Informed Consent –
Strategies to Improve Quality, Enhance Safety, and Reduce Risk

Evolution of Present-Day Informed Consent Doctrine

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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.

Key Elements of Informed Consent
“Consent is the communication process between a patient and a provider of health care services in which both parties ask questions and exchange information, culminating in the patient's agreeing to a specific medical or surgical intervention.”

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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

Why Focus on Informed Consent?

Accreditation/Compliance

- Hospital Accreditation Standards
  - Specifies that an institution must have a policy for informed consent (shared decision-making) – which procedures, process, how documented, surrogates, etc.
  - Specifies the exact elements that must be part of the informed consent discussion
  - Joint Commission Standard RI.2.40

CMS Interpretive Guidelines for Informed Consent [482.51(b)(2)] (revised 4/13/07)
- Hospitals are now responsible for ensuring that physicians performing procedures obtain consent in a manner that is consistent with the hospital’s informed consent policy.

Patient Safety

- National Quality Forum
  - Safe Practices for Better Healthcare
    - Safe Practice No. 2 – Enhanced Informed Consent.

- The Leapfrog Group
  - The Leapfrog Group Hospital Quality and Safety Survey
    - Enhanced Informed Consent – key component
### Informed Consent – Strategies to Improve Quality, Enhance Safety, and Reduce Risk

#### James T. Reason
- British psychologist
- Studied high-reliability organizations
  - Navy Aircraft Carriers
  - Nuclear Power Plants
  - Commercial Air Traffic Control

#### Swiss Cheese Model
- James T. Reason, British psychologist
- An organization’s defenses against failure are modeled as a series of barriers each with individual weaknesses
- Failures occur when holes in each of the slices momentarily align permitting "a trajectory of accident opportunity"

#### Wrong-Site Surgery
- 1 in 112,994 procedures (excluding spine)\(^1\)
- 1 in 30,000 surgeries in Virginia\(^2\)
- 1 in 15,500 surgeries in New York\(^2\)


#### Approach to Evaluating Error
- U.S. Approach – focuses on:
  - Sharp end of the spear
    - Where the knife cuts tissue
- European Approach – focuses on:
  - Blunt end of the spear
    - The organization, policies, and procedures


#### Avoiding Wrong-Site Surgery
- Shared Decision-Making Process
- OR “Time Out”
- Marking the Surgical Site

#### The “Holes” in Shared Decision-Making
- 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

The “Holes” in Shared Decision-Making

- 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.


The “Holes” in Shared Decision-Making

- 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.


Study of Wrong-Part/Side/Procedure/Patient Surgery

Analyzed the factors that contributed to all reported instances in the state of Pennsylvania during a 30-month period.

- A wrong-site surgery event will reach a patient once per year in a 300-bed hospital.
- Failure to verify consent forms was found to be a major contributor to errors resulting in the initiation of wrong-site surgery.
- Verifying consent documents was a common source of successful recovery to prevent wrong-site surgery.


Medical Malpractice Risk

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


Medical Malpractice Claims 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.


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


Connecticut Association for Healthcare Quality
Education Program April 30, 2008 Cromwell, Ct
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**Where To Obtain Consent and How To Document the Process**
- Obtain consent in the office vs. in the preoperative holding area.
  - $65,600 reduction in legal expenses
  - $257,000 reduction in indemnity payments
- Document the informed consent discussion in a supplemental note.
  - $102,000 reduction in legal expenses
  - $352,000 reduction in indemnity payments


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**Veterans Health Administration**
- 155 medical centers
- 5.5 million people received care in VA health care facilities in 2006 (an increase of 29% from 2001)
  - 773,600 inpatient visits
  - 60 million outpatient visits


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**ESPD Initiative**
- September 2004 – Department of Veterans Affairs announced the Electronic Support for Patient Decisions (ESPD) initiative:
  - Employ a software application to standardize and automate the shared decision-making process across all VA medical centers.

Spotswood S. U.S. Medicine. 2005;41:1,37,44.

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**ESPD Initiative**
- A provider-facing tool that produces easy-to-understand consent documents and patient education materials for >2,200 treatments and procedures.

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

<table>
<thead>
<tr>
<th>Percent of Procedures</th>
<th>Progress Note in the Patient Chart</th>
<th>Consent Form in the Patient Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional (paper) consent process</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Automated consent process</td>
<td>6%</td>
<td>0%</td>
</tr>
</tbody>
</table>

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Impact of a Missing Progress Note
- In a study of cases alleging inadequate informed consent, failure to document the informed consent discussion in a supplemental note resulted in:
  - $102,000 in additional legal expenses
  - $352,000 in additional indemnity payments

Prior to automating the process, the VA was missing the note 94% of the time.


Impact of Lost or Misplaced Consent Forms
- An analysis of the time required to find or replace a lost or missing consent form when those forms are lost 8% of the time results in:
  - This translates to $580,000 in additional expenses each year for the average U.S. hospital assuming that consent forms are lost/misplaced 8% of the time.

Prior to automating the process, the VA was missing the consent form 8% of the time.


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

Leverage the “Time Out” Process

Patient Safety Opportunity
- Employ the consent document, rather than the surgical order, to verify:
  - Correct patient
  - Correct procedure
  - Correct site
  - Bring the patient into the “Time Out” huddle

An automated informed consent application can document the patient’s understanding of procedure and site for the surgical team.

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“Teach-Back”

NQF Safe Practice No. 2
Ask each patient or legal surrogate to “teach-back” or “repeat-back” in his or her own words key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.

Implementing “Teach-Back”
- Prompt the provider to ask the 6 questions advocated by the NQF to gauge patient comprehension.
- Provide a means for documenting the patient’s responses.

Automating “Teach-Back”


Questions Regarding the “Repeat-Back” Approach
- What are the patient-level effects?
  - Comprehension
  - Satisfaction
  - Anxiety
- Are providers satisfied with the process?
- What is the impact on work flow?
- What is the cost/benefit ratio?

A Study of the “Teach-Back” Approach
Prospective, Randomized, Multi-Site, Study of Teach-Back

- Benefits of 'Repeat-Back' Protocols Within a Computer-based Informed Consent Program:
  - Funded by the Department of Veterans Affairs Health Services Research and Development Service (HSR&D)
  - 600 patients
  - 7 VA Medical Centers

Prospective, Randomized, Multi-Site, Study of Teach-Back

- Procedures studied:
  - Laparoscopic Cholecystectomy
  - Carotid Endarterectomy
  - Total Hip Arthroplasty
  - Radical Prostatectomy
- Subjects randomized to one of two arms:
  - Automated informed consent process (the VA's standard ESPD process)
  - Automated informed consent process combined with "Repeat Back"

Progress Report
(Interim Statistical Analysis, 10/4/07)

- Comparison of the longest and shortest duration sites
  - Repeat-Back Site
    - Denver: 8 patients, 33.37 minutes (SD: 21.71)
    - Houston: 15 patients, 9.13 minutes (SD: 4.09)
  - Standard Site
    - Denver: 6 patients, 12.17 minutes (SD: 4.62)
    - Houston: 15 patients, 5.00 minutes (SD: 1.89)
- Time spent utilizing the automated informed consent application
  - Standard arm: 8.81 minutes
  - Repeat-Back arm: 14.58 minutes

Potential Informed Consent Pitfalls

- Physicians/Practitioners Other Than the Operating Practitioner
  - RI.2.60
- Observers/Filming/Photography
  - RI.2.50
- Interpreters
  - Meaningful access (Title VI of the 1964 Civil Rights Act)
- Informed Refusal
  - RI.2.70

Other Areas of Attention
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Getting Started

Survey Your Patients
- “Interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients’ representatives to see how satisfied they are with the informed consent discussion prior to their surgery.”

CMS Interpretive Guidelines for Informed Consent (§482.51(b)(2))
(Revised 4/13/07)

Patient Satisfaction
- Study in the Emory University Outpatient Urology Clinic:
  - Overall satisfaction = 4.7 (on a scale of 1 to 5, with 5 = very satisfied)
  - Study of 204 urology procedures:
    - 96.1% of patients preferred the electronic system to the traditional process

Ritenour. 21st TEPR Conference, Salt Lake City, May 17, 2005.

Informed Consent Audit
- Audit your existing process

What Can We Accomplish Immediately?

Questions
Copies of slides and other materials are available at:
www.dialogmedical.com/ctahq.htm