Using Training Modules to Move Informed Consent to Informed Choice

Cindy Brach
Health Literacy Annual Research Conference
October 13, 2016
Overview

• Why create informed consent modules
• Leaders Module
• Health Care Professionals Module
• Baseline findings from 4 pilot sites
• Implementation experience at PinnacleHealth
• Pilot findings
• Your questions answered
Presenters

- Cindy Brach, Agency for Health Care Research and Quality
- Salome Chitavi, The Joint Commission
- Alrick Edwards, Abt Associates
- Kathryn Shradley, PinnacleHealth
- Sarah Shoemaker, Abt Associates
Informed Consent: The Problem

Patients
• Misunderstanding
  ► Benefits, harms, risks, alternatives
• Don’t know they can say no

Clinicians
• Just a form
• Don’t offer choices
• Malpractice top 10
OK, you can choose regal equine therapy, OR fragment adhesion cranioplasty. Which would you prefer?
Why Two Modules?

• Ingredients for successful quality improvement:
  ► Leadership support
  ► Prepared workforce
• Leaders module – for C-suite and other execs
• Health care professionals module – teach skills to clinical teams
• Health literacy relevance: informed consent requires clear communication about choices

Both modules will be available to Joint Commission-accredited Institutions for free continuing medical education credit
Leaders Module Components

• Principles of informed consent
• Policy
• Supportive Systems
• Worksheets throughout
• 34 new and existing resources – e.g., Championing Change, AHRQ HL Universal Precautions Toolkit. HCP module also has resource section.
Principles of Informed Consent

- Clarify patients’ rights
- Legal and patient safety implications
- Patient capacity for decision making

Toni Cordell
Policy

- Purpose
- Who can obtain IC
- When
- Content
- Documentation
- Exceptions
- Clear communications policy (plain language, using teach-back, accommodating communication needs)

- Compliance
- Enforcement
- Dissemination
- Review
# Informed Consent Policy Worksheet

<table>
<thead>
<tr>
<th>Policy Component</th>
<th>Does your policy:</th>
<th>What improvements are needed, if any?</th>
</tr>
</thead>
</table>
| **1. Statement of purpose** | - Have a statement of purpose?  
   - Is your statement of purpose in sync with your hospital’s mission statement?  
   - Will it resonate with your hospital’s culture?  
   - Is the language unambiguous?  
   - Is the goal clear without getting bogged down in detail? |                                      |
| **2. General policy**   | - Outline the key principles of informed consent?  
   - Does it give an overview of what the policy covers?  
   - Clearly list patients’ rights? |                                      |
| **3. Who is responsible** | - Clearly specify:  
   - Who is responsible for obtaining informed consent?  
   - What aspects of the informed consent process can be delegated? To whom?  
   - What role each team member plays? |                                      |
Section 3: Building Systems to Improve the Informed Consent Process

To make informed consent an informed choice, clinicians need supportive systems that include:

- Maintaining a library of clear and simple informed consent forms
- Maintaining a library of high-quality decision aids and other patient education materials
- Removing communication barriers by:
  - Providing language assistance (e.g., qualified medical interpreters)
  - Stocking assistive communication devices
- Establishing efficient workflows
- Training staff at all levels

Select the button to open the Informed Consent Systems Worksheet.
Purpose and Objectives

• Strategies and Tools to Improve the Informed Consent process

• Four Key Objectives
  1. Principles of Informed Consent
  2. Strategies for Clear Communication
  3. Strategies for Presenting Choices
  4. Informed Consent as a Team Process
Approach: Enduring and Interactive Modules

- Video recordings
- Provider illustrations
- Knowledge checks
- Illustrative scenarios

- Patient friendly forms
- Model conversation
- Multiple resources
- Patient stories
Strategies for Clear Communication

- Prepare for the Informed Consent Discussion
- Use Health Literacy Universal Precautions
- Remove Language Barriers
- Use Teach-Back
The Teach-Back Process

- **Chunk and teach information.**
- **Ask patients to teach back in their own words. Allow patients to consult material.**
  - If patient doesn’t teach back correctly:
  - **Re-teach using different words**
  - If patient teaches back correctly and there’s more to explain:

Section 2: Strategies for Clear Communication:
Strategy 4: Use Teach-Back (Continued)

Teach-back Questions and Phrases

- "Just to make sure that I explained things well, can you tell me in your own words what will happen if you choose to have this procedure done?"
- "It's my job to explain...

Select each image of a health care worker for a teach-back example.
Strategies for Presenting Choices

• Offer choices
• Engage patients, families and friends
• Elicit patient goals and values
• Show high-quality decision aids
• Explain benefits, harms and risks of all options
• Help patients choose
Informed Consent as a Team Process

- Confirming Understanding
- Ensuring Appropriate Documentation
- Team Roles and Responsibilities
Informed Consent Team Roles and Responsibilities

It is important for each team member to have a clear understanding of his or her role.

<table>
<thead>
<tr>
<th>Role</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall responsibility for obtaining</td>
<td>Physician, Independent Nurse Practitioner or Independent Physician</td>
</tr>
<tr>
<td>informed consent</td>
<td>Assistant who is delivering the care (non-delegable duty)</td>
</tr>
<tr>
<td>Assess and address special communication</td>
<td>Intake staff, nurse, other clinical staff, and/or Physician, Nurse</td>
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<tr>
<td>needs (such as limited English proficiency</td>
<td>Practitioner or Physician Assistant</td>
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<tr>
<td>or impaired hearing)</td>
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<tr>
<td>Assess the patient’s decision-making</td>
<td>Physician, Independent Nurse Practitioner or Independent Physician</td>
</tr>
<tr>
<td>capacity</td>
<td>Assistant</td>
</tr>
</tbody>
</table>

Important

The actual roles and the persons responsible in your hospital may be different from those shown here.

Select the image for an enlarged table.

In the Resources section of this course, you will find:
- A blank Informed Consent Team Roles and Responsibilities Table
- A training resource on coaching team members on how to be part of a team
## Informed Consent Team Roles and Responsibilities

<table>
<thead>
<tr>
<th>Role</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall responsibility for obtaining informed consent</td>
<td>Physician, Independent Nurse Practitioner or Independent Physician Assistant who is delivering the care (non-delegable duty)</td>
</tr>
<tr>
<td>Assess the patient’s decision-making capacity</td>
<td>Physician, Independent Nurse Practitioner or Independent Physician Assistant</td>
</tr>
<tr>
<td>Interpret for patients with limited English proficiency</td>
<td>Qualified medical interpreter</td>
</tr>
<tr>
<td>Stop the line (i.e., halt any activity that could cause harm) if it appears that the patient did not understand</td>
<td>Any team member</td>
</tr>
<tr>
<td>Document the patient’s choice (may include signing the form and/or documenting informed consent conversations in the patient’s record)</td>
<td>Physician, Independent Nurse Practitioner or Independent Physician Assistant</td>
</tr>
<tr>
<td>Confirm that informed consent discussion has been appropriately documented</td>
<td>Nurse or other clinical staff</td>
</tr>
<tr>
<td>Confirm that the patient understands benefits, harms, and risks immediately before the test, treatment, or procedure is performed</td>
<td>Physicians, Independent Nurse Practitioners and/or Independent Physician Assistants</td>
</tr>
</tbody>
</table>
Baseline Findings from Implementation at Four Hospitals

Alrick Edwards
Abt Associates Inc.
Aims of Baseline Assessments

To:

• Understand patient and provider perspectives on informed consent practices at hospitals.

• Identify opportunities for improvement
<table>
<thead>
<tr>
<th>Data Collection Method</th>
<th>Respondents</th>
<th>Research Domains</th>
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<tbody>
<tr>
<td>Baseline Assessment Survey</td>
<td>• Hospital Liaisons</td>
<td>Informed consent practices &amp; attitudes</td>
</tr>
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<td>• Unit Leads</td>
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<tr>
<td>Baseline Assessment Interview</td>
<td>• Hospital Liaisons</td>
<td>Informed consent practices &amp; attitudes; policies and process</td>
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<td>• Unit Leads</td>
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<tr>
<td>Health Care Professional Survey</td>
<td>• HCP/hospital staff</td>
<td>Informed consent practices &amp; attitudes</td>
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<td>Hospital A (Northeast)</td>
<td>Hospital B (Northeast)</td>
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<tr>
<td><strong>Type</strong></td>
<td>Academic, teaching, not for-profit</td>
<td>Integrated care system, teaching, not for-profit</td>
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<tr>
<td><strong>Average Census</strong></td>
<td>750</td>
<td>205</td>
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<tr>
<td><strong>Hospital liaison’s position</strong></td>
<td>Director, Regulatory Affairs, Corporate Compliance</td>
<td>Nurse Professional Development Specialist</td>
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<tr>
<td><strong>Readiness assessment</strong></td>
<td>Prepared; formal</td>
<td>Broad support from the hospital leadership</td>
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</table>
Informed Consent Process Workflow

Consent Discussion → Signed consent Documentation → Confirm patient understanding before procedure → Procedure

Transfer Unsigned Documentation to Procedure Unit → Confirm patient understanding before procedure → Signed consent Documentation

Challenging workflow for hospital staff
Opportunities for Improvement

Process

• Streamline or standardize the Informed Consent process across units
• Better clarify roles of nurses and physicians in Informed Consent
• Increase focus of Informed Consent on patient understanding
• Provide patients more time to consider treatment options
Opportunities for Improvement

Documentation

• Better document the Informed Consent discussion
• Obtain signed Informed Consent forms prior to arriving for surgery
• Be more consistent with witness and interpreter documentation
Consent Form

- Improve consent forms which can be confusing, cumbersome, difficult to understand and follow
- Translate form into common languages represented in patient population
- Integrate consent forms into electronic health record systems
To what extent do clinician obtaining consent in your hospital/unit agree with the following statements

- Staff attitudes (n=235)
- Leaders' perception of clinician attitudes (n=22)

- Chief purpose of IC is to comply with regulations
- Getting signature is most critical part of informed consent
- Refusing a life-saving procedure demonstrates patient is not capable of making a decision
- Clinicians are in a better position to make decisions than patients
- Clinicians should not present less effective alternatives
- Clinicians should encourage patients to talk about values
- Informed consent process is worth the time
- Lack of patient understanding of IC is safety problem
- Clinicians are responsible for ensuring that patients understand their options

Percentage 'Agree' or 'Strongly Agree' (%)
How frequently do clinicians do the following when obtaining informed consent?

- Assess decision-making capacity
- Call for Qualified Interpreters
- Encourage Questions
- Neutral Explanation
- Engage patients/family in discussion
- Offer choices
- Elicit Goals and Values
- Confirm consent before procedure
- Use decision aids

**Informed Consent Practices**

- **Leaders' perception of clinician IC practices (n=22)**
- **Staff's perception of clinicians' IC practices (n=235)**
- **Clinicians' self-report (n=45)**
How well does your unit/do you ensure patients are making an informed choice?

**Unit**
- 1 to 3: 2%
- 4 to 7: 22%
- 8 to 10: 76%

**Self**
- 1 to 3: 0.5%
- 4 to 7: 16%
- 8 to 10: 84%

Average: 8.2  Median: 8
Average: 8.6  Median: 9
How confident are you in your ability to use teach-back in an informed consent discussion?

Average: 7.8      Median: 8

1 to 3: 4%
4 to 7: 34%
8 to 10: 62%
Implementation at PinnacleHealth
Harrisburg, PA

Kathryn Shradley
PinnacleHealth
Director, Customer Relations & Regulatory

Nurse Professional Development Specialist

Director, Nursing Practice & Research
Why Did We Join?

• Ownership Issues
• Demonstrated Lack of Knowledge
• Distinct Patient Events
  ▶ Delayed Surgical Times
• Health Literacy Education
• Concurrent Interest

....because our Medical Librarian told us to!
## Clinical Teams

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<tr>
<th>Unit</th>
<th>Team Members</th>
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<tbody>
<tr>
<td>Med/Surg ICU</td>
<td>60 RN’s</td>
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<td>1 Pulmonologist</td>
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<tr>
<td>Cath Lab</td>
<td>40 RN’s</td>
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<td>1 Cardiologist</td>
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<td>Perianesthesia</td>
<td>46 RN’s</td>
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<td>1 General Surgeon</td>
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<td>Post-Op Surgical</td>
<td>66 RN’s</td>
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<td>1 Orthopedic Surgeon</td>
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## Project Timeline

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<tr>
<th>Project Support</th>
<th>Baseline Survey</th>
<th>Patient Surveys</th>
<th>Leader Module</th>
<th>HCW Survey</th>
<th>HCW Module</th>
<th>Monthly Reviews</th>
<th>On-Site Visits</th>
<th>Patient Surveys</th>
<th>Project Debriefing</th>
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Response to Modules

Leader Module

- “We’re not doing this well”
- “This is great information”
- “We have a lot to change at the office”
Response to Modules

Staff Module

• “We’re not doing this well”
• “This happens all the time”
• “We need to fix this now”
Challenges

• Staff Engagement
  ► Concurrent Initiatives
  ► Unaware of the “Problem”

• Auditing….Auditing…..Auditing…..

• Module Length & Delivery Method

• Implementation Plan
Success

- Improved Bedside Communication
- Increased Staff Chatter
- Cemented Baseline Knowledge for Leaders
- Inspired Next Steps

...we began to hear the words “Informed Choice”
Self-Evaluation & Next Steps

- Awareness of Good Consent Process
  - Highlighted internal leaders
- Process Map for Cardiology Consents
- Decision Aid Library - to come!
Pilot Test Findings

Sarah J. Shoemaker, PhD, PharmD
Abt Associates Inc.
Aims

To:

• Understand the facilitators and barriers to implementing training modules and strategies

• Determine the effect of the modules
## Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Respondents</th>
<th>Hospital A</th>
<th>Hospital B</th>
<th>Hospital C</th>
<th>Hospital D</th>
<th>TOTAL</th>
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<td><strong>Leaders Training Pre-/Post-Quiz</strong></td>
<td>Leaders</td>
<td>7 / 7</td>
<td>13 / 11</td>
<td>5 / 5</td>
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<td><strong>HCP Training Pre-/Post-Quiz</strong></td>
<td>HCP/Staff</td>
<td>15 / 15</td>
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<td><strong>Check-in Calls</strong></td>
<td>Liaisons</td>
<td>1 x 9 mos.</td>
<td>3 x 9 mos.</td>
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<td>1 x 3 mos.</td>
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### Implementation

<table>
<thead>
<tr>
<th>Leaders Trained (n=23)</th>
<th>Hospital A</th>
<th>Hospital B</th>
<th>Hospital C</th>
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<th>HCP/ Staff Trained (n=95)</th>
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<th>Hospital B</th>
<th>Hospital C</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>73</td>
<td>7</td>
<td></td>
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<table>
<thead>
<tr>
<th>Strategies</th>
<th>Hospital A</th>
<th>Hospital B</th>
<th>Hospital C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Began revisiting policy to clarify whether residents’ can obtain consent</td>
<td>• Began clarifying team roles</td>
<td>• Reviewed and revised policy</td>
</tr>
<tr>
<td></td>
<td>• Tried to address surgical Attending training</td>
<td>• Identified need to re-train staff on interpreter services and resources</td>
<td>• Identified and addressed incomplete documentation</td>
</tr>
<tr>
<td></td>
<td>• An Attending began teaching residents teach-back</td>
<td>•</td>
<td>• Revised consent form</td>
</tr>
<tr>
<td></td>
<td></td>
<td>•</td>
<td>• Translated form</td>
</tr>
</tbody>
</table>
Implementation – Facilitators*

- Covered staff time
- Committed champion with available time to encourage training completion
- Clinical leadership involvement (chief of surgery)
- Reinforcing training in staff meetings
- Aligning improvement need with Joint Commission survey findings

*Potentially a result of pilot test participation, too
Implementation – Barriers

- Training module length and functionality
- Staff turnover
- Competing demands
- Limited leverage over non-employee physicians
- Insufficient time to train and then implement strategies
Effect of training modules and strategies

- Training modules improved knowledge
  - Leaders ($p < 0.05$)
  - Health care professionals/ staff ($p < 0.001$)
Effect of training modules and strategies*

- Increased awareness & fostered dialogue
- Pointed out discrepancies in interpretation of policies (e.g., who can obtain consent)
- Assessed workflow and processes
- Revealed documentation issues
- Reinforced existing interpreter services
- Identified many opportunities for improvement (to be pursued, potentially)

*Potentially a result of pilot test participation, too
Validation of training module content value

- Need to revisit policies, in part, because of different interpretations
- Removing communication barriers still needed
- Breakdowns and inefficiencies in workflows common
- Use of teach-back limited
- Often documentation issues
- Not consistent approach to confirmation
- Unclear on team roles, particularly residents
Lessons learned for future QI

• Use a formal QI process (i.e., determine goals, plan, rollout, timeline, monitoring)
• Get representatives from key departments and hospital units on board for making improvements
• Collect data from leadership, clinicians and patients on current practices
• Examine the workflow to identify inefficiencies
• Start slow and address ‘hot button’ areas first (e.g., form, use of interpreter services)
Lessons for researchers

- Consider the line between research and QI
- Clarify staff roles and relationship to hospital
- Challenge of evaluating effects of training and strategies entangled with effects of participation
- Allow time needed to observe change
- Ensure participating hospitals/organizations’ leadership & champions have reviewed training and know requirements