



U.S. Department of Health and Human Services



Agency for Healthcare Research and Quality

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# **Using Training Modules to Move Informed Consent to Informed Choice**

**Cindy Brach**

**Health Literacy Annual Research Conference**

**October 13, 2016**



# Overview

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- 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

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- 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

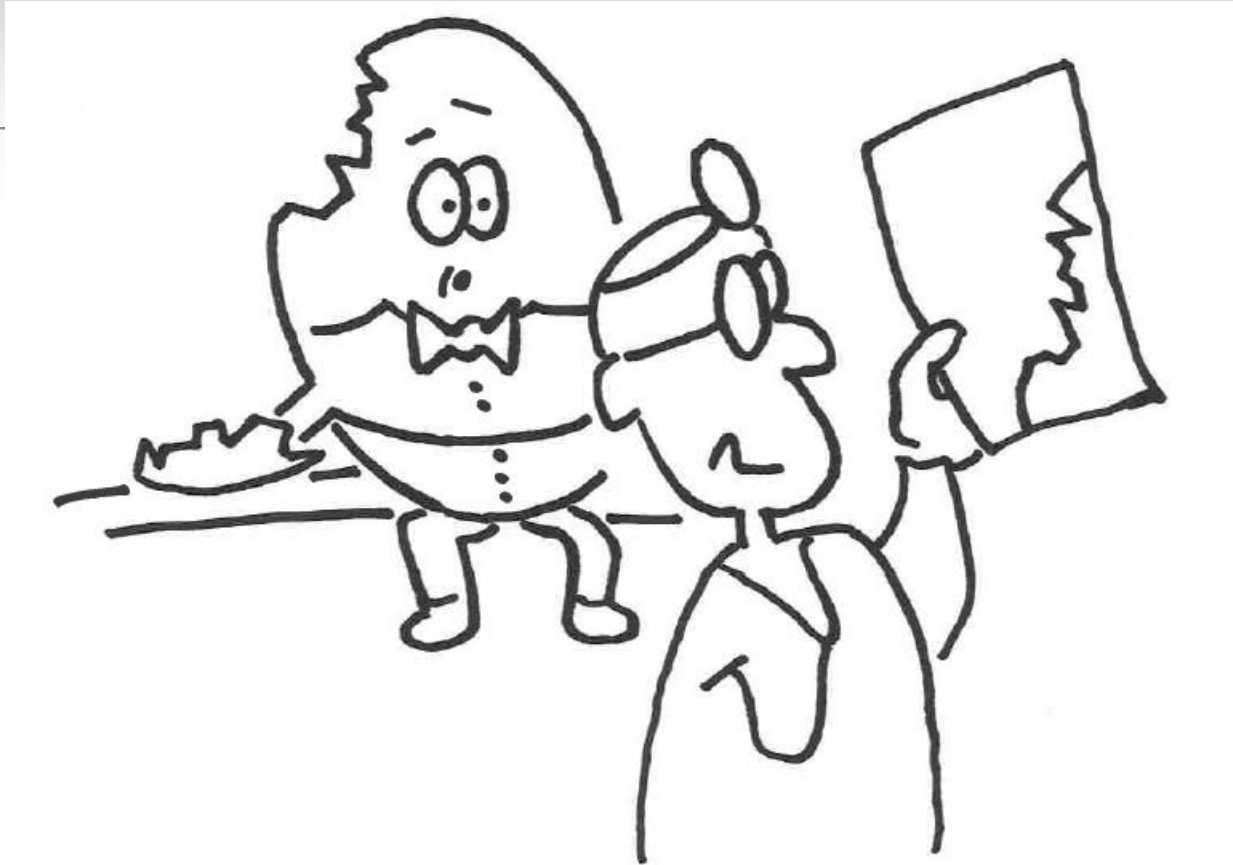
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## Patients

- Misunderstanding
  - ▶ Benefits, harms, risks, alternatives
- Don't know they can say no

## Clinicians

- Just a form
- Don't offer choices
- Malpractice top 10



*HKM M. Wang C. Branch*

OK, you can choose regal equine therapy, OR fragment adhesion cranioplasty. Which would you prefer?

# Why Two Modules?

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- 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

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- 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

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**Toni Cordell**

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



# Policy

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- 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

Policy Component	Does your policy:	What improvements are needed, if any?
1. Statement of purpose	<p>Have a statement of purpose?</p> <p>Is your statement of purpose in sync with your hospital's mission statement?</p> <p>Will it resonate with your hospital's culture?</p> <p>Is the language unambiguous?</p> <p>Is the goal clear without getting bogged down in detail?</p>	
2. General policy	<p>Outline the key principles of informed consent?</p> <p>Does it give an overview of what the policy covers?</p> <p>Clearly list patients' rights?</p>	
3. Who is responsible	<p>Clearly specify:</p> <ul style="list-style-type: none"> <li>• Who is responsible for obtaining informed consent?</li> <li>• What aspects of the informed consent process can be delegated? To whom?</li> <li>• What role each team member plays?</li> </ul>	



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### Section 3: Building Systems to Improve the Informed Consent Process

Clinical staff, however well-intentioned, cannot improve informed consent on their own. Systems need to be put into place to support clinical staff in making informed consent an informed choice.

In this section, we describe the systems that can set the stage for an improved process of informed consent. These systems include:

- Maintaining a library of clear and simple consent forms;
- Maintaining a library of high-quality decision aids

[Audio Script On](#)

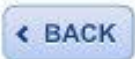
### Section 3: Building Systems to Improve the Informed Consent Process

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

[Systems Worksheet](#)

*Select the button to open the Informed Consent Systems Worksheet.*





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# **Making Informed Consent and Informed Choice: Training for Health Care Professionals Module**

**Salome O. Chitavi**

**The Joint Commission**



# Purpose and Objectives

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- 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

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- Video recordings
- Provider illustrations
- Knowledge checks
- Illustrative scenarios
- Patient friendly forms
- Model conversation
- Multiple resources
- Patient stories

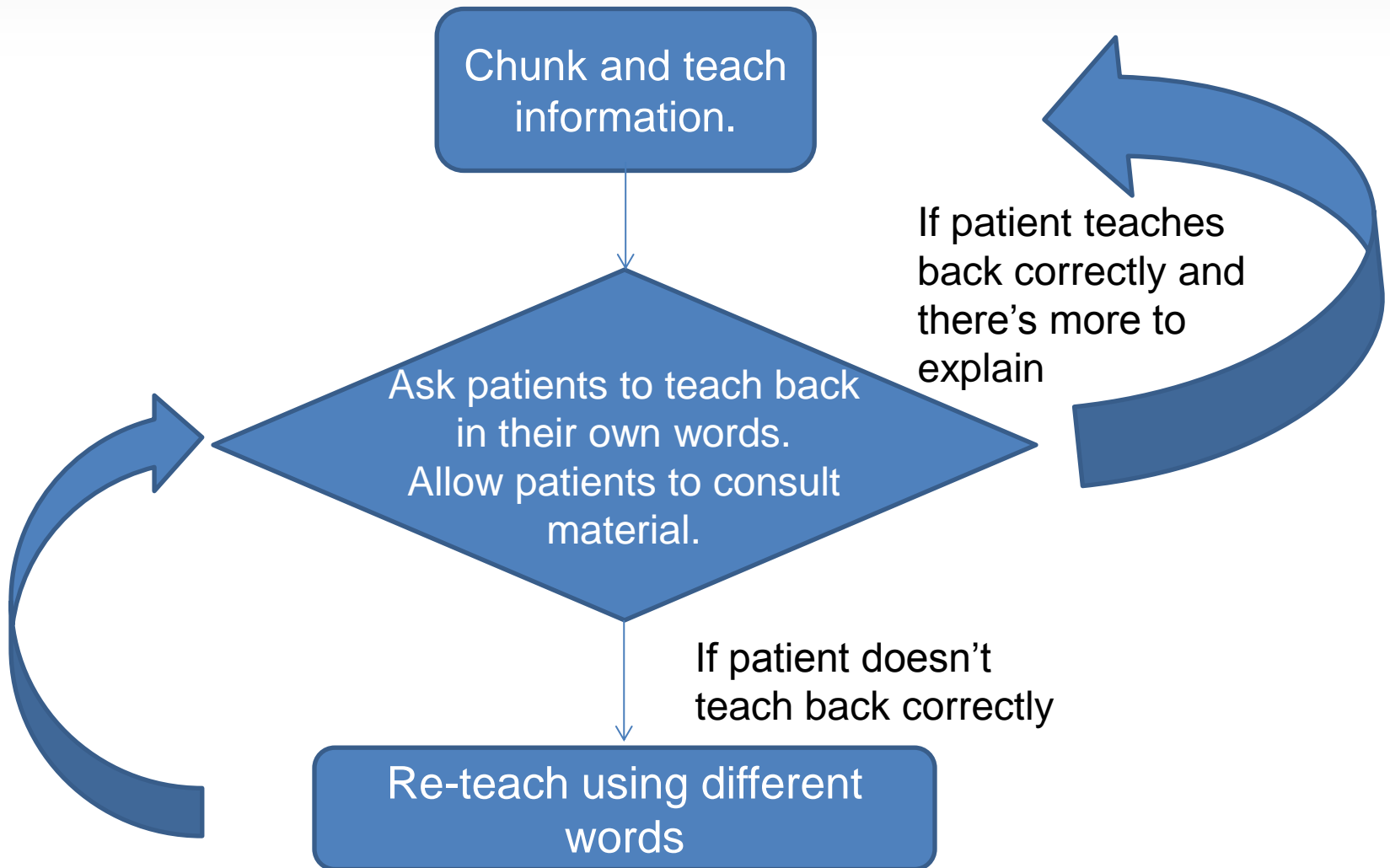


# Strategies for Clear Communication

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

# The Teach-Back Process







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## Making Informed Consent an Informed Choice: Training for Health Care Professionals

Menu

Exit

Some people find it difficult to do teach-back without it feeling like you're testing your patient. It'll take practice, but clinicians have said that once they got the hang of teach-back, they could seamlessly weave it into the informed consent discussion.

Select each image of a health care worker for some examples of 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 crucial to explain

Audio Script On

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

#### Teach-back Questions and Phrases



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



# Strategies for Presenting Choices

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- 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

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



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## Making Informed Consent an Informed Choice: Training for Health Care Professionals

Menu

Exit

[Refresh](#)

Since several care team members may be involved in the informed consent process, it is important for each team member to have a clear understanding of his or her role and the roles of other care team members.

You can use the table to clarify roles and responsibilities within your team with respect to informed consent.

To see the entire table, use the scroll bar to the right or select the image for an enlarged table.

There is a blank table in the Resources area of this course that you can download and customize as appropriate for your team. Complete this

Audio Script On

### Informed Consent Team Roles and Responsibilities

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

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



Select the image for an enlarged table.

#### Important

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

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

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



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# **Baseline Findings from Implementation at Four Hospitals**

**Alrick Edwards  
Abt Associates Inc.**



# Aims of Baseline Assessments

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To:

- Understand patient and provider perspectives on informed consent practices at hospitals.
- Identify opportunities for improvement



# Methods/Data Sources

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Data Collection Method	Respondents	Research Domains
Baseline Assessment Survey	<ul style="list-style-type: none"><li>• Hospital Liaisons</li><li>• Unit Leads</li></ul>	Informed consent practices & attitudes
Baseline Assessment Interview	<ul style="list-style-type: none"><li>• Hospital Liaisons</li><li>• Unit Leads</li></ul>	Informed consent practices & attitudes; policies and process
Health Care Professional Survey	<ul style="list-style-type: none"><li>• HCP/hospital staff</li></ul>	Informed consent practices & attitudes

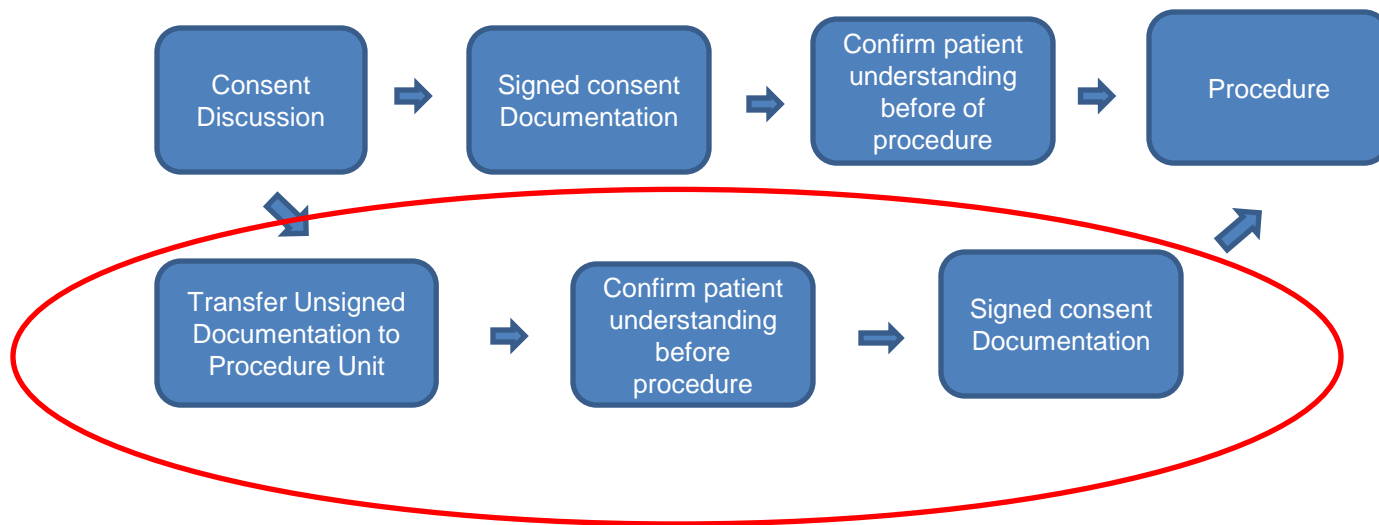




# Hospital Characteristics

	Hospital A (Northeast)	Hospital B (Northeast)	Hospital C (South)	Hospital D (Northwest)
Type	Academic, teaching, not for-profit	Integrated care system, teaching, not for-profit	Academic, integrated care system, teaching, not for-profit, safety net	Teaching, for-profit
Average Census	750	205	285	105
Hospital liaison's position	Director, Regulatory Affairs, Corporate Compliance	Nurse Professional Development Specialist	Quality Analyst	Risk manager
Readiness assessment	Prepared; formal	Broad support from the hospital leadership	Had issue related to informed consent from their stroke review by Joint Commission	Enthusiastic; wanted to implement in entire hospital

# Informed Consent Process Workflow



Challenging workflow for hospital staff



# Opportunities for Improvement - 1

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## 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 - 2

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## 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



# Opportunities for Improvement - 3

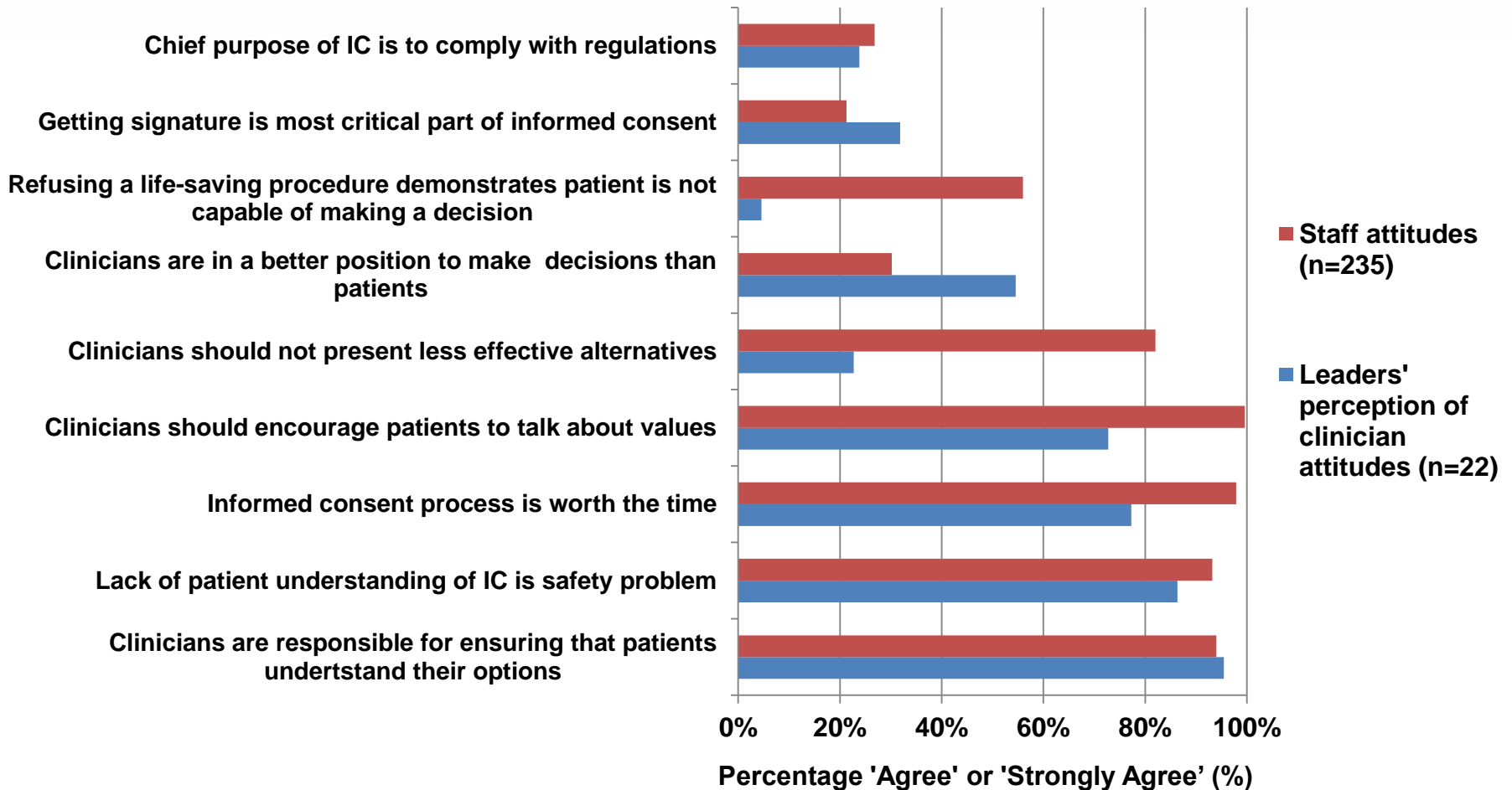
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## Consent Form

- 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

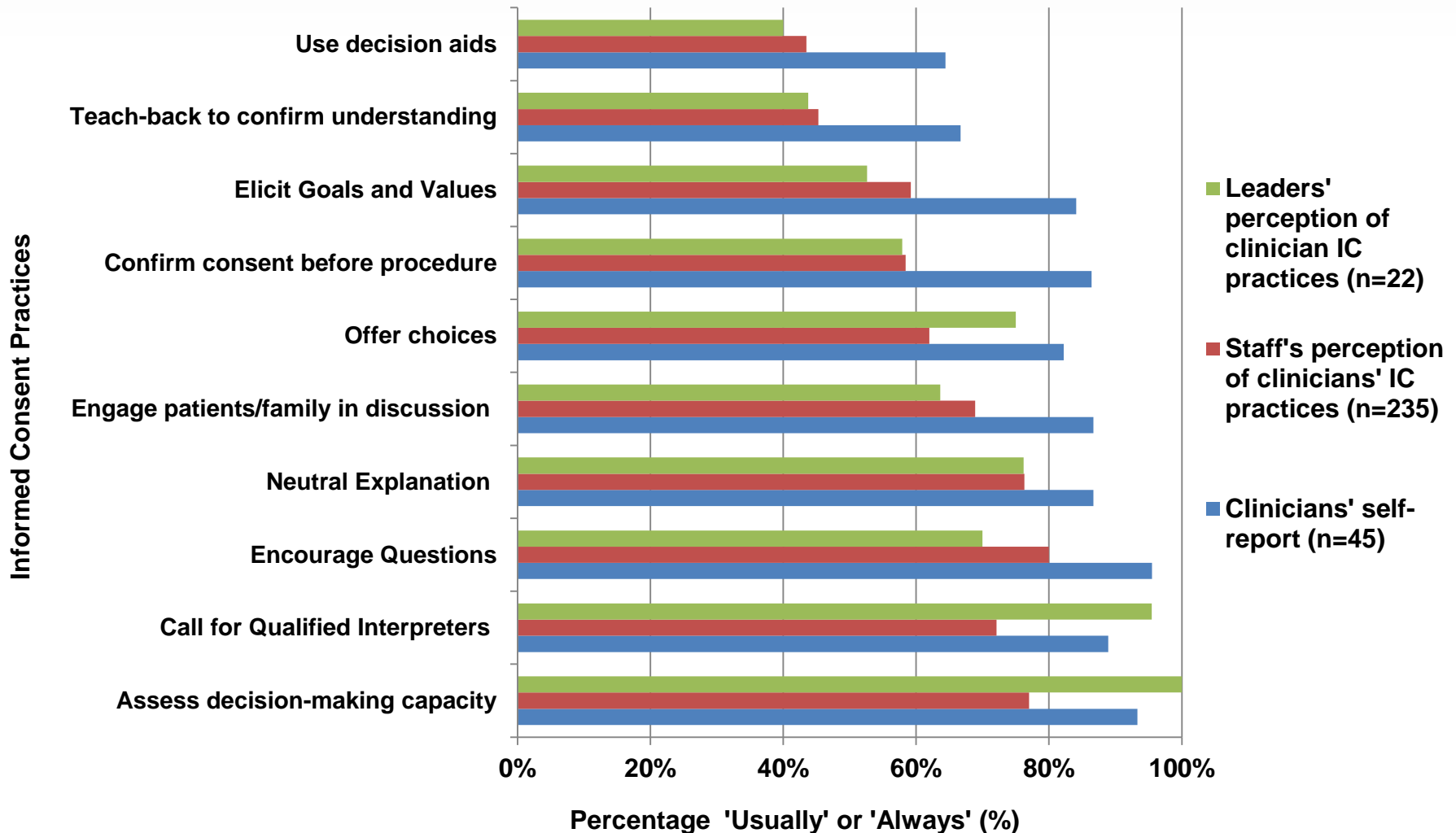


# To what extent do clinician obtaining consent in your hospital/unit agree with the following statements





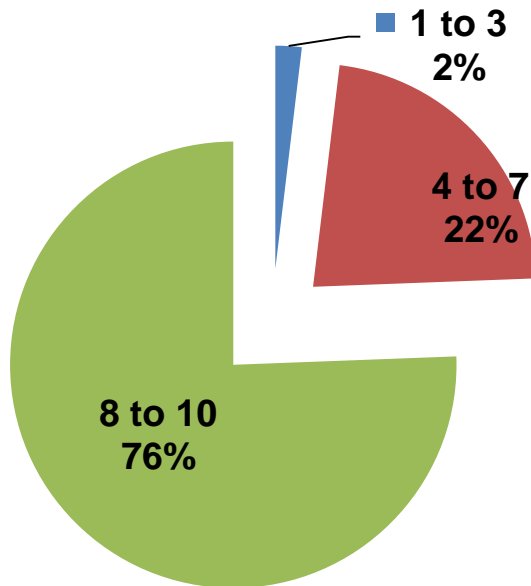
# How frequently do clinicians do the following when obtaining informed consent?





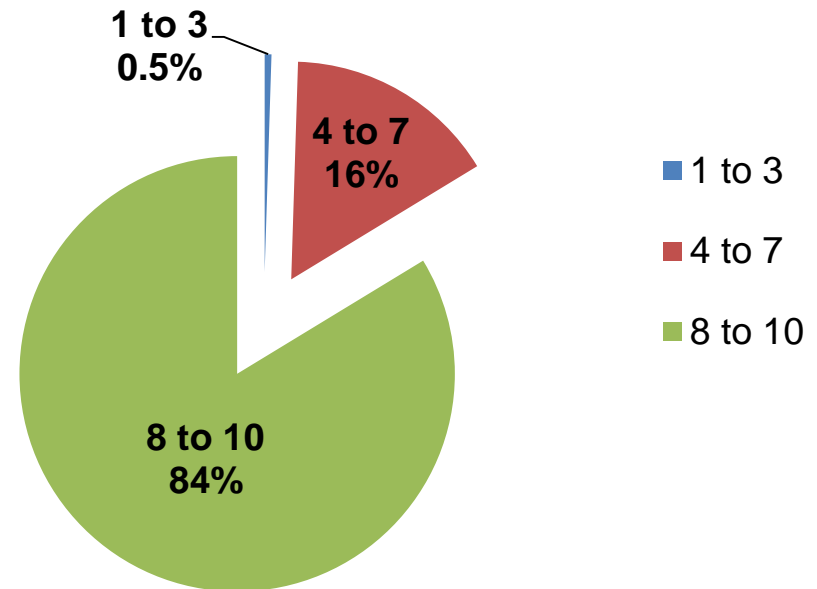
# How well does your unit/do you ensure patients are making an informed choice?

**Unit**



Average: 8.2    Median: 8

**Self**

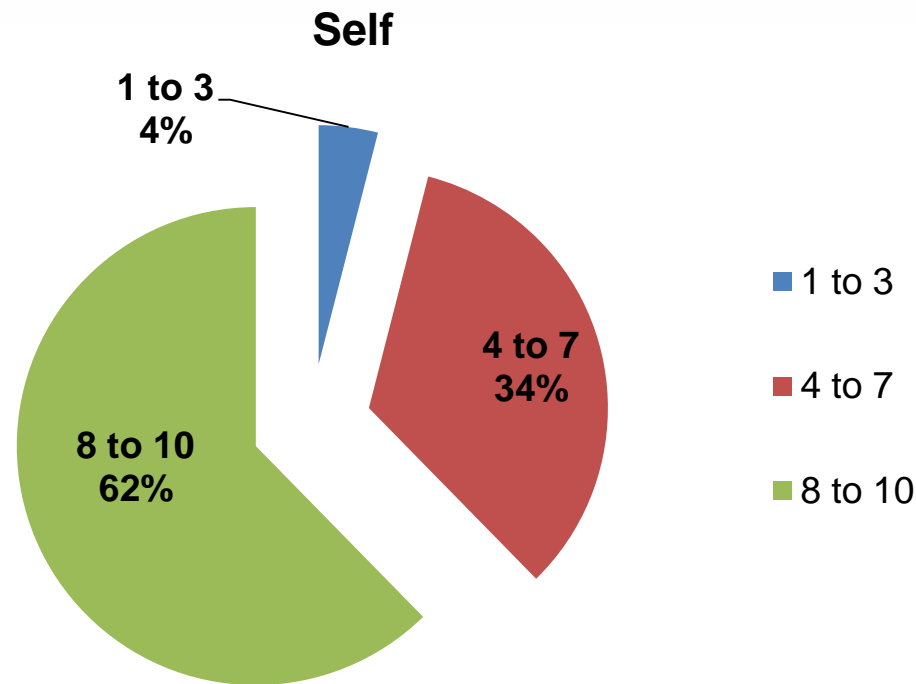


Average: 8.6    Median: 9





## How confident are you in your ability to use teach-back in an informed consent discussion?



Average: 7.8    Median: 8



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# Implementation at PinnacleHealth Harrisburg, PA

**Kathryn Shradley**  
**PinnacleHealth**





Director,  
Customer Relations &  
Regulatory



Nurse Professional  
Development Specialist



Director,  
Nursing Practice &  
Research

# Why Did We Join?

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

*....because our Medical Librarian told us to!*



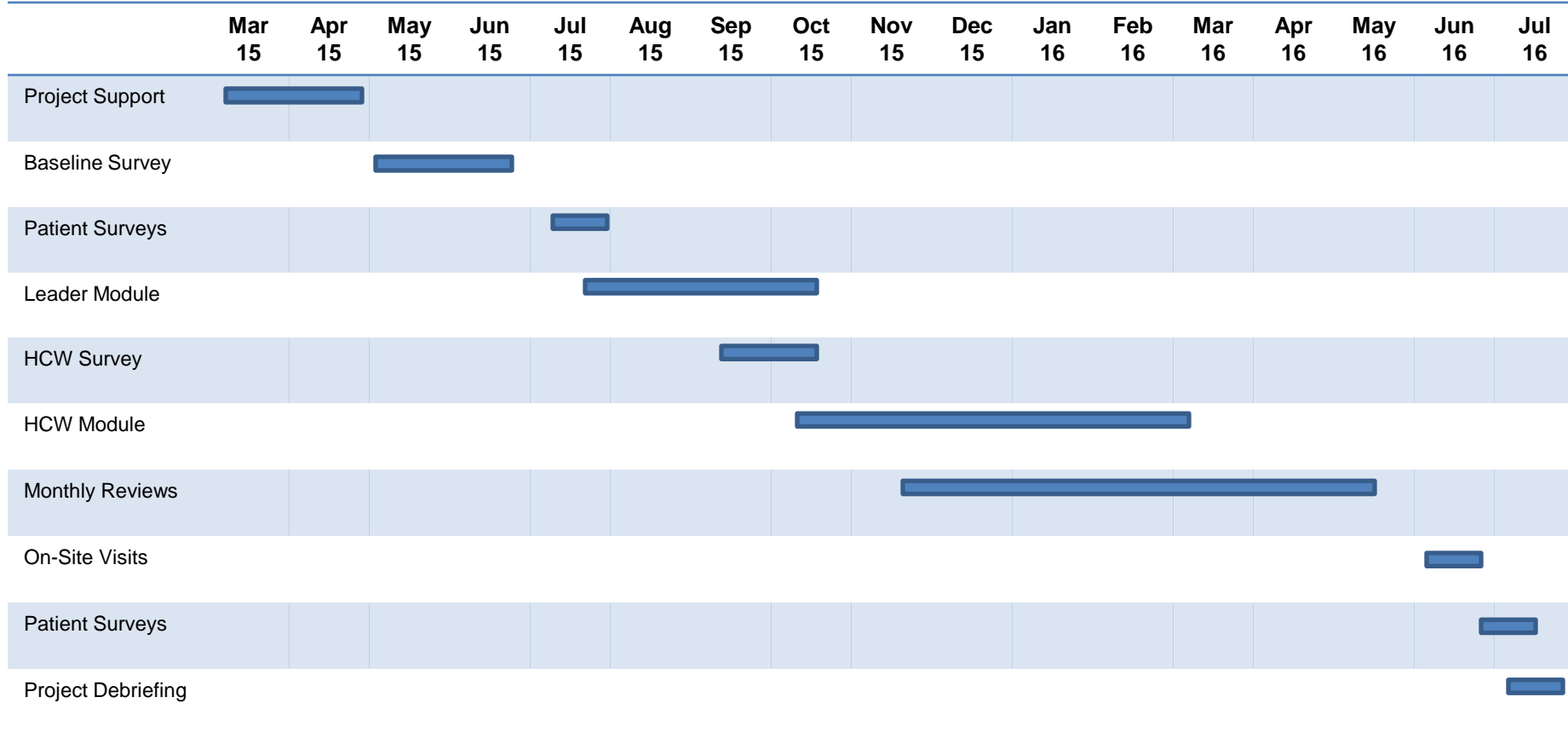
# Clinical Teams

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<i>Unit</i>	<i>Team Members</i>
Med/Surg ICU	60 RN's 1 Pulmonologist
Cath Lab	40 RN's 1 Cardiologist
Perianesthesia	46 RN's 1 General Surgeon
Post-Op Surgical	66 RN's 1 Orthopedic Surgeon

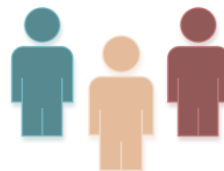
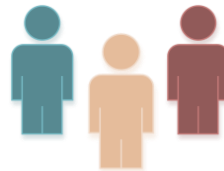
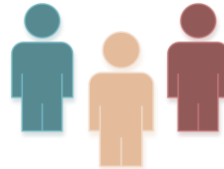
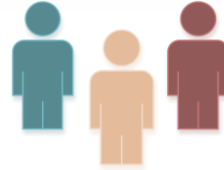
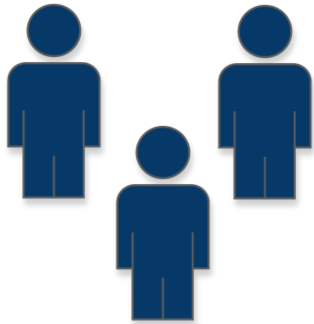


# Project Timeline



# Communication Plan

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# Response to Modules

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## Leader Module

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

# Response to Modules

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## Staff Module

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

# Challenges

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- Staff Engagement
  - ▶ Concurrent Initiatives
  - ▶ Unaware of the “Problem”
- Auditing....Auditing.....Auditing....
- Module Length & Delivery Method
- Implementation Plan

# Success

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- 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

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





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# Pilot Test Findings

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

# Aims

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To:

- Understand the facilitators and barriers to implementing training modules and strategies
- Determine the effect of the modules



# Methods

Method	Respondents	Hospital A	Hospital B	Hospital C	Hospital D	TOTAL
		<b>Pre/Post Sample Sizes</b>				
<b>Leaders Training Pre-/Post-Quiz</b>	<ul style="list-style-type: none"><li>• Leaders</li></ul>	7 / 7	13 / 11	5 / 5	5 / 5	30 / 28
<b>HCP Training Pre-/Post-Quiz</b>	<ul style="list-style-type: none"><li>• HCP/Staff</li></ul>	15 / 15	78 / 73	15 / 7	2 / 1	110 / 96
<b>Check-in Calls</b>	<ul style="list-style-type: none"><li>• Liaisons</li><li>• Unit leads</li></ul>	1 x 9 mos. 1 x 3 mos.	3 x 9 mos.	1 x 9 mos.	2 x 5 mos.	8
<b>Site Visit Interviews</b>	<ul style="list-style-type: none"><li>• Liaisons</li><li>• Unit leads</li><li>• Hospital staff</li><li>• Leadership</li><li>• Dept. staff</li></ul>	13	23	13	---	49





# Implementation

	Hospital A	Hospital B	Hospital C
<b>Leaders Trained (n=23)</b>	7	11	5
<b>HCP/ Staff Trained (n=95)</b>	15	73	7
<b>Strategies</b>	<ul style="list-style-type: none"><li>• Began revisiting policy to clarify whether residents' can obtain consent</li><li>• Tried to address surgical Attending training</li><li>• An Attending began teaching residents teach-back</li></ul>	<ul style="list-style-type: none"><li>• Began clarifying team roles</li><li>• Identified need to re-train staff on interpreter services and resources</li></ul>	<ul style="list-style-type: none"><li>• Reviewed and revised policy</li><li>• Identified and addressed incomplete documentation</li><li>• Revised consent form</li><li>• Translated form</li></ul>



# Implementation – Facilitators\*

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- 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

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- 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

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- Training modules improved knowledge
  - ▶ Leaders ( $p < 0.05$ )
  - ▶ Health care professionals/ staff ( $p < 0.001$ )

# Effect of training modules and strategies\*

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- 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

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- 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

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- 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

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- 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