

**Automating Informed Consent –
Are You Overlooking a Safety Opportunity?**

Neil H. Baum, MD

Associate Clinical Professor of Urology

Tulane Medical School

Louisiana State University Medical School

New Orleans, Louisiana

Timothy Kelly, MS, MBA

Vice President

Dialog Medical

Duluth, Georgia

ABSTRACT

Informed consent is a ubiquitous process that impacts all patients who must undergo a treatment or procedure. The requirements for informed consent are spelled out in the statutes and case law in all 50 states. The manner in which the informed consent process is conducted is also influenced by JCAHO and CMS guidelines. Fully comprehended informed consent is a major patient safety objective that has been recognized by the AHRQ, NQF and The Leapfrog Group.

Automation, such as computerized physician order entry (CPOE), has provided significant opportunities to reduce medical errors; yet one area of care that has resisted automation is the informed consent process. In addition, the traditional, paper-based informed consent process can be the subject of considerable expense including transcription costs, document scanning costs and the costs associated with operating room delays. Healthcare providers can recognize significant advances in patient safety and operating efficiencies via adoption of an automated informed consent solution. Organizations, such as the Department of Veterans Affairs, have achieved marked improvements in quality by automating the informed consent process.

Under a free government at least, the free citizen's first and greatest right, which underlies all others—the right to the inviolability of his person, in other words, his right to himself—is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise, and prescribe (which are at least the necessary first steps in treatment and care), to violate without permission the bodily integrity of his patient by a major or capital operation, placing him under an anesthetic for that purpose, and operating on him without his consent or knowledge. . .

Justice Brown, Appellate Court of Illinois, 1905¹

ORIGINS AND EVOLUTION OF INFORMED CONSENT DOCTRINE

Modern informed consent, as it applies to medical treatments and procedures, has its origin in protection against battery. Opinions such as that of Justice Brown, as stated above, extended the protections against assault and unwanted physical contact to acts committed by physicians without the knowledge or assent of their patients. Since then, courts, legislative bodies, and medical ethicists have expanded the definition of the informed consent process (see Figure 1).

Figure 1

Informed Consent

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and,
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

Source: American Medical Association, Office of the General Counsel, Division of Health Law, www.ama-assn.org, Copyright 1998 and last updated Mar. 07, 2005. Accessed 12-15-05.

Today, informed consent requirements are spelled out in the statutes and case law in all 50 states. Substantial case law exists that defines what a “reasonable” patient should be told², what a patient should comprehend³ and the extent of the physician’s experience that should be communicated⁴. Two states have taken steps to provide guidance as to what risks should be disclosed to a “reasonable” patient. The legislatures of Texas and Louisiana have both created Medical Disclosure Panels (MDPs) that are responsible for establishing a minimum set of risks for various treatments and procedures (see Figure 2). Another example of a state legislature influencing the informed consent process can be found in Pennsylvania’s Medical Care Availability and Reduction of Error (MCARE) Act of 2002, which requires physicians to provide accurate information about their experience, training and credentials whenever a patient asks about a provider’s background.⁵ This legislation is based on the contention that patient knowledge of physician experience with a contemplated treatment or procedure is a vital factor in the informed decision-making process.

Figure 2

Example of Texas Medical Disclosure Panel Mandated Risks

Cholecystectomy with or without common bile duct exploration.

- (A) Pancreatitis.
- (B) Injury to the tube between the liver and the bowel.
- (C) Retained stones in the tube between the liver and the bowel.
- (D) Narrowing or obstruction of the tube between the liver and the bowel.
- (E) Injury to the bowel and/or intestinal obstruction.

Source: Texas Administrative Code. Title 25, Part 7, Chapter 601, Rule §601.2

...our analysis demonstrates that the informed consent forms currently in use provide little substantive content to help patients make decisions, or even meet basic standards for informed consent.

Melissa M. Bottrell, MPH, PhD, et al. (Arch Surg. 2000)⁶

CURRENT STATUS OF INFORMED CONSENT

Many physicians do a sound job of informing their patients and obtaining consent with the bulk of this information being disseminated verbally. Study results also suggest that this verbal communication is typically a one-way process, as physicians have been found to interrupt patients an average of 18 seconds into the patients' descriptions of the presenting problems.⁷ The standard requirement for obtaining a patient’s signature on a consent document risks jeopardizing the focus of the informed consent encounter. It has been observed that in these cases “informed consent is often seen as simply a burdensome administrative practice that involves obtaining a signature on a form for the legal protection of physicians and institutions.”⁸

Written consent documents themselves present a set of unique challenges. A review of 540 written consent forms obtained from 157 hospitals found the necessary elements of informed consent (purpose, risks, benefits, and alternatives) in only 26 percent of the documents.⁹ Another study of patients slated for a radical prostatectomy procedure found that 41.8 percent of the informed consent documents failed to mention any alternative therapies. That same study found that although the potential need for a blood transfusion was disclosed in 90.1 percent of the cases, proper consent for the use of blood products was obtained only 9.9 percent of the time.¹⁰

...informed patients are less likely to experience medical errors by acting as another layer of protection.

AHRQ Evidence Report (2001)¹¹

PATIENT SAFETY AND INFORMED CONSENT

Publication of the 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, catapulted the issue of patient safety to the forefront of public awareness. In response to the IOM report, the Agency for Healthcare Research and Quality (AHRQ) commissioned a report designed to identify the most effective patient safety practices. In 2001, the AHRQ released its evidence report of “best practices.” Of the 79 practices reviewed in the AHRQ evidence report, 11 were rated highest based on the strength of evidence supporting their widespread adoption. One of those 11 patient safety targets was: *missed, incomplete, or not fully comprehended informed consent*, and the corresponding patient safety practice was *asking patient to recall and restate what they have been told during the informed consent process*.¹²

The arguments presented in the literature for enhancing the informed consent process are quite compelling. Better informed patients are more compliant, less anxious, and more satisfied.¹³ Particular attention needs to be paid to the consent form itself, as research suggests that providing informed consent information to patients in written form increases patient comprehension of the procedure.¹⁴ Furthermore, it has been estimated that 45 percent of wrong-site surgeries could be eliminated simply by having a properly completed consent form.¹⁵

The National Quality Forum (NQF) has also recognized the significance of the informed consent process. That organization, which was founded on the recommendation of a presidential commission, is chartered with implementing a national strategy for healthcare quality measurement and reporting. In 2003 the NQF released a report detailing 30 patient safety practices that have strong evidence regarding their effectiveness and which are likely to offer significant patient safety benefits. Those NQF-endorsed safe practices were selected from the AHRQ Evidence Report, and from an open call to health professional specialty societies, and to other organizations. The NQF also recognized the significance of the informed consent process – NQF Safe Practice No. 10 is: *Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion*.¹⁶

Founded in 2000, The Leapfrog Group is a consortium composed of more than 170 companies and organizations that purchase healthcare, representing 36 million covered lives and \$67 billion in healthcare spending. Their mission is to trigger giant leaps in hospital quality and patient safety. To that end, The Leapfrog Group identified and refined four key hospital quality and safety practices:

- Computer Physician Order Entry (CPOE)
- Evidence-Based Hospital Referral (EHR)
- ICU Physician Staffing (IPS)
- The Leapfrog Safe Practices Score

The Leapfrog Safe Practices Score consists of the remaining 27 NQF-endorsed Safe Practices, including NQF Safe Practice No. 10 which outlines the need for enhanced informed consent.

The key quality and safety criteria developed by The Leapfrog Group – CPOE, EHR, IPS and the Safe Practices Score – have been codified in The Leapfrog Group Hospital Quality and Safety Survey. The 2005 survey contains four questions regarding an organization’s approach to the informed consent process.¹⁷ At the end of 2004, this survey had been completed by 862 hospitals with the results available for consumer review on The Leapfrog Group website. Less than one-third of those hospitals (287 institutions) reported that they had fully implemented programs to help meet the goals of NQF Safe Practice No. 10.¹⁸

Informed consent problems are more likely to arise for a doctor who doesn't communicate well.

Michelle Mello, PhD, JD, Harvard School of Public Health¹⁹

LEGAL IMPLICATIONS OF INFORMED CONSENT

Although legal considerations are often the primary influence behind informed consent documents, public accessibility of databases that show a correlation between medical malpractice claims and inadequate informed consent is limited. One large database, tort claims against the Department of Veterans Affairs (VA), has been analyzed in some detail. Between 1989 and 2000, the VA spent an average of \$57.6 million per year on malpractice claims and related legal expenses. Lack of informed consent was cited as a primary cause in 2.7 percent of those claims equating to an annual cost to the VA of \$1.6 million.²⁰

Other studies have shown that informed consent can play at least some role in the majority of malpractice cases. Inadequate informed consent has been found to be a secondary cause in more than 90 percent of ophthalmologic malpractice cases.²¹ Most physicians and hospitals recognize that treatment risks that are not adequately disclosed to a patient, or comprehended by the patient, may ultimately pose a malpractice threat. This is especially true if those risks detail the potential for specific post-surgical complications. One study of medical malpractice claims against urologists found that postoperative complications were the most common claim of negligence.²² Experts

postulate that physicians who do not communicate well with their patients may find those patients more likely to sue, rather than forgive, in the face of a bad outcome.²³

Lack of adequate informed consent is one of the top ten most common reasons for hospital malpractice claims²⁴, and yet it is relatively easy to address. Physicians and institutions should endeavor to have a signed, detailed informed consent document that is written in easy-to-understand language and thoroughly reviewed with the patient. However, a well-executed informed consent document may not by itself provide adequate protection against a claim involving informed consent. A contemporaneously prepared note recording the full informed consent discussion should also be included in the patient's chart.^{25, 26, 27}

In addition to reducing malpractice risk, hospitals can realize financial and operational benefits through a standardized, automated informed consent process.

James E. Gottesman, MD and Robert J. O'Hara, MD (*Most Wired OnLine*, 2005)²⁸

COSTS ASSOCIATED WITH TRADITIONAL INFORMED CONSENT

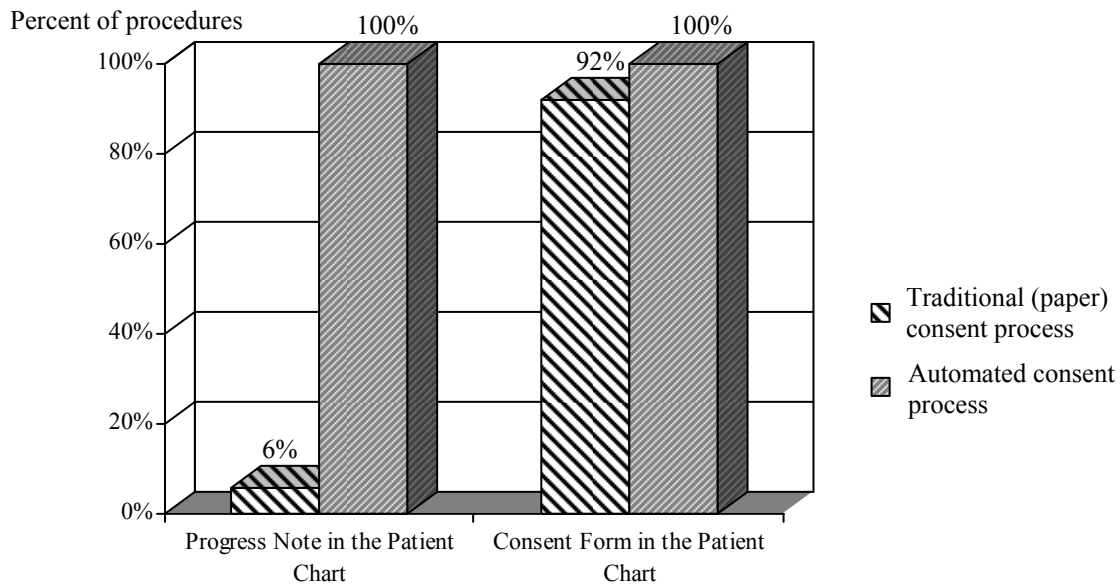
The costs associated with traditional methods of informed consent may vary considerably. There may be costs associated with an imperfect process, which can include incremental legal and malpractice expenses due to inadequate consent, incremental compliance and regulatory outlays resulting from poor documentation and loss of patient goodwill due to inferior patient safety scores. In addition to these difficult-to-quantify costs, very significant costs exist that are associated with a traditional, paper-based informed consent process.

As mentioned previously, the inclusion of a note documenting the informed consent discussion is strongly recommended. In practice, however, the documentation of this critical discussion in the patient's chart occurs quite rarely. The Department of Veterans Affairs, despite having an electronic medical record system that dramatically simplifies the production of progress notes, found that those notes were only prepared six percent of the time when paper-based consent forms were employed (see Figure 3). The factors that most likely come into play concerning the preparation of a note documenting the informed consent discussion were: 1) the time involved in that process, and 2) any incremental costs associated with that process. The cost alone of transcribing an 18-line note documenting an informed consent encounter at \$0.13²⁹ per line is \$2.34. For the physician performing 20 procedures each week, the annual cost of transcribing consent notes alone approaches \$2,340. Furthermore, at only 60 seconds of dictation per encounter, the time spent documenting those encounters slightly exceeds two days each year.

Figure 3

Study of Traditional vs. Automated Informed Consent

(Conducted in two VA Medical Centers)



Source: O'Hara R. Electronic Support for Patient Decisions: Automating and Integrating the Informed Consent Process. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

As more hospitals endeavor to become “paperless”, traditional documents are scanned into the hospital’s document management system. An analysis of the cost of scanning both patient consent forms and advance directive documents in three VA Medical Centers found the average annual cost to be approximately \$80,000 per facility.³⁰ Significantly, a far greater cost is realized when signed informed consent documents are not readily available. An analysis in two VA Medical Centers found that 92 percent of the time the consent form was present in the patient’s chart prior to a procedure; however, that critical document had been lost or misplaced 8 percent of the time (see Figure 3). If a consent form cannot be located prior to a procedure, the patient or a family member will be required to execute a new document. The resulting delay - and at times, postponement of a treatment or procedure - serves to frustrate the clinical staff and can represent significant cost to the institution in terms of lost OR time. In fact, it is estimated that the cost of lost or misplaced consent documents may represent an expense of over one-half million dollars to the average U.S. hospital (see Figure 4).

Figure 4

Annual Cost of Lost or Misplaced Consent Documents

| | |
|---------------------|---|
| 212,000,000 | Procedures performed in the U.S. each year ¹ |
| <u>x</u> 8% | Percentage of consents that are lost or misplaced ² |
| 16,960,000 | Approx. number of lost or misplaced documents |
| | |
| <u>x</u> 10 minutes | OR time spent replacing a lost/misplaced consent |
| 2,826,667 | Hours of wasted OR time each year |
| | |
| <u>x</u> \$1,200 | Average cost of OR time per hour ³ |
| \$3,392,000,000 | Cost of lost or misplaced consent documents in U.S. |
| | |
| <u>÷</u> 5,764 | Number of U.S. hospitals ⁴ |
| \$588,480 | Average Cost per U.S. hospital due to lost or misplaced consent documents |

Sources:

¹ Inpatient Surgery, Data for the U.S. for 2002, National Center for Health Statistics (NCHS) NHAMCS: 2001 Outpatient Department Summary. 2002 Emergency Department Summary.

² O’Hara R. Electronic Support for Patient Decisions: Automating and Integrating the Informed Consent Process. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

³ Salvati EA, Wright TM. *The Journal of Bone and Joint Surgery*. 2003;85(3):428. Brodsky JB. *Anesthesiology* 1998;88(3):834.

⁴ AHA Hospital Statistics. 2004.

In general the informed consent process in use in U.S. healthcare facilities is woefully in need of major improvements in the communication that occurs between providers and patients and in order to ensure that informed patient decision making occurs.

National Quality Forum (2005)³¹

KEY GUIDANCE AND REQUIREMENTS RELATED TO INFORMED CONSENT

Several organizations provide guidance to hospitals and providers on the informed consent process. The requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) carry significant weight with hospitals. JCAHO’s Critical Access Hospital Standards specify that an institution must have an established policy for informed consent (JCAHO Standard RI.2.40). An institution must determine which procedures require informed consent, establish the process for collecting informed consent, specify how consent is to be documented, and address the issue of surrogate decision makers. The JCAHO standard also enumerates the exact elements that must be part of the informed consent discussion.

In May 2004, the requirements placed upon hospitals' informed consent procedures increased with the release of new guidelines from the Centers for Medicare and Medicaid Services (CMS). The Interpretive Guidelines set forth in the State Operations Manual (SOM) – the federal publication employed by state survey agencies charged with determining whether facilities are in compliance with federal health and safety standards – expanded the definition of informed consent. In addition to requiring that informed consent forms contain a description of the procedure, a list of risks, identification of alternatives, and appropriate signatures, the new interpretive guidelines state:

A properly executed informed consent form contains at least the following: Name of patient, and when appropriate, patient's legal guardian; Name of hospital; Name of procedure(s); Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues),³²

Thus, the new Interpretive Guidelines punctuate the need for detailed, procedure-specific consent forms, requiring institutions to pay special attention to procedures involving multiple practitioners.

In September 2005, the National Quality Forum (NQF) provided additional guidance on the informed consent process with the release of an Implementation Report and User's Guide in support of NQF Safe Practice No. 10. The need for this guidance is particularly acute given that fully informed consent remains a rare phenomenon – occurring as infrequently as 9 percent of the time.³³ The two NQF documents detail the efforts of institutions that have implemented mechanisms for confirming patient comprehension of the informed consent process. They also provide specific recommendations for both employing the “teach back” strategy and verifying patient understanding through questioning.

The program has improved patient satisfaction and eliminated the need to track down informed consent documents before surgery.

Sally Kellum, Durham VA Medical Center (*Healthcare IT News*, July 12, 2005)

AUTOMATING THE INFORMED CONSENT PROCESS

Computerized Physician Order Entry (CPOE) systems have long been recognized for the impact that they can make toward reducing medication errors and adverse drug events. Many of the challenges associated with the traditional informed consent process can be addressed equally efficiently via the strategic use of automation. An automated informed consent solution can afford many benefits to an institution, including:

- Ensuring compliance with state statutes relative to the required elements for procedure-specific informed consent forms.
- Complying with the latest patient safety recommendations and permit affirmative responses to safety surveys, such as The Leapfrog Group Hospital Quality and Safety Survey.
- Posting notes documenting the informed consent encounter automatically to the institution's electronic medical record (EMR).
- Storing copies of signed consent forms directly to a document management system or electronic medical record, thus eliminating the costs associated with both document scanning and OR delays resulting from lost or misplaced documents.
- Creating a formal computer-based process that meets JCAHO standards and ensures provider compliance with hospital informed consent policy.
- Meeting the requirements of the CMS Interpretive Guidelines requiring the identification of all practitioners involved in a procedure along with a definition of their responsibilities.
- Facilitating the verification of patient comprehension and automate the documentation of the patient's understating of the risks, alternatives, and other key aspects of proposed treatments in support of NQF Safe Practice No. 10.
- Alleviating the burden of an institution needing to continually maintain and update the clinical content of its informed consent and patient education materials.

Many other benefits can result when an automated informed consent solution is put into practice. Teaching facilities may find that the use of detailed, procedure-specific informed consent forms, coupled with an automated mechanism for confirming patient comprehension, helps ensure that procedures are explained consistently regardless of the tenure and experience of the practitioner obtaining the consent. In addition, automated informed consent systems that produce patient education materials can help alleviate patient fears and provide useful information to family members.³⁴

We owe it to our veterans to do all we can to ensure that they understand the care they receive and to make sure that the informed consent process is as patient-friendly as possible. This new program is a great complement to the success of VA's electronic patient records systems.

Anthony J. Principi, Secretary of Veterans Affairs (September 3, 2004)

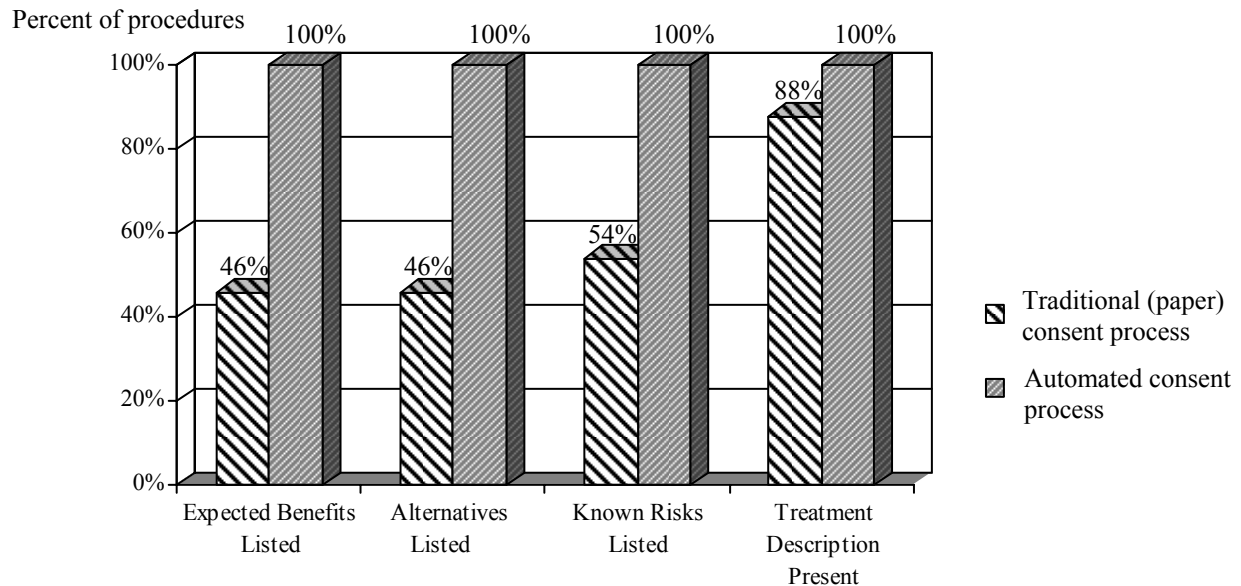
EXPERIENCE WITH AN AUTOMATED INFORMED CONSENT SOLUTION

In 2004 the Department of Veterans Affairs (VA) announced its Electronic Support for Patient Decisions (ESPD) initiative for the 162 VA Medical Centers. The ESPD initiative consisted of standardizing and automating the informed consent process using the iMedConsent™ application (Dialog Medical, Duluth GA). The goals of the

ESPD initiative included enhancing the information provided to patients to allow them to make informed choices about their treatments while simultaneously standardizing that process across the thousands of providers within the VA Health System.

A formal pilot study comparing the traditional paper-based informed consent process to the computer-assisted informed consent solution was conducted in two large VA Medical Centers (Atlanta VAMC and Hines VAMC, Chicago). The expected benefits, key risks and practical alternatives were found to be missing from approximately one-half of the paper-based consent documents. Those same critical elements were present in all of the consent forms generated by the automated informed consent solution (see Figure 5).

Figure 5
Study of Traditional vs. Automated Informed Consent
 (Conducted in two VA Medical Centers)



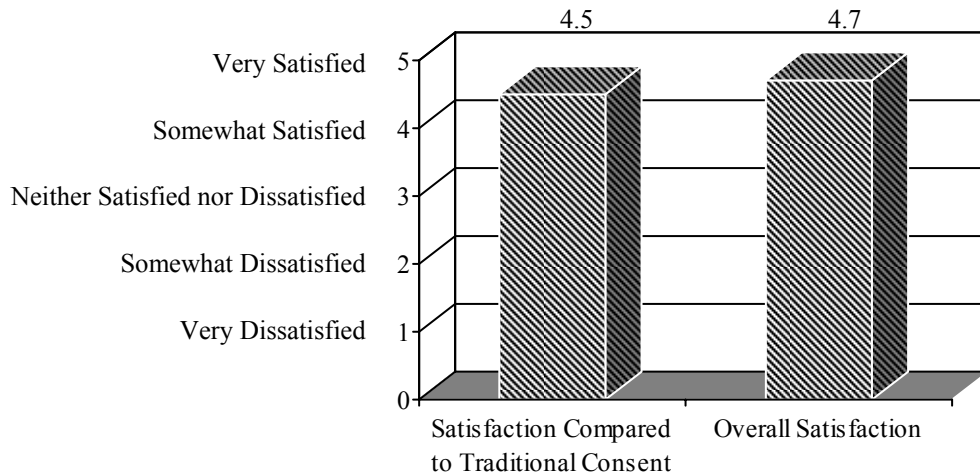
Source: O’Hara R. Electronic Support for Patient Decisions: Automating and Integrating the Informed Consent Process. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

The impact of an automated informed consent system upon practitioner and patient satisfaction was evaluated in a study of urology procedures at a large teaching hospital. Patients undergoing outpatient urology procedures were asked to rate their experience with the automated informed consent system; physicians were asked to evaluate the system in terms of their satisfaction and ease of learning the computer-based approach to the informed consent process. Patients reported very high satisfaction with the automated informed consent system, rating it 4.7 on a scale of 1 to 5 (with 1 being very dissatisfied and 5 being very satisfied). Those patients who had undergone prior

procedures at the institution, and who were thus exposed to both paper-based and computer-assisted processes, rated their satisfaction a 4.5 (see Figure 6). Physicians also reported very high satisfaction with the automated informed consent solution ranking the system a 4.7 and scoring the ease of learning of such a system a 4.9 (see Figure 7).

Figure 6

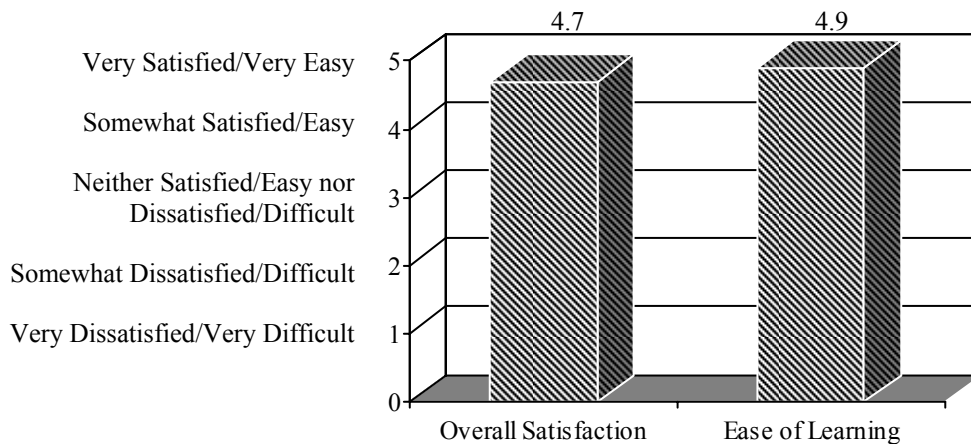
Patient Satisfaction with an Automated Informed Consent Solution



Source: Ritenour C. Experience with an Automated Informed Consent Solution – Impact on Clinical Workflow and Patient Satisfaction. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

Figure 7

Clinician Satisfaction and Ease of Learning with an Automated Informed Consent Solution



Source: Ritenour C. Experience with an Automated Informed Consent Solution – Impact on Clinical Workflow and Patient Satisfaction. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

CONCLUSION

Informed consent is a ubiquitous process that involves virtually every patient who enters a healthcare facility – a process that can have significant effects on patient safety. This typically non-standardized and paper-based process can be dramatically improved through investment in computerization and automation. Automated informed consent solutions enhance safety, ensure compliance, increase efficiency, reduce costs, and strengthen patient and physician satisfaction. The opportunity to positively impact such a critical process is not one that should be overlooked.

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