tradeoff method in rectal cancer patients: is surgery preference related to outcome utilities? *Med Decis Making* 2008;28:888-98.
35. Bossema E, Stiggelbout A, Baas-Thijssen M, et al. Patients' preferences for low rectal cancer surgery. *Eur J Surg Oncol* 2008;34:42-8.
36. Harrison JD, Solomon MJ, Young JM, et al. Patient and physician preferences for surgical and adjuvant treatment options for rectal cancer. *Arch Surg* 2008;143:389-94.
37. Ashraff S, Malawa G, Dolan T, et al. Prospective randomised controlled trial on the role of patient information leaflets in obtaining informed consent. *Aust N Z J Surg* 2006;76:139-41.
38. Langdon II, Hardin R, Learmonth ID. Informed consent for total hip arthroplasty: does a written information sheet improve recall by patients? *Ann R Coll Surg Engl* 2002;84:404-8.
39. Brown TF, Massoud E, Bance M. Informed consent in otologic surgery: prospective study of risk recall by patients and impact of written summaries of risk. *J Otolaryngol* 2003;32:368-72.
40. Mauffrey C, Premph EM, John J, et al. The influence of written information during the consenting process on patients' recall of operative risks. A prospective randomised study. *Int Orthop* 2008;32:425-9.
41. Winterton RI, Alaani A, Loke D, et al. Role of information leaflets in improving the practice of informed consent for patients undergoing septoplasty. *J Laryngol Otol* 2007;121:134-7.
42. Layton S, Korsen J. Informed consent in oral and maxillofacial surgery: a study of the value of written warnings. *Br J Oral Maxillofac Surg* 1994;32:34-6.
43. Henry E, Brown T, Bartlett C, et al. Informed consent in otologic surgery: prospective randomized study comparing risk recall with an illustrated handout and a nonillustrated handout. *Otolaryngol Head Neck Surg* 2008;37:273-8.
44. Felley C, Perneger TV, Goulet I, et al. Combined written and oral information prior to gastrointestinal endoscopy compared with oral information alone: a randomized trial. *BMC Gastroenterol* 2008;8:22.
45. Brown H, Ramchandani M, Gillow JT, et al. Are patient information leaflets contributing to informed consent for cataract surgery? *J Med Ethics* 2004;30:218-20.
46. Harwood A, Harrison JE. How readable are orthodontic patient information leaflets? *J Orthod* 2004;31:210-9; discussion, 201.
47. Beaver K, Luker K. Readability of patient information booklets for women with breast cancer. *Patient Educ Couns* 1997;31:95-102.
48. Sarma M, Alpers JH, Prideaux DJ, et al. The comprehensibility of Australian educational literature for patients with asthma. *Med J Aust* 1995;162:360-3.
49. Zion AB, Aiman J. Level of reading difficulty in the American College of Obstetricians and Gynecologists patient education pamphlets. *Obstet Gynecol* 1989;74:955-60.
50. Fox R. Informed choice in screening programmes: do leaflets help? A critical literature review. *J Public Health (Oxf)* 2006;28:309-17.
51. Mayer RE. Cognitive theory and the design of multimedia instruction: an example of the two-way street between cognition and instruction. In: Halpern DF, Hakel MD, eds. *Applying the Science of Learning to University Teaching and Beyond: New Directions for Teaching and Learning*. 1st ed. San Francisco, CA: Jossey-Bass; 2002.
52. Bollschweiler E, Apitzsch J, Obliers R, et al. Improving informed consent of surgical patients using a multimedia-based program? Results of a prospective randomized multicenter study of patients before cholecystectomy. *Ann Surg* 2008;248:205-11.
53. Stergiopoulou A, Birbas K, Katostaras T, et al. The effect of interactive multimedia on preoperative knowledge and postoperative recovery of patients undergoing laparoscopic cholecystectomy. *Methods Inf Med* 2007;46:406-9.
54. Wilhelm D, Gillen S, Wirnhier H, et al. Extended preoperative patient education using a multimedia DVD—impact on patients receiving a laparoscopic cholecystectomy: a randomised controlled trial. *Langenbecks Arch Surg* 2009;394:227-33.
55. Eggers C, Obliers R, Koerfer A, et al. A multimedia tool for the informed consent of patients prior to gastric banding. *Obesity (Silver Spring)* 2007;15:2866-73.
56. Luck A, Pearson S, Maddern G, et al. Effects of video information on precolonoscopy anxiety and knowledge: a randomised trial. *Lancet* 1999;354:2032-5.
57. Danino AM, Chahraoui K, Frachebois L, et al. Effects of an informational CD-ROM on anxiety and knowledge before aesthetic surgery: a randomised trial. *Br J Plast Surg* 2005;58:379-83.
58. Keulers BJ, Welters CF, Spauwen PH, et al. Can face-to-face patient education be replaced by computer-based patient education? A randomised trial. *Patient Educ Couns* 2007;67:176-82.
59. Rossi M, McClellan R, Chou L, et al. Informed consent for ankle fracture surgery: patient comprehension of verbal and videotaped information. *Foot Ankle Int* 2004;25:756-62.
60. Rossi MJ, Guttman D, MacLennan MJ, et al. Video informed consent improves knee arthroscopy patient comprehension. *Arthroscopy* 2005;21:739-43.
61. Evrard S, Mathoulin-Pelissier S, Larue C, et al. Evaluation of a preoperative multimedia information program in surgical oncology. *Eur J Surg Oncol* 2005;31:106-10.
62. Jeste DV, Dunn LB, Folsom DP, et al. Multimedia educational aids for improving consumer knowledge about illness management and treatment decisions: a review of randomized controlled trials. *J Psychiatr Res* 2008;42:1-21.
63. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA* 2004;292:1593-601.
64. Ryan RE, Prictor MJ, McLaughlin KJ, et al. Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane Database Syst Rev* 2008;1:CD003717.
65. O'Connor AM, Bennett CL, Stacey D, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2009;3:CD001431.
66. Whellan T, Levine M, Willan A, et al. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: a randomized trial. *JAMA* 2004;292:435-41.
67. Tamhankar A, Mazari F, Everitt N, et al. Use of the internet by patients undergoing elective hernia repair or cholecystectomy. *Ann R Coll Surg Engl* 2009;91:460.
68. Murphy JO, Sweeney KJ, O'Mahony JC, et al. Surgical informatics on the internet: any improvement? *Surgeon* 2003;1:177-9.
69. Scurr JR, Hufton A, Jeffrey V, et al. www.Accurate information for varicose vein patients.com? *Ann R Coll Surg Engl* 2008;90:554-6.
70. Evans R, Elwyn G, Edwards A. Making interactive decision support for patients a reality. *Inform Prim Care* 2004;12:109-13.

71. [Atrey A, Leslie I, Carvell J, et al. Standardised consent forms on the website of the British Orthopaedic Association. J Bone Joint Surg Br 2008;90:422–3.](#)
72. [Dawes PJ, O’Keefe L, Adcock S. Informed consent: the assessment of two structured interview approaches compared to the current approach. J Laryngol Otol 1992;106:420–4.](#)
73. [Dawes PJ, O’Keefe L, Adcock S. Informed consent: using a structured interview changes patients’ attitudes towards informed consent. J Laryngol Otol 1993;107:775–9.](#)
74. [Fink AS, Prochazka AV, Henderson WG, et al. Enhancement of surgical informed consent by addition of repeat back: a multicenter, randomized controlled clinical trial. Ann Surg 2010;252:27–36.](#)
75. [Medical Council of Ireland. Guide to Professional Conduct and Ethics for Registered Medical Practitioners. 7th ed. Dublin 2: Medical Council of Ireland; 2009.](#)
76. [Lee CN, Ko CY. Beyond outcomes—the appropriateness of surgical care. JAMA 2009;302:1580–1.](#)
77. [Elwyn G, O’Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ 2006;333:417.](#)
78. [Berman L, Dardik A, Bradley EH, et al. Informed consent for abdominal aortic aneurysm repair: assessing variations in surgeon opinion through a national survey. J Vasc Surg 2008;47:287–95.](#)
79. [Feldman-Stewart D, Brundage MD, Hayter C, et al. What the prostate cancer patient should know: variations in urologists’ opinions. Can J Urol 1997;4:438–44.](#)
80. [Childers R, Lipsett PA, Pawlik TM. Informed consent and the surgeon. J Am Coll Surg 2009;208:627–34.](#)
81. [Janz NK, Mujahid MS, Hawley ST, et al. Racial/ethnic differences in adequacy of information and support for women with breast cancer. Cancer 2008;113:1058–67.](#)
82. [Bleicher RJ, Abrahamse P, Hawley ST, et al. The influence of age on the breast surgery decision-making process. Ann Surg Oncol 2008;15:854–62.](#)
83. [Fink AS, Prochazka AV, Henderson WG, et al. Predictors of comprehension during surgical informed consent. J Am Coll Surg 2010;210:919–26.](#)
84. [Hawley ST, Griggs JJ, Hamilton AS, et al. Decision involvement and receipt of mastectomy among racially and ethnically diverse breast cancer patients. J Natl Cancer Inst 2009;101:1337–47.](#)
85. [Keating NL, Guadagnoli E, Landrum MB, et al. Treatment decision making in early-stage breast cancer: should surgeons match patients’ desired level of involvement? J Clin Oncol 2002;20:1473–9.](#)
86. [Hack TF, Degner LF, Watson P, et al. Do patients benefit from participating in medical decision making? Longitudinal follow-up of women with breast cancer. Psychooncology 2006;15:9–19.](#)
87. [Hudak PL, Armstrong K, Braddock C 3rd, et al. Older patients’ unexpressed concerns about orthopaedic surgery. J Bone Joint Surg Am 2008;90:1427–35.](#)
88. [Dartey W, Borase H, Organ A, et al. Preoperative assessment and consent for surgery: a role for the gynaecology nurse-practitioner. J Obstet Gynaecol 2010;30:166–70.](#)
89. [Vohra HA, Ledsham J, Vohra H, et al. Issues concerning consent in patients undergoing cardiac surgery—the need for patient-directed improvements: a UK perspective. Cardiovasc Surg 2003;11:64–9.](#)
90. [Ivarsson B, Larsson S, Luhrs C, et al. Extended written pre-operative information about possible complications at cardiac surgery—do the patients want to know? Eur J Cardiothorac Surg 2005;28:407–14.](#)
91. [Garrud P, Wood M, Stainsby L. Impact of risk information in a patient education leaflet. Patient Educ Couns 2001;43:301–4.](#)
92. [Bytzer P, Lindeberg B. Impact of an information video before colonoscopy on patient satisfaction and anxiety—a randomized trial. Endoscopy 2007;39:710–4.](#)