The Informed Consent Process and the Electronic Medical Record

Surgical Grand Rounds
Emory University
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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”
Informed Consent – Legal Principle

• “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**
Informed Consent and Georgia Law

- **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

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
• 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
Patient Safety

• 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”

Malpractice Expenses and Informed Consent

- **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
Study of Missing Consent Documents
(Two VA Medical Centers)

Percent of Procedures

Traditional (paper) consent process
Automated consent process

Progress Note in the Patient Chart
Consent Form in the Patient Chart

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

OR time spent replacing a lost/misplaced consent
10 minutes

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

- 162 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
Emory Urology Clinic Study

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

• Applicable procedures
  – Vasectomy
  – Bladder Biopsy
  – Cystoscopy
  – Ureteral Stent Removal
  – Prostate Biopsy
Procedure-Specific Consent Document

THE EMMORY CLINIC, INC.
SECTION OF UROLOGY
Request and Consent for Voluntary Sterilization

Date:          Time:          Procedure: VOLUNTARY STERILIZATION

Method of sterilization:

1. In connection 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: BLEEDING, INFECTION, SPIERM GRANULOMA, RECIDIVABLE (spontaneous reconnection of the vas deferens), KIDNEY STONE, CHRONIC PAIN, ALLERGIC REACTION, AND THE NEED FOR FURTHER PROCEDURES.

   Additional risks 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

2. 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 the procedure by Dr. and any assistants who may be present. I also consent to the administration of local anesthetic to be applied by or under the direction of the physician performing the procedure. I am eighteen (18) years of age or older and am competent to provide this consent on my own behalf.

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

4. 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 and request the above named physician/surgeon and any assistants who may be present to perform additional or different operations or procedures the physician deems necessary or advisable.

5. Any tissue, organ, specimen, specimen, or implant, removed or received in any operation or procedure, may be retained, preserved, used for scientific or teaching purposes or disposed of by Emory University Hospital, Crawford Long Hospital, or the Section of Pathology of The Emory Clinics at the discretion of the Hospital or Section, except for the following:

6. If acceptable to the physician/surgeon, I authorize observers to be present during the surgery or procedure. ( ) Yes ( ) No. I further authorize the physician/surgeon, or his/her designee, to photographs/recordings made before, during, or after this surgery or procedure, for purposes related to my care and treatment and/or for purposes of medical education. ( ) Yes ( ) No.

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

(Witness) ____________________________ (Patient Signature) ____________________________
( ) ____________________________ ( ) ____________________________
(Signature of Person Obtaining Consent)
(Signature of person authorized to consent for patient)
(Cert) ____________________________ (Relationship to patient) ____________________________
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 (Range: 3-5, SD 0.78, n=13)
- Somewhat Satisfied
- Neither Satisfied nor Dissatisfied
- Somewhat Dissatisfied
- Very Dissatisfied: 4.7 (Range: 1-5, SD 0.88, n=23)

Clinicant Satisfaction and Ease of Learning

<table>
<thead>
<tr>
<th>Overall Satisfaction</th>
<th>Ease of Learning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range: 4-5</td>
<td>Range: 4-5</td>
</tr>
<tr>
<td>SD 0.44</td>
<td>SD 0.33</td>
</tr>
<tr>
<td>n=9</td>
<td>n=9</td>
</tr>
</tbody>
</table>

- **Very Satisfied/Very Easy**
- **Somewhat Satisfied/Easy**
- **Neither Satisfied/Easy nor Dissatisfied/Difficult**
- **Somewhat Dissatisfied/Difficult**
- **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
- Sept, 05: Installed and implemented in all 162 VA medical centers
- Templates developed and approved for all specialties except Hematology-Oncology
DEMOnSTRATION

Mr. Michael Burke, President
Dialog Medical
Duluth, GA
• In 2003, NQF published *Safe Practices for Better Healthcare*

• Endorsed a set of national voluntary consensus standards designed to improve patient safety

• “*Safe Practice 10*” seeks to ensure proposed treatments and their complications are understood
Safe Practice 10

Ask each patient or legal surrogate to recount what he or she has been told during the informed consent process.
A National Standard for Informed Consent – National Quality Forum (NQF)

**Further specifications of Safe Practice 10**

- Use simple sentences and the patient’s primary language in informed consent forms.
- Engage the patient in a dialogue about the nature and scope of the proposed procedure.
- Use interpreters or readers for patients with limited English proficiency, visual or hearing impairments, or low literacy.
- Convey the higher risk associated with suboptimal volumes for select high-risk surgeries and procedures:
  - CABG, coronary angioplasty
  - Pancreatectomy
  - AAA repair
  - Esophageal cancer surgery
Repeat Back Module

Your Facility Name Here
3075 Breckenridge Blvd
Suite 425
Duluth, GA 30096
770-982-7851
Fax 770-736-5725

CONSENT FOR TREATMENT/PROCEDURE

A. IDENTIFICATION

1. PATIENT NAME AND SSN
SMITH, JOE E
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
PROSTATE BIOPSY
If the “Patient Understood Immediately” button is pressed, the following text is automatically inserted into the Progress Note:

“The patient satisfactorily communicated his or her diagnosis.”

If the “Patient Understood with Additional Training” button is pressed, the following text is automatically inserted into the Progress Note:

“After further discussion, the patient was able to satisfactorily communicate his or her diagnosis.”
If the “Patient Understood Immediately” button is pressed, the following text is automatically inserted into the Progress Note:

“The patient satisfactorily communicated the anatomical location where the treatment or procedure will be performed.”

If the “Patient Understood with Additional Training” button is pressed, the following text is automatically inserted into the Progress Note:

“After further discussion, the patient was able to satisfactorily communicate the anatomical location where the treatment or procedure will be performed.”

Comprehension Check

Anatomical Location

Describe where on your body the treatment or procedure will be performed.

Anatomical location as presented on the consent form:

Text appearing in the progress note (EDIT AS NEEDED)

The patient was asked to describe where the treatment or procedure would be performed on the patient’s body.

Help

Ask the patient to describe where on his or her body the treatment or procedure will be performed. Ensure that the patient understands where the procedure will be performed. Ensure that the anatomical locations described by the patient, and detailed in the care plan, are in exact agreement.

The process of confirming a patient’s comprehension of the informed consent process has been found to improve patient safety. This “teach back” or “repeat back” process has been endorsed by the Agency for Healthcare Research and Quality, the National Quality Forum and the Leapfrog Group.
If the “Patient Understood Immediately” button is pressed, the following text is automatically inserted into the Progress Note:

“The patient satisfactorily communicated the procedure described on the consent form.”

If the “Patient Understood with Additional Training” button is pressed, the following text is automatically inserted into the Progress Note:

“After further discussion, the patient was able to satisfactorily communicate the procedure described on the consent form.”
If the “Patient Understood Immediately” button is pressed, the following text is automatically inserted into the Progress Note:

“The patient satisfactorily communicated the potential benefits detailed on the consent form.”

If the “Patient Understood with Additional Training” button is pressed, the following text is automatically inserted into the Progress Note:

“After further discussion, the patient was able to satisfactorily communicate the potential benefits detailed on the consent form.”
If the “Patient Understood Immediately” button is pressed, the following text is automatically inserted into the Progress Note:

“The patient satisfactorily communicated the risks detailed on the consent form.”

If the “Patient Understood with Additional Training” button is pressed, the following text is automatically inserted into the Progress Note:

“After further discussion, the patient was able to satisfactorily communicate the risks detailed on the consent form.”
If the “Patient Understood Immediately” button is pressed, the following text is automatically inserted into the Progress Note:

“The patient satisfactorily communicated the alternatives detailed on the consent form.”

If the “Patient Understood with Additional Training” button is pressed, the following text is automatically inserted into the Progress Note:

“After further discussion, the patient was able to satisfactorily communicate the alternatives detailed on the consent form.”
iMedConsent – Issues

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

• ? Provider satisfaction

• ? Impact on work flow

• ? Cost/Benefit ratio
• “Benefits of Repeat Back Protocols within a Computer-based Informed Consent Program”

• Total Funds requested = $834,700 over three years

• Randomized, prospective study of selected patients in 7 VA Medical Centers:
  – Laparoscopic Cholecystectomy
  – Carotid Endarterectomy
  – Total Hip Arthroplasty
  – Radical Prostatectomy

• Patients randomized to iMedConsent or iMedConsent + Repeat Back module
Outcome variables:
- Patient comprehension
- Patient satisfaction with informed consent process
- Patient anxiety
- Patient compliance with pre/post-op health care
- Provider use and satisfaction
- Occurrence of mortality or post-op morbidity

CONDITIONALLY APPROVED AND FUNDED!!!!