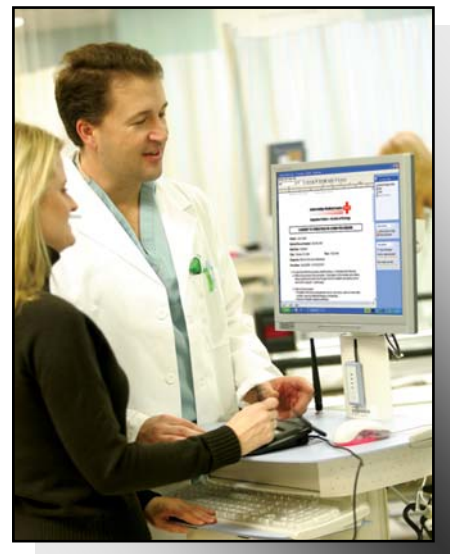


# Healthcare's Most Expensive Piece of Paper



A Strategy for Lowering  
Costs, Reducing Risk, and  
Enhancing Safety by  
Automating the Informed  
Consent Process

## Executive Summary

Obtaining informed consent is a ubiquitous process that forms the cornerstone of medical documentation. This process impacts every patient who enters a healthcare facility to receive a treatment or procedure. The product of this process is typically a signed, informed consent form – *healthcare's most expensive piece of paper*.

Unlike any other process in an institution, the informed consent process impacts a hospital's: accreditation requirements, compliance with CMS conditions, medical malpractice risk, traditional paper-based workflow costs, potential for avoiding wrong-site surgery, operating room efficiency, and ability to successfully capture all appropriate charges. This paper will examine these key issues and detail the ways an automated informed consent application can help ensure compliance, lower risk, enhance safety, improve efficiency, and reduce costs.

## Accreditation

Nearly 15,000 healthcare organizations and programs employ the Joint Commission for evaluation and accreditation. The survey process is expensive, costing the average 500-bed institution \$80,000 to \$100,000.<sup>1</sup> Thus, most hospitals invest significant effort to ensure that their informed consent policies comply with the standards set forth by the Joint Commission – primarily, standard RI.2.40 (see Figure 1). Other Joint Commission standards may also impact the informed consent process, including: Standard RI.2.50 (consent for recording or filming) and Standard PC.6.10 (requirement to provide sufficient information to allow patient to make decisions).

**Use of an automated informed consent application ensures compliance with Joint Commission standards and ensures that providers can respond appropriately during unannounced surveys.**

Many healthcare institutions find that the most effective way to ensure compliance with Joint Commission standards for obtaining and documenting informed consent is to employ an automated informed consent application. The everyday use of automated systems yields additional benefits during a survey. In 2006, the Joint Commission changed its policy so that all triennial accreditation visits are unannounced. In addition, Joint Commission auditors employ a "tracer methodology" during audits. Upon arrival at a hospital, surveyors will request a list of all active patients. The surveyors will then select representative patients and "trace" those patients' courses of treatment through the facility. This survey methodology brings intense scrutiny to areas of patient "hand-offs" and care coordination. It is essential that any provider can respond to a surveyor's request to provide evidence that

### Figure 1. Joint Commission Standard RI.2.40 – Informed Consent

#### Elements of Performance

1. The hospital's policy describes:
  - which procedures require consent;
  - the process to obtain consent;
  - how consent is documented;
  - when surrogates may provide consent; and
  - when procedures may be performed without prior consent.
2. Informed consent is obtained and documented.
3. A complete consent process includes a discussion of the following:
  - Nature of the proposed treatment or procedure
  - Potential benefits
  - Potential risks
  - Likelihood of achieving goals
  - Reasonable alternatives, including the risks and benefits of the alternatives
  - Any limitations on confidentiality

2007 Hospital Accreditation Standards. Oakbrook Terrace, IL: Joint Commission Resources, 2007.

informed consent for a given treatment or procedure has been obtained.

Healthcare institutions that have implemented automated informed consent applications have easily met Joint Commission surveyors' demands during prospective, real-time, and evidence-driven audits.<sup>2</sup> These institutions have demonstrated that hand-offs and service delivery are seamless, and that appropriate documentation of informed consent exists as patient care is delivered across the continuum.

### CMS Compliance

The nation's Medicare and Medicaid programs represented \$684 billion in healthcare spending in 2006.<sup>3</sup>

Approximately one-third of those funds are spent in hospitals.<sup>4</sup> Thus, it is incumbent on healthcare institutions to ensure that they are reimbursed for the services that they provide to the nation's elderly, poor, and disabled.

The Centers for Medicare and Medicaid Services (CMS) charges state healthcare agencies with ensuring institutional adherence to Conditions of Participation (CoPs). CoPs are minimum health and safety standards that hospitals must meet in order to participate in the Medicare and Medicaid programs. CMS publishes a State Operations Manual (SOP) that guides state surveyors in interpreting the CoPs. Appendix A of the CMS SOP moves beyond a discussion of the informed consent process; it specifies the elements that should be present on the informed consent form itself (see Figure 2). These recommended elements punctuate the need for detailed, procedure-specific consent

forms, which are best produced by an automated informed consent application. Compliance with informed consent guidelines is essential to a hospital's eligibility for CMS reimbursement.<sup>5</sup>

#### Figure 2. CMS Recommendations for an Institution's Informed Consent Form

A well-designed and properly executed informed consent form contains the following:

- Patient and/or legal representative name
- Hospital name
- Procedure or treatment name(s)
- Name of practitioner(s) performing the procedure(s)
- Name of practitioner who conducted the informed consent discussion
- List of the material risks
- Statement that the procedure or treatment, risks, benefits, and alternatives were explained to the patient
- Statement that other physicians, including residents, who will perform tasks related to the surgery, will do so based on their skill set and under supervision
- Statement that practitioners, who are not physicians, and who perform important parts of the surgery, will do so within the scope of their practice and hospital-granted privileges
- Date and time
- Signature of patient or legal representative
- Signature of witness

State Operations Manual. Interpretive Guidelines for Medical Records §482.24(c)(2)(v). (Revised 4-13-07). Centers for Medicare and Medicaid Services.

### Medical Malpractice Risk

According to a large medical malpractice insurer, one in every six physicians is subject to a medical malpractice claim each year. The frequency of claims is significantly higher for high-risk specialties: one in two neurosurgeons will be subject to a medical malpractice claim each year, as will one in three obstetricians, emergency room physicians, trauma surgeons, and orthopedic surgeons.<sup>6</sup> The location where alleged injuries occur is of great interest to hospitals.

**50% to 65% of injuries that result in malpractice claims occur in hospitals.**

Malpractice insurance providers in seven states are required by state law to submit data on closed malpractice claims. Those states, in turn, provide that data to the U.S. Department of Justice. A review of that data suggests that injuries are most likely to occur in the hospital setting, which accounts for approximately 50 to 65 percent of all injuries (see Figure 3).

The majority of medical malpractice claims consist of a claim of negligence. The plaintiff alleges injury due to an unexpected outcome. Many of these claims further allege that the potential for the negative outcome was not communicated to the patient. Similarly, plaintiffs will often allege that the availability of alternative treatments – treatments that may not be associated with the actual outcome – was not communicated. Thus, lack of informed consent is frequently a claim in these cases. Studies bear this out; inadequate informed consent has been found to be a secondary cause in more than 90 percent of ophthalmologic malpractice cases.<sup>7</sup>

Failure to obtain informed consent is one of the top ten reasons why medical malpractice claims are filed against hospitals.<sup>8</sup> The reasons for claims involving inadequate documentation of informed consent can vary significantly. A recent Risk Analysis report prepared by ECRI, a nonprofit health services research agency, detailed several representative jury awards:<sup>9</sup>

- \$150,000 for failing to disclose an alternative treatment to a urology procedure (Pennsylvania).
- \$547,000 for a missing consent form for laparoscopic gynecologic surgery (Maryland).
- \$1.8 million for failing to disclose relevant risks prior to spinal surgery (New Jersey).

Key to minimizing the risk of a lawsuit is good communication between physician and patient.<sup>10</sup> Other factors, including where informed consent is obtained and how the informed consent discussion is documented, are also critical. A recent study of 28 lawsuits alleging inadequate informed consent yielded two statistically significant findings:<sup>11</sup>

- Consent should be obtained in the physician's office as opposed to the preoperative holding area. Failing to obtain consent in the office can result in incremental legal expenses and indemnity payments of up to \$322,000.
- The informed consent discussion should be documented in the office or in the operative notes, in addition to being documented on the signed consent form. Failing to have that supplemental note can result in incremental costs associated with litigation of up to \$454,000.

**Figure 3. Facility Where Injury Occurred – Closed Medical Malpractice Insurance Claims, 2000-2004**

	Florida	Missouri	Illinois <sup>†</sup>
Hospital	65.9%	62.0%	49.6%
Inpatient Facility	50.6%	49.2%	42.2%
Outpatient Facility	4.8%	3.4%	4.4%
Emergency Room	10.5%	9.4%	3.0%
Physician's Office	10.1	20.1%	24.0%
Other*	24.0	17.9%	26.4%

\*Includes nursing homes, patient's homes, other outpatient facilities and facilities not identified by the states.

<sup>†</sup>Illinois data for physicians and surgeons only. Florida and Missouri data is for any healthcare provider.

Cohen TH, Hughes KA. Medical malpractice insurance claims in seven states, 2000-2004. Bureau of Justice Statistic Special Report. Washington DC: U.S. Department of Justice. NCJ 216339. March 2007.

**To reduce medical malpractice risk, it is essential that hospitals employ automated informed consent systems that facilitate obtaining consent in the physician's office and produce a supplemental note in addition to the signed consent form.**

The recommendation to have a contemporaneously prepared note that details the informed consent discussion has been echoed by other experts who note that a signed consent form alone does not provide adequate documentation of the informed consent process.<sup>12,13</sup> The solution for hospitals is to employ an automated informed consent application that can be easily accessed by physicians in their remote offices. The informed consent discussion will then result in a detailed, signed document prepared on the hospital's template consent form. In addition, the critical note, documenting that informed consent discussion, is automatically prepared by the informed consent software. That note is then available for printing and inclusion in the patient's chart or it is automatically placed in the patient's electronic medical record.

### Eliminating Paper

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.<sup>14</sup> Somewhat more challenging to quantify are the costs of handling both the signed paper consent forms and the blank forms. Even if a document management system is in place, signed consent

**Scanning informed consent forms and advance directives costs the average hospital \$80,000 per year.**

forms, which contain confidential information about patients and their conditions, must be destroyed in a manner that is compliant with the institution's HIPAA security procedures. Blank forms, too, pose their own unique problems for organizations. Blank, paper-based consent forms typically "hide" throughout a hospital, if those forms are changed or updated, quality personnel are challenged with locating those outdated documents throughout the organization and destroying them, so that outdated documents, or multiple standards of care, are not employed.

### Wrong-Site Surgery

A study published in 2006 found that the incidence of wrong-site surgery remains high, occurring once in every 112,994 operations.<sup>15</sup> Encouragingly, informed consent can play a key role in reducing the incidence of wrong-patient/wrong-procedure/wrong-site surgeries. The informed consent discussion affords providers an exceptional opportunity to confirm the patient's understanding of the planned procedure and the specific anatomical location(s) that will be affected. By employing a procedure-specific consent form, providers are afforded a unique opportunity to corroborate the patient's expectations for procedure type and surgical location. It has been estimated that 45 percent of wrong-site surgeries could be eliminated simply by having a properly completed consent form.<sup>16</sup>

**45 percent of wrong-site surgeries can be avoided with a properly completed consent form.**

Certain opportunities exist for leveraging the use of an automated informed consent application to assist with the "Time Out" process specified by the Universal Protocol For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ (Universal Protocol™).<sup>17</sup> A note, automatically generated by an electronic informed consent application, can be used by the surgical team to verify the patient, the procedure, and the operative site. The operating room team can review that note on a computer monitor, which affords convenient access to the Electronic Medical Record, or on paper printout prior to the start of a case.<sup>18</sup>

### **Operating Room Efficiency**

It is well known that most surgeons prefer to perform cases at the very start of the day, this practice frees afternoons for office visits and also ensures that the days' schedule will not be impacted by cases that run long or fail to start on time. A major source of operating room inefficiency is delays due to lost or misplaced consent forms. Although occurring only eight percent of the time in one study, the expenses associated with lost revenue and inefficient use of OR resources due to lost or misplaced consent documents is estimated to be \$580,000 per year for the average U.S. hospital.<sup>19</sup> The use of an automated informed consent application ensures that the note documenting the informed consent encounter is always present in the patient's chart or in the electronic medical record (EMR) and that additional copies of the signed consent document are always instantly retrievable from the document management system.

**\$580,000 – the average annual cost of lost or misplaced informed consent documents.**

### **Charge Capture**

Informed consent is obtained from patients for all procedures that pose more than a minimal risk to the patient. More and more, procedures of some complexity, that do involve some risk, are being performed at the bedside. These procedures range from paracentesis to insertion of a PICC line to obtaining a biopsy. With these more invasive procedures, sound financial management requires consistent charge capture for both the provider and the institution. An automated informed consent application can assist in this regard. Given that the patient's consent must be documented for these treatments, an automated informed consent application can ensure that these procedures are accurately documented on the patient's record so that charges may be apportioned appropriately.<sup>20</sup> An automated informed consent application can also prompt the formal, documented "Time Out" process to confirm the correct site, the correct patient, and the correct procedure. Thus, the automated informed consent application also facilitates the auditability of the processes governed by the Joint Commission's Universal Protocol™ - processes that may well occur outside of the operating room.

**An automated informed consent application, integrated with an EMR, can ensure that appropriate charges for procedures performed at the bedside are captured by the institution.**

### **Automated Informed Consent**

An automated informed consent application, such as the iMedConsent™ application (Dialog Medical, Duluth, GA), typically consists of two components: the software application itself and the clinical content library. The application will typically be customized for a given institution to facilitate integration with other software applications and systems. Meanwhile, the clinical content library reflects the standard of care for informed consent that is practiced by thousands of physicians. It has been theorized that consistent use of the same clinical content throughout the enterprise and across the country, provides "herd immunity" against claims of inadequate informed consent.<sup>21</sup>

### Software Application

An automated informed consent application, such as the iMedConsent™ application, consists of a core subset of features and functionality that include the following:

- Ability to produce and store documents in paper-based or paperless configurations
- Flexible means for implementing the application, including web-based, server-based, and workstation-based architectures
- Capability to interface with key hospital applications including the EMR, OR scheduling system, document management system, and patient information systems
- Support for the distributed use of the application in affiliated clinics and the remote offices of physicians with privileges at the subject hospital
- Capacity to reconcile patients for whom consent is obtained and who do not have a medical record in place at the facility
- Functionality to confirm and document patient understanding of what is discussed during the informed consent process
- Ability to document the presence of multiple providers and enumerate their specific surgical tasks for complex procedures
- Means to allow for the customization and automation of common hospital forms (e.g., HIPAA forms, Advance Directives, history and physical forms, etc.)

### Clinical Library

The clinical library of the iMedConsent™ application includes the following elements:

- Procedure-specific informed consent documents
- Patient education documents
- Pre- and post-procedure patient instructions
- A gallery of anatomical and procedure-specific images
- Standard patient forms for use in the practice or hospital
- Patient information sheets for prescription and over-the-counter medications

It is essential that the clinical library provided by an automated informed consent application be comprehensive. If a facility elects to standardize upon an electronic means of obtaining informed consent, it is imperative that consent documents and other materials be available for all procedures performed in the institution; this is the case with the over 2,000 informed consent documents available via the iMedConsent™ application. It is also critical that the clinical content library be updated on a regular basis and that the content meet the needs of patients with low medical literacy or for whom English is not their primary language.

Dialog Medical's iMedConsent™ application is used by thousands of physicians and in hospitals located in every state, Washington DC, and Puerto Rico. The application is employed in every VA Medical Center, in renowned specialty hospitals such as M. D. Anderson Cancer Center and the Texas Heart Institute/St. Luke's Episcopal Health System, and in world-class teaching institutions such as the University of Miami. Over 160 hospitals employ the iMedConsent™ application to lower costs, reduce risk, and enhance safety, as they have worked to automate the informed consent process and address *healthcare's most expensive piece of paper*.

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