The Complete EMR: Leveraging Informed Consent Capability

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Session Objectives

- Understand the impact of informed consent on medical malpractice risk.
- Recognize the patient safety and institutional compliance impact of a sound consent process.
- Describe the patient’s role as a source of high level orders and the role of permissions and revocations in the context of electronic documentation.
- Identify the mechanisms for integrating an automated informed consent application (AICA) with an electronic medical record (EMR).
- Describe how an AICA, integrated with an EMR, can drive improvements in workflow, efficiency, patient safety, and charge capture.
Evolution of Present-Day Informed Consent Doctrine

Legal Origins of Informed Consent

- Consent was a physician courtesy
  - 1700’s and 1800’s
- Protection against battery
  - Justice Brown, Appellate Court of Illinois, 1905¹
- Affirmative duty of disclosure
  - Courts of North Carolina, California and Minnesota²

¹Pratt v. Davis, 118 Ill. App. 161, 1905 WL 1717 (Ill. App. 1 Dist.)
Informed Consent Today

- Spelled out in statutes and case law in ALL 50 states.

State Statutes

- Texas and Louisiana have Medical Disclosure Panels that detail specific risks that must be disclosed on the consent form.
### Necessary Elements of Informed Consent

- **Diagnosis**
- **Purpose** of treatment or procedure
- **Risks and benefits** of treatment or procedure
- **Alternatives** including risks and benefits
- The risks and benefits of **not receiving** treatment

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### Current Status of Informed Consent
How Are We Doing?

- A large study of 3,552 patient decisions:
  - Only 9% met the criteria for a completely informed decision.
  - For complex decisions – only 0.5% were completely informed.


How Are We Doing?

- Note:
  - Limited descriptions
  - Illegible handwriting
  - Use of unacceptable abbreviations
How Are We Doing?

- A review of 540 written consent forms, from 157 hospitals, found the necessary elements of informed consent (purpose, risks, benefits, & alternatives) in only 26% of the documents.


How Are We Doing?

- A review of 89 written consent forms for radical prostatectomy:
  - The potential need for blood transfusion was disclosed on 88.8% of the consent forms.
  - HOWEVER, proper consent for blood products was ONLY obtained in 25.8% of the cases.
  - 92.1% of patients ultimately received a transfusion.

Medical Malpractice Risk

Malpractice Expenses and Informed Consent

- Inadequate informed consent is often used as a secondary cause in malpractice complaints – studies have shown this strategy was pursued in more than 90% of ophthalmologic malpractices cases.

Jury Awards & Informed Consent

- $150,000 award for failing to disclose an alternative treatment – Pennsylvania/Urology Procedure.
- $547,000 award for a missing consent form – Maryland/Laparoscopic Gyn. Surgery.
- $1.8 million award for failing to disclose relevant risks – New Jersey/Spinal Surgery.


Predictors for Malpractice Lawsuits

- "One of the strongest is the doctor's ability to communicate effectively with the patient. Informed consent problems are more likely to arise for a doctor who doesn't communicate well. But perhaps even more importantly, a doctor who doesn't communicate well is not likely to build a healthy relationship with a patient such that if a bad outcome did happen in medical care, the patient would be inclined to forgive rather than sue."

Michelle Mello, PhD, JD, Harvard School of Public Health. NPR Radio Interview: January 15, 2005.
Litigation Risk

- Lack of adequate informed consent is one of the top 10 most common reasons for hospital malpractice claims.
  

- A signed consent form is a minimum standard, but it's not an adequate substitute for a note recording the detailed informed consent discussion in the patient’s chart.
  
  Rice B. Medical Economics. July 8, 2005.

Where To Obtain Consent and How To Document the Process

- Obtain consent in the office vs. in the preoperative holding area.
  - $65,600 in additional legal expenses
  - $257,000 in additional indemnity payments

- Document the informed consent discussion in a supplemental note.
  - $102,000 in additional legal expenses
  - $352,000 in additional indemnity payments

The Cost of Paper

Costs of Handling Paper

- Paper Costs:
  - Scanning
  - Storage
  - Secure disposal
- Costs associated with scanning consent documents:
  - Annual costs of scanning consent forms and advanced directives at 3 VA facilities
    \(~\$80,000 per facility\)

Cost of Lost or Misplaced Consent Documents

Study of Missing Consent Documents (Two VA Medical Centers)

Percent of Procedures

- Traditional (paper) consent process
- Automated consent process

Cost of Lost or Misplaced Consent Documents

- Cost of OR time = $20 per minute
- Time required to find missing consent or obtain replacement consent from patient or surrogate ~ 10 minutes
- Cost per case = $200!
- Expenses associated with lost revenue and inefficient use of OR resources for the average U.S. hospital = $580,000¹


Eliminating Cancellations

- A large teaching facility implemented a program of verifying patient comprehension during the informed consent process.
- The cancellation/delay rate dropped from 8 percent to 0.8 percent.

Patient Safety

- IOM Report – To Err Is Human
  - More than 1 million injuries and nearly 100,000 deaths occur annually in the United States due to mistakes in medical care.

- Agency for Healthcare Research and Quality Evidence Report
  - Identified 79 evidence-based patient safety practices (e.g. use of perioperative Beta-blockers, use of CPOE, use of antimicrobial impregnated CVC catheters, active management of ICU patients by intensivists, etc.)

Patient Safety

- The AHRQ Evidence Report identified 11 practices that were rated most highly in terms of strength of evidence – one of the 11 – Enhanced Informed Consent.
  - Incomplete or not fully comprehended informed consent is a significant patient safety issue.
  - Better informed patients "are less likely to experience medical errors by acting as another layer of protection."

Patient Safety

**National Quality Forum**
- *Safe Practices for Better Healthcare*
  - Safe Practice No. 10 – Enhanced Informed Consent.

**The Leapfrog Group**
- *The Leapfrog Group Hospital Quality and Safety Survey*
  - Enhanced Informed Consent – key component
Compliance Requirements

Hospital Accreditation Standards
- Specifies that an institution must have a policy for informed consent – which procedures, process, how documented, surrogate decision makers, etc.
- Specifies the exact elements that must be part of the informed consent discussion.
- JCAHO Standard RI.2.40
Accreditation/Compliance

- CMS Interpretive Guidelines for Informed Consent [§482.51(b)(2)]
- Name of patient, procedure, risks, alternatives, date, **time**, signatures: patient, provider, witness.
- Documentation of all practitioner names and “significant surgical tasks” on the informed consent form.

Automated Informed Consent Application (AICA)
Components of an AICA

- Software Application
- Clinical Library:
  - Procedure-specific informed consent documents.
  - Patient education documents.
  - Pre- and post-procedure patient instructions.
  - Anatomical and procedure-specific images.
  - Standard forms for use in the practice or hospital.
  - Patient monographs for prescription and over-the-counter medications.

Automated Informed Consent Meets the EMR
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Configurations for an AICA

**Configuration A**
AICA is separate from, and does not communicate with, the EMR.

**Configuration B**
AICA communicates with the EMR—typically via an HL7 interface.

**Configuration C**
AICA is embedded within the EMR.

Implementation of an AICA Utilizing a Service-Oriented Architecture (SOA)

- **Clinic Station** (MDACC’s EMR)
  - AICA ActiveX Control
- **AICA Server**
- **Patient Information Database**
- **Middle Tier Servers**
- **.NET Web Service Calls**
- **OR Manager (MDACC’s OR Scheduling Application)**
- **Pathology Application**
- **Other Clinical Applications**
- **Microsoft IIS/.NET Application Server**
Service-Oriented Architecture (SOA)

- Signed consent forms in a SOA facilitate the exchange of information with other clinical applications:
  - Does a consent exist for a particular patient?
  - What procedures are listed on the consent form?
  - What anatomical location or laterality for the surgical or treatment site(s) are specified on the consent form?
  - Has the patient provided consent for tissue banking?
  - Does the procedure(s) for which the patient is scheduled match the procedure(s) specified on the consent form?

Leveraging the System
Patient Orders

- Patients are a source of “high level” orders:
  - Personal health information.
  - Financial arrangements.
  - Informed consent for surgical procedures.
  - Consent for tissue banking.

Patient Orders

- What is the “CPOE” for patient orders?
- Challenges with patient orders:
  - Processes are manual.
  - Poor integration with the medical record.
- OPPORTUNITY – Leverage an AICA to computerize traditional processes and integrate information with the EMR.
Universal Protocol™

- JCAHO’s Universal Protocol For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™
  - “Time Out” to confirm:
    - Correct patient
    - Correct procedure
    - Correct site

Universal Protocol™

- OPPORTUNITY – Employ the electronic consent, rather than the surgical order, to verify:
  - Correct patient.
  - Correct procedure.
  - Correct site.

- Brings the patient into the “Time Out” huddle.
OR Scheduling

- Booking a procedure is critical for streamlined patient flow on the day of surgery.
- Necessary elements:
  - Surgical procedure(s)
    - Including “possible” procedures
  - Site/Laterality
  - Anticipated surgical length
  - Special equipment needs
  - Preferred time of the procedure

OR Scheduling

- OPPORTUNITY – Make the consent encounter the starting point for an on-line workflow:
  - Posting surgeon may add additional elements within a single process.
  - Resulting electronic document contains the surgical posting with links to the informed consent document.
- Ensures that the case posting always reflects the procedure for which consent has been obtained.
  - If changes or additions are required, the surgeon is alerted that the informed consent record no longer supports the posted procedure.
- The informed consent record is the ultimate arbiter of the posted procedure.
Tissue Banking

- Tissue archives, combined with the pathologic and therapeutic medical record information, are used to create new and more effective molecular therapies for the treatment of cancer and other chronic diseases.

- These specimens contain patients’ DNA and may in the future reveal health data for patients and their close biological relatives.

Tissue Banking

- Patients must have the ability to grant, and at any time – revoke, the institution’s right to use tissue specimens.

- The ability to track the use and disposition of tissue specimens exists in most electronic pathology management systems.

- HOWEVER, the paper-based workflow for revocation or modification of rights to tissue specimens is slow, error-prone and expensive.
Tissue Banking

- OPPORTUNITY – Use an AICA to:
  - Allow the ability to ascertain the exact state of patient directives.
  - Provide seamless integration.
  - Enable instantaneous updates.
  - Ensure that changes with consent for tissue banking and information release flow back to the pathology databases into their patient specimen tables.

- Ensures compliance with federal regulations and with patient directives.

Charge Capture

- Many procedures are now performed at the bedside:
  - Thoracentesis.
  - Small biopsies.

- OPPORTUNITY – Automate the consent process to ensures that:
  - Consent is obtained.
  - Detailed information required by the billing department is readily available.
Conclusions

- Informed consent and other permissions form the patient’s legal relationship with the institution.
- Use of an AICA can be leveraged by an EMR to:
  - Enhance a critical process that is the cornerstone of medical documentation.
  - Avoid wrong patient/wrong procedure/wrong site surgery.
  - Improve OR scheduling and efficiency.
  - Ensure that charges are captured for procedures performed at the bedside.
  - Confirm that patient directives for use of tissue specimens and other permissions are observed.