

# The Case for Improved Informed Consent

---

## Informed Consent – Background

### Definition

- Informed consent is the communication process between a patient and his or her physician that results in the patient's agreement to undergo a particular medical procedure or treatment.

### History

- The concept of informed consent is rooted in medical ethics and codified as legal principle – it is based on the assertion that a competent person has the right to determine what is done to him or her.<sup>1</sup>

### Rationale

- The American Medical Association recommends that its members disclose and discuss the following with their patients:<sup>2</sup>
  - 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.
- The requirement for informed consent is spelled out in statutes and case law in all 50 states.

---

<sup>1</sup> Shojania K, Duncan B, McDonald K, Wachter RM, eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality; 2001. *Evidence Report/Technology Assessment No. 43*; AHRQ publication 01-E058.

<sup>2</sup> *Informed Consent*. American Medical Association. <http://www.ama-assn.org/ama/pub/category/4608.html> (accessed 5-18-04).

# The Case for Improved Informed Consent

---

## Inadequacy of the Conventional Informed Consent Process

### Shortcomings of Written Consent Forms

- The typical informed consent process, particularly one that relies solely on traditional written consent forms, is often incomplete or offers the potential for not fully explaining a particular treatment or procedure to a given patient.
  - A review of 540 written consent forms, from 157 hospitals, found the four basic elements of informed consent (risks, benefits, alternatives and other key aspects of the procedure) to be present in only 26% of the documents.<sup>3</sup>
  - A review of 91 written urological procedure consent forms, from a VA Medical Center, found that only 15% contained all appropriate risks of the procedure.<sup>4</sup>

### Other Challenges with a Paper-Based Informed Consent Process

- Traditional paper consent forms are subject to other errors and omissions:
  - Missing signatures (patient, provider or witness) and missing dates place the validity of the consent document at risk.
  - Lost or misplaced forms may result in delayed or postponed procedures often at a cost of expensive operating room time.

---

<sup>3</sup> Bottrell MM, Alpert H, Fischbach RL, et al. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. *Archives of Surgery*. 2000;135:26-33.

<sup>4</sup> Issa MM, Miller E, Kimberl J, et al. Standardization of consent forms for urological procedures: a new standard of care. Association of VA Surgeons - Twenty-sixth Scientific Symposium. Houston, Texas, April 27-30, 2002.

# The Case for Improved Informed Consent

---

## Patient Safety

### Patient Safety Background

- More than 1 million injuries and nearly 100,000 deaths occur annually in the United States due to mistakes in medical care (Source: *IOM Report – To Err Is Human*).<sup>5</sup>
- Based on the need to make health care safer, the Agency for Healthcare Research and Quality (AHRQ) undertook a study to identify patient safety issues and develop recommendations for “best practices”.<sup>6</sup>

### AHRQ Evidence Report

- The AHRQ report identified the challenge of addressing shortcomings such as missed, incomplete or not fully comprehended informed consent; as a significant patient safety opportunity.<sup>7</sup>
- The authors of the AHRQ report hypothesized that a better informed patients “are less likely to experience medical errors by acting as another layer of protection”.
- The AHRQ study ranked a more interactive informed consent process among the top 11 (of the 79 practices reviewed in detail) in terms of strength of the evidence supporting more widespread implementation.

### Priority for IT Executives and CIOs

- Patient safety is rapidly becoming a top priority for Information Technology Executives and Chief Information Officers.
  - 47% of IT executives report that increasing patient safety is their main focus (Source: 15<sup>th</sup> Annual HIMSS Leadership Survey).<sup>8</sup>
  - Nearly 40% of CIOs and other executives said the main factor for growth in their information technology budgets is medical error reduction and patient safety (Source: Health Data Management 2004 CIO Survey).<sup>9</sup>

---

<sup>5</sup> Kohn KT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Committee on Quality Health Care in America, Institute of Medicine, National Academy Press; 1999.

<sup>6</sup> Shojania K, Duncan B, McDonald K, Wachter RM, eds. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Rockville, MD: Agency for Healthcare Research and Quality; 2001. *Evidence Report/Technology Assessment No. 43*; AHRQ publication 01-E058.

<sup>7</sup> Leape LL, Berwick DM, Bates DW. What practices will most improve patient safety? Evidence-based medicine meets patient safety. *JAMA*. 2002;288:501-507.

<sup>8</sup> HIMSS survey: security, safety top concerns. *Health Data Management*. April 2004;12:10.

<sup>9</sup> Survey: CIOs Stay Focused on Patient Safety. *Health Data Management*. April 2004;12:36.

# The Case for Improved Informed Consent

---

## Litigation

### Malpractice Insurance and Litigation

- A GAO report found that malpractice insurance premiums were relatively flat for most of the 1990's but began to increase dramatically beginning in 1999 and 2000 with some increases as high as 165%.<sup>10</sup>
- Malpractice insurance rates continue to rise. The largest malpractice insurer in the state of Massachusetts recently announced that it will raise premiums 11 percent on July 1.<sup>11</sup>
- In an effort to combat the spiraling cost of malpractice insurance, the U.S. House of Representatives passed the Help Efficient, Accessible, Low Cost, Timely Healthcare (HEALTH) Act (H.R. 4280) on May 12. That proposed legislation would cap non-economic damages in medical malpractice cases at \$250,000.

### Consequences of Improper Informed Consent

- Failure to obtain adequate informed consent, depending on state law, may place hospitals and care givers at risk for litigation ranging from medical negligence to battery.

### Proceedings Involving Informed Consent

- Informed consent is often a factor in medical malpractice litigation. Some attorneys note that physicians are liable, and that plaintiffs may be able to recover damages, in cases involving improper informed consent, even if the procedure is successful.<sup>12</sup>
- Inadequate informed consent is often used as a secondary cause in malpractice complaints – studies have shown this strategy has pursued in more 90% of ophthalmologic malpractices cases.<sup>13</sup>

---

<sup>10</sup> Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates. United States General Accounting Office. Washington, D.C. June 2003. Report GA-03-702.

<sup>11</sup> Kowalczyk L. Premiums rising 11% for doctors. *The Boston Globe*. May 17, 2004.

<sup>12</sup> Practice Areas: Informed Consent. Loncar & Associates. Dallas, TX. <http://www.brianloncar.com/FSL5CS/practiceareadescriptions/practiceareadescriptions18.asp> (accessed 5-18-04).

<sup>13</sup> Kiss CG, Richter-Mueksch S, Stifter E, Diendorfer-Radner G, Velikay-Parel M, Radner W. Informed consent and decision making by cataract patients. *Archives of Ophthalmology*. 2004;122:94-98.

# The Case for Improved Informed Consent

---

## Litigation (continued)

### Avoiding Litigation

- The AMA advises its membership of the following regarding informed consent:  
*“To protect yourself in litigation, in addition to carrying adequate liability insurance, it is important that the communications process itself be documented. Good documentation can serve as evidence in a court of the law that the process indeed took place. A timely and thorough documentation in the patient's chart by the physician providing the treatment and/or performing the procedure can be a strong piece of evidence that the physician engaged the patient in an appropriate discussion.”<sup>14</sup>*

---

<sup>14</sup> *Informed Consent*. American Medical Association.  
<http://www.ama-assn.org/ama/pub/category/4608.html> (accessed 5-18-04).

# The Case for Improved Informed Consent

---

## Comprehensive Informed Consent – Impact and Ethics

### Impact of Comprehensive Informed Consent

- One study has found that providing informed consent information to patients in written form increases the patients' comprehension of the procedure.<sup>15</sup>
- It has also been hypothesized that:
  - Better informed patients are more compliant with medical advice and recover faster.
  - Informed consent discussions strengthen physician-patient relationships and increase patients' confidence in their doctor.
  - Well informed patients are less likely to experience medical errors – this may result from the patient acting as another layer of protection (e.g. a patient is able to inform his or her physician about correct medications or the exact surgical procedure that he or she is scheduled to undergo).<sup>16</sup>

### Ethics

- The ethical foundation of informed consent is based on the creation of an environment that supports respect for patients and protects their right to autonomous, informed participation in health care decisions.<sup>17</sup>
- A comprehensive informed consent dialog is imperative when contemplating high-risk procedures. Ethicists around the world, including the Vatican, support this pretext.
  - John Paul II discussed the *“great ethical import: the need for informed consent”* as it related to organ donation:  
*“The human ‘authenticity’ of such a decisive gesture requires that individuals be properly informed about the processes involved, in order to be in a position to consent or decline in a free and conscientious manner.”*<sup>18</sup>

---

<sup>15</sup> Winfield AC, Ford CV, James AE, et al. Response of patients to informed consent for excretory urography. *Urol Radiol.* 1986;8:35-9.

<sup>16</sup> Pizzi LT, Goldfarb NI, Nash DB. Procedures For Obtaining Informed Consent in Shojania K, Duncan B, McDonald K, Wachter RM, eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality. *Evidence Report/Technology Assessment No. 43*; AHRQ publication 01-E058. 2001:546-554.

<sup>17</sup> VHA Informed Consent for Clinical Treatments and Procedures. Department of Veterans Affairs. Veterans Health Administration. Washington DC. *VHA Handbook 1004.1* January 29, 2003.

<sup>18</sup> Address of John Paul II to the 18th International Congress of the Transplantation Society. August 29, 2000.

# The Case for Improved Informed Consent

---

## Veterans Health Administration

### Electronic Support for Patient Decisions Initiative

- Veterans Health Administration
  - 15,000 physicians
  - 5.1 million patients
  - 158 medical centers
- In 2004 the VHA announced its Electronic Support for Patient Decisions Initiative:
  - Developed under the direction of the National Center for Ethics in Health Care.
  - *“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,”* said Secretary of Veterans Affairs Anthony J. Principi. *“This new program is a great complement to the success of VA’s electronic patient records systems.”*
  - *“We are always looking for ways to enhance the care we provide,”* said Dr. Ellen Fox, center director. *“By supporting patient decisions on a systems level, we are preventing problems before they arise. We like to call this ‘preventive ethics’.”*

# The Case for Improved Informed Consent

---

## The iMedConsent™ Solution

### Description

- iMedConsent™ is a comprehensive, computer-based, patient education and informed consent solution developed by Dialog Medical.

### Benefits

- iMedConsent™ solution enhances communication between the patient and the physician by offering:
  - A comprehensive library of education materials that describe different medical conditions and treatments.
  - Detailed informed consent materials that facilitate a broad discussion of the given procedure or treatment including:
    - Description of the procedure
    - Risks
    - Benefits
    - Alternatives
    - Likely outcomes if no treatment is elected
  - An expansive collection of anatomical diagrams and images that facilitate the physician's ability to describe the nuances associated with a given condition or procedure.
  - A wide range of post procedural care instructions.
  - A comprehensive library of drug information documents.
- iMedConsent™ solution facilitates the documentation of the consent process by:
  - Providing printed copies of the procedure-specific consent form.
  - Offering the ability to store the signed consent form electronically.
  - Automatically noting in the patient's electronic medical record the details associated with the consent process and the distribution of any education materials.

iMedConsent is a trademark of Dialog Medical.

Copyright © 2005 by Dialog Medical. All rights reserved.