Review of the "Quality of Informed Consent Documents" Proposed Measure
Is Your Organization Prepared for a New Approach to Consents?

Taylor Healthcare Webinar Series
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Webinar Outline

• Examine shared decision-making and informed consent
• Review what influences the informed consent process today
• Study the genesis of the new informed consent measure
• Analyze the measure itself
• Discuss the probability of the measure being implemented
• Consider next steps for organizations
Shared Decision-Making and Informed Consent

**Shared Decision-Making**: evaluation of all treatment options for a particular condition considering patient goals and objectives

**Informed Consent**: evaluation of a particular treatment or procedure including alternatives and prognosis if declined

**Disclosure**: evaluation of the risks and complications specific to the planned treatment or procedure
Regional Variations in Care

- Mastectomy vs. lumpectomy – rates of mastectomy per 1,000 Medicare beneficiaries adjusted for age and race
  - 1.1 U.S. average
  - 2.5 in Victoria, TX
  - 0.3 in Muncie, IN
- **8X difference**

Influencing Patient Decisions

- Not exclusively the purview of providers
- Payers and insurers are employing “choice architecture”

Acknowledgement: Fay Rozovsky, JD, MPH. The Rozovsky Group.
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Shared Decision-Making

- Receiving significant attention
- No single “best” treatment – depends on the values and objectives on the patient


### Table: Study Design, Results, and Interpretations of 3 Surgical Clinical Trials

<table>
<thead>
<tr>
<th>Study Name and Patient Population</th>
<th>Standard Treatment vs Experimental Alternative</th>
<th>Absolute Differences (Standard vs Experimental)</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPAC: Uncomplicated appendicitis in adults</td>
<td>Open appendectomy vs antibiotics (3 d IV, then 7 d PO)</td>
<td>Freedom from recurrence of appendicitis within 1 y: 100% vs 72.7% (95% CI, 67.5-78%)</td>
<td>Relapse rate of 27% with antibiotics did not meet noninferiority threshold of 24%, thus favoring surgery over antibiotics</td>
</tr>
<tr>
<td>SCANDIV[2]: Perforated diverticulitis without recurrent peritonitis</td>
<td>Colectomy (all types) vs laparoscopic lavage and interval coonscopy</td>
<td>Severe complications within 90 d: 30.7% vs 26.0% (P = .53)</td>
<td>Colectomy preferable owing to lower reoperation rate</td>
</tr>
<tr>
<td>“A Randomized, Controlled Trial of Total Knee Replacement”</td>
<td>Total knee replacement followed by 12 wk of nonsurgical treatment (exercise, education, diet, insoles, pain medications) vs nonsurgical treatment alone for 12 wk</td>
<td>Clinically significant (15%) improvement in symptom score: 85% vs 68%</td>
<td>“Nonsurgical treatment can significantly improve my symptoms, without the risks of surgery.”</td>
</tr>
</tbody>
</table>

**Notes:** IV, intravenous; PO, by mouth; QOL, quality of life.
Shared Decision-Making
- A priority for CMS
- Two active models:
  - Shared Decision-Making Model for accountable care organizations (ACOs)
  - Direct Decision Support Model for decision support organizations (DSOs)

What Determines the Content of Your Informed Consent Form(s) and Policy(ies) Today?
Requirements that Shape Informed Consent

- Medicare Conditions of Participation (CoPs)
- State statute and requirements
- Accreditation standards
- Case law
- Surveyors

CMS CoPs – Interpretive Guidelines

- A properly executed informed consent form contains the following **minimum** elements:
  - Name of the hospital
  - Name of the specific procedure(s) or type of medical treatment
  - Name of the responsible practitioner who is performing the procedure or administering the medical treatment
  - Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative
  - Signature of the patient or the patient’s legal representative
  - Date and time the informed consent form is signed by the patient or the patient’s representative
CMS CoPs – Interpretive Guidelines

• A well-designed informed consent form might also include:
  – Name of the practitioner who conducted the informed consent discussion
  – Date, time, and signature of the person witnessing the patient or the patient’s legal representative signing the consent form
  – Indication or listing of the material risks of the procedure or treatment that were discussed
  – Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records
State Law

- Texas Medical Disclosure Panel
  - Established by the Texas Legislature in 1977
  - Comprised of 9 members: 3 attorneys and 6 physicians
  - The panel determines:
    - Which procedures require disclosure
    - The risks and hazards that physicians must disclose to their patients
    - General form to be employed


Accreditation Organizations

- Joint Commission – Hospital Accreditation Standard
- DNV
  - Integrates ISO 9001 with the CoPs
  - Does require ISO 9001 certification
  - Quality focus with emphasis on compliance with policies/procedures

Case Law

- Example: Wisconsin Supreme Court expansion of the duty to disclose diagnostic options that may not be fully supported by the presenting symptoms


CMS Survey

- Review policies and procedures
  - Procedures that require informed consent
  - When procedures may be considered emergent (no consent required)
- Review a minimum of six non-emergent informed consent forms
  - Will ideally review the records of patients who are about to undergo surgery or who are located in a surgical recovery area
- Confirm presence in chart prior to surgery
- 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

Interpretive Guidelines §482.51(b)(2) – Surgical Services
Genesis of the Measure

History with CMS

- Yale New Haven received the contract to develop the measure on 9/16/13
  - $91.7M
  - 3 consultants
  - 9 Working Group members
  - 13 Technical Expert Panel members
Call for Public Comment
• Public comment period ran from July 18, 2016 through August 17, 2016
• Public comment summary was published on September 14, 2016

3. Measure at the Level of the Surgeon, Not the Hospital
Informed consent is a critical aspect of a surgeon’s relationship with the patient and the surgeon is responsible for obtaining informed consent. Yet, the proposed methodology measures informed consent at level of the hospital. ACS believes that this is a missed opportunity to enhance the surgeon/patient relationship and promote patient-centered decision-making. The responsibility for informed consent should be measured by the party whom is responsible for working with the patient to ensure comprehensive informed consent.

The Veterans Health Administration (VHA) is the nation’s largest health care provider with nearly 9,000,000 veterans enrolled in 2015 and over 3,400,000 written informed consent forms completed in 2015. The National Center for Ethics in Health Care (NCEHC) is the VHA program office responsible for maintaining strong ethics practices through informed consent policy and management of our electronic iMedConsent™ software, used to document signature informed consent.
CMS Response to the Proposed Measure Comments

- CMS adjusted the sampling methodology in response to the comments
  - Made it random
    - Addressed concerns about gaming the process
    - CMS will use a stratified random sampling method

Hospital IQR Program – Proposed “Quality of Informed Consent Documents Measure”
Hospital IQR Program

- On April 28, CMS announced that it is inviting public comment on seven new measures to be included in the Hospital IQR Program
- One of the seven new measures is the “Quality of Informed Consent Documents Measure”


Hospital IQR Program

- Incentivizes hospitals to report designated quality measures (ability to recoup a 2 percent Medicare holdback)
- Makes the information available to consumers through the Hospital Compare website
Quality of Informed Consent Documents Proposed Measure

• CMS notes that comprehensive informed consent documents can:
  – Improve patient comprehension and satisfaction
  – Support patients in making decisions that are aligned with their expectations, preferences, and goals

Quality of Informed Consent Documents Proposed Measure

• CMS further observed that in spite of their importance, informed consent documents are frequently:
  – Generic
  – Lack information relevant to the procedure
  – Include illegible, hand-written information
  – Presented to patients for signature minutes before the start of a procedure when they are most vulnerable and least likely to ask questions
Quality of Informed Consent Documents Proposed Measure

- Measure Development
  - Developed in 8 hospitals
  - Validated in an additional 25 hospitals
- The participating hospitals reported that the information generated by the measure was useful to the hospitals’ efforts to improve their informed consent documents and processes by identifying important gaps in their existing documentation.

Quality of Informed Consent Documents Measure

- Abstraction Tool
  - 8 items will be rated
  - Maximum score of 20
  - Likely no more than 100 documents to be sampled
  - Abstractors can rate between 15 and 20 documents in an hour
  - Frequency of the data submission process has not been determined (it may be annually, every 6 months or quarterly)
Consent Form Scoring

Description of the Procedure

- Is language describing **what** the procedure is (beyond the medical name) provided for the patient?  
  - 2 points

- If provided, is the information typed?  
  - 1 point

- Is language describing **why** the procedure is needed provided for the patient?  
  - 2 points

- Is language describing **risk** of the procedure provided for the patient?  
  - 2 points

- Is language describing **benefit** of the procedure provided for the patient?  
  - 2 points

- Are all statements clear, concise, and understandable?  
  - 2 points
Description of the Procedure

- Is a description of how the procedure will be performed provided for the patient?
  - 2 points

- If provided, is the information typed?
  - 1 point

Rationale for the Procedure

- Is the clinical rationale (condition-specific justification) for why the procedure will be performed provided?
  - 2 points - Context and condition given and fully meet criteria
  - 1 point - Context and condition given, but do not fully meet criteria
Patient-Oriented Benefit(s)

- Is any patient-oriented **benefit** provided (intended impact on patient's health, longevity, and/or quality of life)?
  - 2 points

Probability of Procedure-Specific Risks

- Is a **quantitative probability** provided for any procedure-specific **risk**?
  - 2 points
- Is a **qualitative probability** provided for any procedure-specific **risk**?
  - 1 point
Probability of Procedure-Specific Risks

- American College of Surgeons ACS NSQIP Surgical Risk Calculator
  - Detailed, quantitative surgical risks based on patient age, history and co-morbidities

Alternative(s) to the Procedures

- Is any *alternative* provided for the patient?
  - 2 points
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Timing

- List the date of the procedure
- Date of patient's/proxy's signature – **at least one day before procedure** or patient opted out of viewing the informed consent document at least 1 day prior
  - 5 points

Consent Form Timing
Medical Liability Risk

- In MedMal cases, alleging inadequate informed consent, consents obtained in the pre-operative holding area, compared to in the surgeon’s office, resulted in significantly higher legal expenses and indemnity payouts — $322,000 higher, on average.


OR Start Time Delays

- 66 percent of patients had the consent missing from their record at the time of surgery
- Delayed 14 percent of cases


OR Start Time Delays

- Missing or problematic consents had a negative impact upon OR start times in 46 percent of cases
- Declined to less than 1 percent of cases with implementation of an electronic informed consent process


Will the Proposed Measure Stick?
Hospital IQR Program Inclusion – Public Comments

• Published August 14, 2017
• Mixed bag of comments:
  – Risks should include disclosure of any financial incentives
  – Measure focuses on documentation instead of the actual communication process


We strongly support the addition of the Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures Measure and applaud CMS’ move to elevate the critical issue of patient consent in the IQR Program and support the recommendation to deploy the Quality of Informed Consent Documents measure immediately.

Compliance Update
3 Take-Away Action Items

1. Score Your Forms
   - Test your forms against the proposed quality measure
     - General consent-to-treat
     - Procedure-specific forms

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### Table 1.3: Abstraction Tool Scoring Approach (Item-Specific Weighting)

<table>
<thead>
<tr>
<th>Description of Procedure</th>
<th>Response</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Is language describing what the procedure is (beyond the medical name) provided for the patient?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td>1a) If provided, is it typed?</td>
<td>&quot;Yes&quot;</td>
<td>1</td>
</tr>
<tr>
<td>2) Is a description of how the procedure will be performed provided for the patient?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td>2a) If provided, is it typed?</td>
<td>&quot;Yes&quot;</td>
<td>1</td>
</tr>
<tr>
<td>Rational for Procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Is the clinical rationale (condition-specific justifications) for why the procedure will be performed provided?</td>
<td>&quot;Yes, context and condition given and fully meet criteria&quot;</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&quot;Context and condition given, but do not fully meet criteria&quot;</td>
<td>1</td>
</tr>
<tr>
<td>Patient-Oriented Benefits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Is any patient-oriented benefit provided (intended impact on patient’s health, longevity, and/or quality of life)?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&quot;No&quot;</td>
<td>0</td>
</tr>
<tr>
<td>Probability of Procedure-Specific Risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Is a quantitative probability of any procedure-specific risk?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&quot;No&quot;</td>
<td>0</td>
</tr>
<tr>
<td>6) Is a qualitative probability of any procedure-specific risk?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&quot;No&quot;</td>
<td>0</td>
</tr>
<tr>
<td>Alternative(s) to the Procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7) Is any alternative provided for the patient?</td>
<td>&quot;Yes&quot;</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&quot;No&quot;</td>
<td>0</td>
</tr>
<tr>
<td>Timing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8a) Date of patient’s/proxy’s signature</td>
<td>21 days or less before (a) or b (b) is checked</td>
<td>3</td>
</tr>
<tr>
<td>8b) Date of procedure</td>
<td>≤ 3 days before (a) or (b) is not at least 1 day before (b)</td>
<td>0</td>
</tr>
<tr>
<td>9) Patient signed out of receiving the consent document at least one day prior to the procedure</td>
<td>Missing either (a) or (b) is missing</td>
<td>0</td>
</tr>
</tbody>
</table>

**Maximum Quality Score: 20**
2. Evaluate Your Process and Timing

• Where are consent forms typically executed?
• What percent of consents for elective procedures are executed at least a day prior to the date of the procedure?

3. Consider Automation

• Do you have an issue today with compliance?
• Do you have an issue today with OR start time delays?
• Are your consent forms a legal permission document or a confirmation of the patient’s expectations?
  — A patient safety initiative?
Questions

Additional Information

Slides and Audio
www.iMedConsent.com

Becker’s article
(Go to Becker’s Hospital Review and search ‘informed consent’)