The Informed Consent Process and the Electronic Medical Record

Mercer Medical Center
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Aaron S. Fink, MD
Professor of Surgery
Emory University
Manager, Surgical and Perioperative Care
Atlanta VAMC
Informed Consent Process

• Critical health care process

• **Clinically:**
  – Provide patient with vital information about benefits, risks and alternatives

• **Ethically:**
  – Preserves patient autonomy – the belief that a competent person has the right to determine what will be done to them
AMA Code of Medical Ethics

- **Obligates a physician to:**
  - “Present the medical facts accurately”
  - “Help the patient make choices from among the therapeutic alternatives consistent with good medical practice”
• “Every human being of adult years and sound mind has the right to determine what shall be done with his body, and a surgeon who performed an operation without his patient’s consent commits an assault for which he is liable for damages”

Judge Benjamin Cardoza; Schloendorff v NY Hosp, 211 N.Y. 125 at 129, (1914)
Informed Consent and State Law

• Legislation in all 50 states requires that a patient be advised of all possible complications and alternative treatment options before he or she is allowed to sign a consent form

• Extent of discussion varies from state to state
Standards for Informed Consent

• **Prudent patient standard:**
  – Provider must disclose “all that an average, reasonable pt would consider material to his decision whether to undergo the proposed treatment”
  – **Includes:**
    • Risks that could affect the decision of a “reasonable person”
    • Incidence of injury and degree of possible harm
    • Alternative choices of treatment
    • Chance of death or disability

• **Prudent physician standard:**
  – What an expert (usually a physician) would or would not have done in a particular situation

*Canterbury v Spence 464 F2d 772 [DC Cir 1972]*
Standards Applicable to Informed Consent

- JCAHO
- CMS
- Individual Hospital Policy
- State Law
  - Texas and Louisiana require disclosure of specific risks
JCAHO: Necessary Elements of Informed Consent

- Diagnosis
- Purpose of Rx or procedure
- Risks and benefits of Rx or procedure
- Alternatives to the Rx or procedure
- The risks and benefits of not receiving treatment
• **Butler v South Fulton Medical Center:**

  Even if provided proper and legal disclosure, a patient must comprehend what the physician is saying and understand the information on the consent form so (s)he can voluntarily offer permission for the proposed intervention.

*452 ES 2d 768 GA [1994]*
Comprehension and Informed Consent

- Patients’ comprehension of surgical procedures is suboptimal, even if measured immediately following informed consent.

- A survey of 11 studies (n =704) revealed that patients’ comprehension averaged 48%.

- Significant patient factors:
  - Age
  - Education
  - IQ
  - Impaired cognitive function
  - Locus of control
  - Anxiety

- Other significant factors:
  - Instrument used
  - Content area of questions
  - Time since consent
Challenges

• Physicians *may* do a good job with the communication aspects of informed consent

• The process varies significantly from clinician to clinician

• Documentation is typically weak
Traditional Written Consent Form

Note:

- Limited descriptions
- Illegible handwriting
- Use of unacceptable abbreviations
Challenges with the Traditional Current Consent Form

- Time-consuming
- Details may be limited
- Content varies from provider to provider
- Risk of missing sections, signatures or dates
- Involves paper
  - Often lost or misplaced
Limitations of Conventional Informed Consent Documents

- Review of 540 written consent forms from 157 hospitals

- The four basic elements of informed consent (risks, benefits, alternatives and other key aspects of the procedure) were present in only 26% of the documents

VA Experience

A review of 91 written consent forms for radical prostatectomy:

- 29% -- inadequate information regarding Rx benefits
- 42% -- no mention of alternative Rx
- 85% -- all five standard risks not listed

Issa MM, et al. AVAS Scientific Symposium, Houston, April 2002
VA Experience

• A review of 91 written consent forms for radical prostatectomy:
  • The use of blood transfusion was disclosed on 90% of the consent forms
  • HOWEVER, proper consent for blood products was not obtained in 82% of the cases

– Issa MM, et al. AVAS Scientific Symposium, Houston, April 2002
Potential Opportunities !!!

Patient Safety

Malpractice Issues

Documentation Issues
Providing informed consent information to patients in written form may increase the patients’ comprehension of the procedure.

Better informed patients may be more compliant, less anxious and more satisfied.
Potential Patient Safety Impact of Informed Consent

- Improving missed, incomplete or poorly understood informed consent is a significant patient safety opportunity

- Better informed patients “are less likely to experience medical errors by acting as another layer of protection”

• Impact on malpractice claims
  – From 1989 – 2000, the VA paid $555,752,354 in malpractice claims (mean = $46,314,363/yr)
  
  – Legal expenses associated with these claims was ~ $11.3 million/year
  
  – Lack of informed consent cited as primary cause in 2.7% of claims (> $ 1.55 M/yr)

Weeks WB et.al.: Law Med Ethics 2001; 29:335-345
“One of the strongest [predictors] 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, Assistant Professor of Health Policy and Law, Harvard School of Public Health. NPR Radio Interview: January 15, 2005.
Other Opportunities to Improve Traditional Informed Consent

- Lost or misplaced consent documents that delay OR procedures
- Costs associated with scanning consent documents
Cost of Lost or Misplaced Consent Documents

- Cost of OR time = $20 per minute
- Time to find or re-obtain lost consent document ~ 10 minutes
- Cost per case = $200!
Annual Cost of Lost or Misplaced Consent Documents

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

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

\(^2\) Pilot Study of iMedConsent - Report to the Health Systems Committee and the Informatics and Data Management Committee, Veterans Health Administration.


\(^4\) Brodsky, J.B. *Anesthesiology* 1998; 88:834.

Other Opportunities to Improve Traditional Informed Consent

- Lost or misplaced consent documents that delay OR procedures
- Costs associated with scanning consent documents
  - Annual costs of scanning consent forms and advanced directives at 3 VA facilities ~ $80,000 per facility
Veterans Healthcare Administration

- 158 Hospitals

- 5.1 million patients treated annually
  - 742,000 patients received inpatient services
  - 49.8 million outpatient clinic visits
Veterans Healthcare Administration

• 15,000 physicians

• VA facilities are affiliated with:
  – 107 medical schools
  – 55 dental schools
  – 1,200 other schools

• 81,000 health professionals receive training in VA facilities each year
Project to Improve the Informed Consent Process

• The VA is the nation’s leader in the application of computer technology to patient medical record

• Potential Issues:
  – Need to document the informed consent discussion as a progress note within the patient’s EMR
  – Lack of standardization from physician to physician and facility to facility
    • Particularly acute for facilities with many residents
iMedConsent™

- Developed by Dialog Medical (Duluth, GA)
- Interfaces with VISTA and CPRS
- Allows providers to generate customized documents and handouts supporting informed consent and patient education
- Deemed to offer significant promise of improving informed consent by VHA
- Purchased by 15 VA Medical Centers
Urology Study

- Evaluate the automated informed consent application in the Outpatient Urology Clinic

Applicable procedures
- Vasectomy
- Bladder Biopsy
- Cystoscopy
- Ureteral Stent Removal
- Prostate Biopsy
THE EMMORY CLINIC, INC.
SECTION OF UROLOGY
Request and Consent for Voluntary Sterilization

Date: ____________________  Time: ______________  Procedure: VOLUNTARY STERILIZATION

Method of sterilization: ____________________________________________________________

1. In conjunction with undergoing the procedure identified above, I understand the following:
   a. Nature and purpose of the procedure: To make me permanently unable to father children
   b. Material risk of the procedure: BLOODING, INFECTION, SPREMB GRAVIDOVIS, RECANALIZATION
      (spontaneous reformation of the vas deferens), KIDNEY STONE, CHRONIC PAIN, ALLERGIC REACTION,
      AND THIS NEED FOR FURTHER PROCEDURES.

2. Additional risk of this procedure: ____________________________
   c. Likelihood of success: ( ) Good ( ) Fair ( ) Poor ( ) Unknown because: ____________________________
   d. Practice alternatives to procedure: Temporary methods of birth control
   e. Prognosis if procedure rejected: Not applicable

3. Consent: The procedure identified above has been explained to me and all my questions have been answered. I acknowledge that no guarantees have been made concerning the outcome of the surgical or medical treatment, and I realize that the practice of medicine
   and surgery is not an exact science. I hereby request and consent to the performance of this procedure by the physician
   and/or any assistants who may be present. I also consent to the administration of local anesthesia to be applied by or under
   the direction of the physician performing the procedure. I am eighteen (18) years of age or older and an adult competent to provide this consent
   on my own behalf.

4. Following successful performance of the procedure, I understand that I will be sterile and unable to achieve pregnancy through
   intercourse.

5. I realize that, during the procedure, the physician/surgeon may become aware of conditions which were not apparent before the start
   of the procedure, or may determine that additional or different operations or procedures are necessary or appropriate. I therefore
   authorize the above-named physician/surgeon and/or any assistants who may be present to perform additional or different
   operations or procedures the physician deems necessary or advisable.

6. Any tissue, organs or implant, removed, observed, or recovered in any operation or procedure, may be retained, preserved,
   used for scientific or teaching purpose or disposed of by Emory University Hospital, Crawford Long Hospital, or the Section of
   Pathology of The Emory Clinic, at the discretion of the Hospital or Section, except for the following:

7. In order to assure proper identification, accurate tracking, and timely follow-up after the procedure, I authorize the Emory Clinic to enter
   and maintain my name on a tracking list.

(Witness) ____________________ (Patient Signature) ____________________
(Rev) ____________________ (Date) ____________________
(Signature of Person Obtaining Consent) ____________________
(Signature of person authorized to consent for patient) ____________________
(Cert) ____________________ (Relationship to patient) ____________________

• Developed a procedure-specific consent for vasectomy

• Addressed the issues of standardization and lack of detail
Automated Consent System

- Mobile computer cart
- Software
- Printer
- Digital signature pad
Automated Informed Consent
Overview

• Consent typically obtained by a PA or physician using the computer

• Patient, physician and witness digitally sign the consent document

• Document is printed for inclusion in the patient chart

• Document is digitally stored
Patient Satisfaction

- Very Satisfied: 4.5
- Somewhat Satisfied: 4.7
- Neither Satisfied nor Dissatisfied: Range 3-5, SD 0.78, n=13
- Somewhat Dissatisfied: Range 1-5, SD 0.88, n=23
- Very Dissatisfied

Satisfaction Compared to Traditional Consent

Overall Satisfaction
Clinician Satisfaction and Ease of Learning

- **Very Satisfied/Very Easy**: 4.7
- **Somewhat Satisfied/Easy**: 4.9
- **Neither Satisfied/Easy nor Dissatisfied/Difficult**: Range: 4-5, SD 0.44, n=9
- **Somewhat Dissatisfied/Difficult**: Range: 4-5, SD 0.33, n=9
- **Very Dissatisfied/Very Difficult**
Conclusions

• Enhanced consistency and efficiency across practice patterns

• Produced complete and clear documentation

• Afforded high patient and clinician satisfaction
Following favorable Phase I trial, Phase II trial run by VA Center for Ethics in Healthcare 11/03 – 1/04 in 5 VA Medical Centers

Program modified to correct policy, safety, and clinical quality issues raised during Phase I trial

Results:
- “Most patients generally liked iMedConsent”
- “Progressive improvement” in practitioner (n = 41) and chief of surgery (8 of 14) responses
- Ease of use = “very good” in final week
- Substantial improvement in compliance with VA policy

Issues:
- Only 3 of 5 sites were able to fully participate
- “Due to the low number of [practitioner] responses, results may not be representative”
iMedConsent – Current Status

- HSC and IDMC recommended natl. purchase
- Supported by VA Natl. Leadership Bd. 2/19/04
- July, 05: installed and implemented in 125/158 medical centers
  - Completion anticipated by mid August, 2005
- Templates developed for all specialties except Neurosurgery and Hematology-Oncology
iMedConsent – Issues

• ? Patient level effects:
  – Comprehension
  – Satisfaction
  – Anxiety
  – Compliance with directed care

• ? Provider satisfaction

• ? Impact on work flow

• ? Cost/Benefit ratio
iMedConsent™ Demonstration
Verify patient and treatment: To ensure you have chosen the correct patient in CPRS, ask the patient (or surrogate) to verbally state to you the patient's full name AND date of birth. Also verify that you have selected the correct treatment/procedure for this patient.

Select decision-making capacity status: A patient is presumed to have the capacity to make health care decisions (decision-making capacity) unless an appropriate clinical assessment determines that the patient lacks decision-making capacity, or the patient is considered a minor under state law, or the patient has been ruled incompetent by a court of law.

Confirm each of the following with the patient or surrogate:
1. Patient name: **SMITH, JOE D**
2. Date of birth: **NOV 05, 1981**
3. Treatment/Procedure:

   **GALL BLADDER - Cholecystectomy (Laparoscopic) VQDE**

Does the patient have decision-making capacity?
- Yes
- No

If the patient's decision-making capacity is questionable, you must exit this program (click Cancel) and return after a formal clinical assessment is performed and documented in the patient's record.

If the patient is a minor or has been declared incompetent by a court of law, click "No."
Provider(s) is(are) Selected
Final Consent Document

Dialog Medical Center
3075 Breckenridge Blvd
Duluth, GA 30096
770-982-7851
Fax 770-736-5725

CONSENT FOR TREATMENT/PROCEDURE

A. IDENTIFICATION

1. PATIENT NAME AND SSN
Smith, Joe D
117-55-0707

2. PATIENT'S DECISION-MAKING CAPACITY
The patient HAS decision-making capacity.

3. SURROGATE NAME AND RELATIONSHIP TO THE PATIENT (IF APPLICABLE)

4. TREATMENT/PROCEDURE
Gall Bladder - Cholecystectomy (Laparoscopic) W/ CDE

5. PRACTITIONER OBTAINING INFORMED CONSENT (SIGNING PRACTITIONER)
Jones, Adam
Signatures are Collected

Signature: Patient (or Surrogate)

By signing below, I attest to the following:
- Someone has explained this treatment/procedure and its purpose.
- Someone has explained how this treatment/procedure could help me and things that could go wrong.
- Someone has told me about other treatments or procedures that might be done instead, and what would happen if I have no treatment/procedure.
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not lose my health care or any other VA benefits.
- I have read the consent form and I understand it.
- I choose to have this treatment/procedure.

SMITH, JOE D

[Signature]

John Smith
Patient: SMITH, JOE D  Procedure: Gall Bladder - Cholecystectomy (Laparo ...
Common Bile Duct Stones

Definition

The common bile duct serves to transfer bile from the gallbladder, liver, and pancreas to the small intestines.

Bile is used to help the body digest fats. It contains water, fats, bile salts, and bilirubin.

If the liquid bile contains too much cholesterol, bile salts, or bilirubin, it can harden into "stones."
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Fax 770-736-5725

General Post-Operative Instructions

In order to continue your care, please follow the instructions checked below.

1. GENERAL ANESTHESIA, LOCAL + SEDATION, OR LOCAL WITH NO SEDATION
   - Do not drive or operate machinery for the next 24 hours.
   - Do not consume alcohol, tranquillizers, sleeping pills, or non-prescription medication for 24 hours.
   - Do not make important decisions or sign any important papers in the next 24 hours.
   - You should have someone with you at home for 24 hours.

2. ACTIVITY
   - You are advised to go directly home. Restrict your activities and rest for today.
   - No strenuous activity or heavy lifting.