

Informed Consent, Risk Management, and Technologies for Patient Informing

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Introduction

A substantial proportion of medical malpractice is due to inadequate informed consent rather than true negligence. Despite challenges posed by the episodic, face-to-face delivery model, more effective clinician-patient communications and informed consent processes are attainable. This issue explores informed consent and its relationship to risk management, as well as the benefits of Internet-based physician-patient communication. Such advances that support the informed consent process are core to the “informed care” practice model.

Medical Malpractice: Technical or Communication Errors?

Some 80,000 to 90,000 medical malpractice claims are filed in the United States every year. While unfortunate outcomes do occur, not all malpractice cases involve negligence in the strictest sense. In fact, technical error plays only a small role in malpractice claims (Bhattacharyya). Instead, many lawsuits arise from adverse outcomes that were known risks of certain procedures. In these cases, whether or not the physician adequately informed the patient of such outcomes is at issue.

Research into predictive factors in medical malpractice claims repeatedly demonstrates little to no correlation with the clinician’s technical skills, the quality of care, the complexity of the illness, or the

patient characteristics (Brennan; Entman; Localio; Sloan). Instead, studies suggest that communication between patient and physician and the quality of their relationship are strong predictors in determining whether a patient will sue his or her physician (Hoffman; Tongue).

One key aspect of patient-physician communication is informed consent. Technically, informed consent is a communication process in which the physician discusses the risks and benefits of a test, treatment, or other procedure with the patient. Ideally, this process includes a thorough explanation of this information, discussion of alternatives, assessment of the patient’s capacity to understand the information, and written, signed verification of the patient’s understanding. However, when the informed consent process is inadequate, many patients and their loved ones may feel angry and resentful if adverse outcomes occur. The patient may feel that the physician did not care enough to inform him or her of possible risks or of other available treatment options. For reasons such as these, incomplete or inadequate informed consent is a common basis for medical malpractice cases (National Quality Forum).

Informed Consent Crucial to Risk Management

At the minimum, informed consent involves the disclosure of a procedure’s risks to the patient, culminating with the

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patient’s signature on a consent form. But according to the American Medical Association (AMA), true 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.” Informed consent is both an ethical and a legal issue, and requirements of this process are spelled out in statutes and case law in all 50 states. The AMA’s Office of the General Counsel issued a statement regarding the informed consent process that outlined topics to be disclosed and discussed, as well as considerations regarding documentation forms (see Table 1).

Measurement and documentation of comprehension is crucial to completion of the informed consent process. Physicians can judge a patient’s comprehension by providing him or her with educational

resources, including written materials, Internet-based information, videos, and graphics, and then questioning the patient either verbally or through tests and questionnaires. If the patient demonstrates sufficient comprehension, the process may be completed and documented.

Challenges of Effective Informed Consent

Ideally, the informed consent process proceeds as just described. But the real world of busy patient care can present many roadblocks to effective informed decision making. Physicians may find themselves with little time for thorough discussions and in-depth presentations of treatment options, and they often receive little reimbursement for these efforts. The consent process can be further complicated by the challenge of communicating with patients who have literacy or cultural barriers. In addition, the traditional, episodic, face-

Table 1: AMA’s Statement Regarding Informed Consent

Topics to be Disclosed and Discussed

- 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.

Documenting the Process

- Overly broad consent forms may not preclude assertion that the disclosure didn’t contain risks later discovered after treatment
- Highly detailed / comprehensive list consent forms may be difficult for the patient to understand and omissions will likely be presumed undisclosed

to-face delivery model is not designed to inform patients of risks or encourage them to ask questions, even at a time when the Internet has made patients more information-savvy than ever: “Healthcare has been slow to respond to society’s appetite for communication and has not reorganized itself to provide high-quality information about options and outcomes” (Woolf).

These barriers result in an informed consent process that is inadequate at best. One review of 540 written consent forms from 157 hospitals found that four basic requirements of informed consent (identifying risks, benefits, alternatives, and other aspects of a procedure) were present in only 26 percent of the documents (Bottrell). Other research suggests that even after receiving care or agreeing to receive it, up to 45 percent of patients cannot remember the major risks of surgery, 44 percent do not know the exact nature of their operation, many are unable to answer basic questions about the services or procedures they agreed to receive, and most do not read or understand the information contained in informed consent forms, despite signing them (National Quality Forum). Another study found that 69 percent of people admitted to not having read a consent form before signing it, yet more than half were dissatisfied with the

amount of information they had received (Pizzi).

Patients who feel that they receive inadequate consent are more likely to sue, regardless of whether they have signed a consent form. One study of malpractice claims against orthopedic surgeons found that having a signed consent form alone mattered little in most cases: Twenty-eight claims alleged a lack of informed consent, even though 26 of those 28 patients had signed consent forms (Bhattacharyya). Indeed, the majority of such malpractice cases involve communication issues. Patients may have valid claims even when their adverse outcome is a known complication of a procedure if the physician cannot prove that the patient thoroughly understood the risks involved.

In addition to the malpractice implications of suboptimal informed consent, some studies suggest detrimental impact on quality of care. According to the Institute of Medicine, patients who do not adequately understand their condition and treatment options are four times more likely to experience adverse outcomes, which cost the US healthcare system more than \$58 billion annually.

Benefits of Optimal Informed Consent

Despite the challenges involved, optimal informed decision making is both possible and beneficial. Some rewards are obvious: Physician-patient communication styles have been linked to lower rates of malpractice claims (Pizzi). Research shows that such positive communication both increases patients’ perceptions of physician competence and significantly reduces patients’ intent to sue, regardless of adverse outcomes (Moore).

A successful informed consent process may also reduce litigation through more subtle avenues. Positive communication fosters the sort of relationship that encourages the patient to share in the responsibility for his or her health, which

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Informed Consent Process Often Lacking

- **Consent Forms Often Lack Critical Elements**

74% of procedural consent forms did not contain sufficient information (all four basic components - risks, benefits, alternatives and other procedural details) (Bottrell)

- **Patients Don’t Read Forms**

69% of patients did not read the consent forms they signed (Pizzi)

- **Signed Consent No Guarantee**

26% of 28 claims alleging lack of informed consent had consent forms signed by the patient (Bhattacharyya)

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may in turn reduce litigation (Bottrell). Providing the patient with complete and understandable information and assessing the patient’s understanding of his or her condition, diagnosis, and treatment options activates the patient to team with the physician and own his or her health maintenance, potentially making the patient less likely to place blame for adverse outcomes solely on the physician (Hoffman). Research suggests that physicians with no malpractice claims tend to do more to facilitate patient participation than do those who have been sued (Wissow).

Well-informed patients also have enhanced understanding of the need for compliance. By educating the patient on the need for compliance, the physician increases the chances that the patient will follow directions and adhere to treatment regimens. Anecdotal evidence suggests that patients who have been made aware of their condition and treatment options are more compliant with medical advice and generally recover faster.

Technology’s Role in Informed Consent and Risk Management

Time constraints, limited reimbursement, low literacy, and cultural barriers create a situation where physicians may be less likely to provide optimal informed consent. In addition to an inadequate informed consent process on the physician’s

part, many patients admittedly do not read or comprehend informed consent forms before they sign them (National Quality Forum; Pizzi). At the same time, technology—in particular, the Internet—is playing an increasingly larger role in patients’ search for health-related information. Most Americans under age 70 use the Internet and have expressed interest in communicating with their physician online (Pew). The convergence of these two trends presents the opportunity for physicians to enhance patient counseling with web-based applications and decision-making tools. Healthcare information technologies, and in particular Internet-based clinical portals, offer effective adjuncts and thus viable solutions to the challenges of achieving optimal informed consent.

Internet tools and portals include stand-alone communication tools (secure email), practice websites (patient portals), and integrated communication tools that combine both in the form of secure websites with messaging capabilities. Integrated communication tools may offer patients access to their medical records, along with pre-visit questionnaires, pre- and post-op instructions, risk assessments, medication logs, and educational materials (MacDonald).

There are several ways in which Internet portals—and integrated communication tools in particular—can support the informed consent process and therefore potentially reduce liability risk. First, Internet portals enhance a patient’s learning process. Web-based decision aids offer physicians a balanced format for presenting unbiased, accurate, and up-to-date information about a patient’s condition and test and treatment options. Because these tools can be accessed at the patient’s convenience, they also allow the physician to extend informed consent counseling beyond the time constraints of busy offices, allowing the patient time to digest and reflect upon the information being presented (Woolf). By directing the patient

How Internet Portals Can Improve Consent and Lower Liability Risk

- **Improved patient understanding**
24/7, convenient web access promotes comprehension and review
- **Documentation of patient review and understanding**
Internet-guided content and quizzes automatically document clinician’s “information prescription” and patient’s responses
- **Patient appreciation and enhanced patient relationships**
Studies indicate that patients’ decisions to sue are tied to their relationships with their physician

“In one survey, 57 percent of patients stated that a website containing health information had improved their relationship with their physician and 84 percent believed that the site better helped them understand their condition.”

to Internet-based educational materials and then discussing this material with the patient, physicians gain an added layer of assurance that the patient understands the risks, benefits, alternatives, and responsibilities of specific treatment options.

Second, Internet portals provide both physician and patient with documentation of this part of the informed consent process. This is useful from a legal perspective and also allows patients to refer to Internet-based educational materials and increase their comprehension of the information (Baum).

Third, although assessment of a patient’s understanding of a procedure or treatment is a crucial aspect of informed consent, studies show that many patients do not understand or remember this information, despite signing consent forms (National Quality Forum; Pizzi). Internet portals offer a novel and effective way for patients to retain information: Web-based educational materials can include quizzes, questionnaires, patient-physician email messaging capabilities, and other tools that engage the patient and assess his or her comprehension of the information.

Email messaging between physician and patient further increases the patient’s ability to understand critical information. Patients may not remember to ask questions during a face-to-face encounter, then recall their concerns after leaving the physician’s office. Two-way email capability allows the patient to query the physician about information received at the office visit or read in physician-directed educational materials. This in turn results in better-focused face-to-face encounters and reduced call volumes at practices and helps ensure that the patient fully comprehends his or her procedure or treatment.

Lastly, Internet portals may increase patients’ appreciation of physicians and help improve physician-patient relationships. Online communications create additional opportunities for patients to

connect with their physicians. Patients who receive online education tend to be more comfortable taking part in their own care (Forkner-Dunn). In fact, studies show that decision aids, such as interactive software and Internet applications, can increase patient participation in the informed consent process (Woolf). As described previously, increased patient involvement in this process can foster feelings of responsibility for one’s health as well as reduce the likelihood of malpractice litigation.

Although more studies are needed on the effect of Internet portals on malpractice claims, preliminary figures from surveys on the subject suggest that Internet-based educational materials can have impressive effects on patients’ comprehension of medical information as well as on their relationship with their physician. In one survey, for example, 57 percent of patients stated that a website containing health information had improved their relationship with their physician and 84 percent believed that the site better helped them understand their condition (NorthPoint Domain). A larger survey found that 92 percent of patients reported increased confidence in their ability to take care of themselves while 68 percent said the health website studied increased their knowledge to make a positive lifestyle change (Gwinn). Numbers like these show the promise of Internet portals as an effective tool for both physicians and patients in the informed consent process.

Conclusion

Inadequately informing patients of the risks and benefits of procedures is a common cause of malpractice claims. However, physicians can reduce the risk of litigation by fostering good relationships with patients, improving communication, and supporting patient understanding and engagement through the use of educational materials and decision aids.

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