Implementation Guide for

AHRQ's Making Informed Consent an Informed Choice

Training Modules

Agency for Healthcare Research and Quality

Implementation Guide for

AHRQ's Making Informed Consent an Informed Choice

Training Modules

Prepared for:

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. HHSA290201000031I, TO #3

Prepared by:

Sarah J. Shoemaker, Ph.D., Pharm.D.
Abt Associates, Inc.

Cindy Brach, M.P.P.
Agency for Healthcare Research and Quality

AHRQ Publication No. 17-0016-1-EF
January 2017

Disclaimer of Conflict of Interest

None of the authors has any affiliations or financial involvement that conflicts with the material presented.

Funding Statement

This project was funded under contract number HHSA290201000031I, TO #3 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the U.S. Department of Health and Human Services.

Public Domain Notice

This document is in the public domain and may be used and reprinted without permission except those copyrighted materials that are clearly noted in the document. Further reproduction of those copyrighted materials is prohibited without the specific permission of copyright holders.

Acknowledgements

The authors acknowledge the staff of the four hospitals that participated in the pilot testing of the modules, who shared their insights with the research team.

Suggested Citation

Suggested citation: Shoemaker S, Brach C. Implementation Guide for AHRQ's Making Informed Consent an Informed Choice Training Modules. Prepared under Contract No. HHSA290201000031I, TO #3. AHRQ Publication No. 17-0061-1-EF. Rockville, MD: Agency for Healthcare Research and Quality; January 2017.

Contents

Introduction 1
About This Guide 1
About The Training Modules 1
Who Is This Guide For? 2
Organization of the Guide 3

Why Improve Informed Consent? 4

Getting Started 6
Where to Begin? 6
Determining Readiness 7
Quick Starts 8

Implementing the Leaders Module 10
Articulate a Vision 10
Recruit Change Leads, Executive Sponsors, and Change Team Members 10
Assess Existing Informed Consent Policies and Practices 12
Select Your Strategies 14
Phase In Implementation 14
Take Advantage of Implementation Guidance 15
Define Measurable Objectives, Monitor, and Report 16

Implementing the Health Care Professionals (HCP) Module 18

Identify Champions 18
Engage Staff 19
Target Key Trainees 19
Encourage Participation 19
Select Your Strategies 21
Follow These Implementation Tips 21
Implement Gradually 21
Reinforce the Training 22
Think Creatively 22
Define Measurable Objectives and Monitor Unit Improvements 23

Troubleshooting Implementation Challenges 25

References 26

Appendix A: Patient Survey to Assess Informed Consent – English Version 27
Appendix B: Patient Survey to Assess Informed Consent – Spanish Version 34
Appendix C: Health Care Professional Survey to Assess Informed Consent 42

Introduction

About This Guide

This guide is a companion to the AHRQ training modules: Making Informed Consent an Informed Choice: Training for Health Care Leaders (Leaders Module) and Making Informed Consent an Informed Choice: Training for Health Care Professionals (HCP Module). It provides guidance for implementing the training modules using a quality improvement (QI) approach. This guide offers ideas and suggestions for overcoming challenges in getting staff to take the modules and for putting the recommended improvement strategies into practice smoothly. The guidance is based on the implementation experiences of four hospitals that participated in a pilot test of these training modules, and on the experiences of other hospitals implementing quality improvements. Start by viewing the training modules. Viewing these modules will mark the beginning of your effort to improve informed consent.

About The Training Modules

The Leaders Module addresses improvements that can be made on the hospital level. The HCP Module addresses strategies that clinical teams can use to help patients make informed choices. Both modules cover the principles of informed consent, including patients' rights, legal and patient safety implications, and patients' capacity for decisionmaking. Each module can be taken for free continuing education credits on The Joint Commission's learning management system (LMS) for hospitals accredited by The Joint Commission.[1] Hospitals can also host the modules on their own learning management systems[2]. PDFs of module screenshots and audio scripts are available at: https://www.ahrq.gov/professionals/systems/hospital/informedchoice/index.html

[1]To enroll to take the modules for continuing education credit on The Joint Commission's learning management system, go to www.jointcommission.org/informed_consent_process_training.aspx.

[2]To request the modules to run on your own learning management system, or a PowerPoint file containing screenshots and the audio scripts of the modules, email healthliteracy@ahrq.hhs.gov.

Key Elements of Leaders Module

- Crafting a clear and comprehensive informed consent policy
- Establishing libraries of easy-to-understand informed consent forms and high-quality decision aids
- Removing communication barriers
- Establishing efficient workflows

Key Elements of Health Care Professionals Module

- Clear communication strategies
  - Prepare for the informed consent discussion
  - Use health literacy universal precautions
  - Remove language barriers
  - Use teach-back
- Strategies for presenting choices
  - Offer choices
  - Engage patients, families, and friends
  - Elicit goals and values
  - Show high-quality decision aids
  - Explain benefits, harms, and risks of all options
  - Help patients choose

Who Is This Guide For?

This guide is primarily for two audiences. The first is any individual or team that is charged with making hospital-wide improvements to how consent for tests, treatments, and procedures is obtained. Anyone asked to lead improvements to informed consent policies—such as staff from departments of patient safety, accreditation, or compliance; hospital leadership; nursing leaders or educators; physician leadership (e.g., chiefs or chairs of specific hospital units/areas)—may find this guide helpful. The second audience is leaders of hospital units who want to make improvements to informed consent processes, even if there is no hospital-wide initiative. Additionally, this guide may also be helpful to community clinics and office-based practices, especially large clinical groups, seeking to improve informed consent.

Pilot hospitals reported that the modules were very helpful in gaining consensus around the need to improve informed consent policies and practices. Reactions to the modules included:

- We're not doing this well.
- This is great information.
- We have a lot to change.
- This happens all the time.
- We have to fix this now.

Organization of the Guide

This guide begins by explaining why improving informed consent is important. It then describes how to get started and briefly discusses how you might determine whether your hospital is ready to engage in informed consent improvement. The guide is then divided into two sections that correspond to the two training modules:

- Implementing the Leaders Module—this section takes you through the process of launching and implementing strategies from the Leaders Module, from creating a vision to measuring implementation.
- Implementing the Health Care Professionals (HCP) Module—this section contains guidance on implementing any of the 10 strategies in the HCP Module, including tips on identifying champions and engaging staff.

The guide concludes with Appendices, consisting of survey tools (i.e., a survey of patients and health care professionals to assess your hospital's informed consent practices) that you might use to support your implementation efforts.

Why Improve Informed Consent?

Patients and health care teams alike benefit when a patient's consent to treatment is fully informed as the result of a clear, comprehensive, and engaging communication process. Unfortunately, there are many problems with the informed consent process in hospitals today. Both clinicians and patients often treat informed consent as a formality—an obstacle on the way to care. As a result, many patients do not understand basic information about the benefits, harms, and risks of their proposed treatment, including the possibility of poor outcomes, even after signing a consent form. Some patients also may not understand their rights, including that they can say "no" to any treatment.

A high-quality process of informed consent has many advantages. Here are some messages you might use to communicate why your hospital would want to make it a priority to improve informed consent.

- It's a patient safety issue.
  - It is a medical error if patients are given care they would not have chosen if they had understood what it entailed and what their options were.
- It's a liability issue.
  - Failure to obtain informed consent can be considered negligence, battery, or malpractice by a court of law.
  - Problems with informed consent are among the top 10 reasons for medical malpractice suits. When patients and their families understand the benefits, harms, and risks of treatment in advance, they can better cope with any poor outcomes that may happen as a result of treatment and may be less likely to sue.
- It's a patient-centered care issue.
  - Patient-centered care requires an informed consent process that is respectful of patients' right to choose.
  - When patients make informed choices, it strengthens the therapeutic relationship, and can improve followup and aftercare.
- It's a financial issue.
  - Improving informed consent could increase Hospital CAHPS® scores and payments based on them.
  - Improving informed consent can reduce payouts when settling malpractice claims.

Why Improve Informed Consent in Your Hospital?

- ❒ Your patients often do not understand what they have consented to even after signing the form.
- ❒ Your patients are not making informed choices.
- ❒ You are at risk of malpractice lawsuits related to informed consent.
- ❒ Your hospital had a Joint Commission accreditation finding related to informed consent.
- ❒ Your hospital's periodic audits revealed incomplete documentation.
- ❒ Your hospital's policy is imprecise.
- ❒ Your hospital's consent forms are long and confusing.
- ❒ Qualified interpreter services are not always available or used with patients with limited English proficiency.

Getting Started

An initiative to make informed consent an informed choice can be launched in a variety of ways. You may be wondering who should take which module when, whether your hospital is equipped to make improvements to informed consent at the present time, or whether you can make some rapid improvements without launching a full blown QI initiative. The sections in this chapter can help you begin.

Where to Begin?

Has your hospital already decided to improve informed consent? If your hospital has already committed to informed consent improvement, we recommend that the leadership of your hospital take the Leaders Module; designate one or more change leads to direct an assessment of the hospital's policies, supportive systems, and workflow; and form a change team to develop and implement a Hospital Level Action Plan.

Are you a hospital leader who recognizes the opportunities to improve informed consent and wants to address policy, forms, decision aids, or supports (e.g., language assistance)? Start by taking the Leader's Module yourself. Then choose a staff member to take the Leader's Module and have that person assess current policy and practice. These findings can be brought to other members of the leadership team and be used to identify problems with the status quo. Once you reach consensus that change is needed, encourage others to take the Leaders Module. Then you're ready to designate a change lead and embark on the change process.

Are you a hospital leader who makes decisions about training health care professionals? Although ideally improvements will be made at the hospital level first, the HCP Module can be used independently of the Leaders Module. You can direct staff to take the HCP module, which covers a variety of strategies to improve their communication and patient engagement skills, as well as documentation and team processes around informed consent. Hospital leadership can make decisions about which of the strategies they want clinical teams to learn and implement, or they can leave these decisions to the units themselves.

Are you the head of a department or unit and want to make improvements to informed consent? Even if there is no hospital-wide QI initiative, you can use this guide and the HCP Module to implement improvements in communication, presenting choices, and team processes in your area. Take the HCP modules and decide whether you want to direct your department or unit to implement particular strategies or whether to let your department or unit decide which strategies to pursue. In either case, you will need to be figure out how to implement the strategies so they work in your department or unit.

Determining Readiness

Improving informed consent is similar to other hospital QI efforts. QI efforts often are derailed because organizations were not ready for them. Organizational readiness for change can be defined as "the extent to which organizational members are psychologically and behaviorally prepared to implement" a new evidence-based practice or intervention(s).[2] Readiness can be understood as 1) motivation—the willingness and commitment of the hospital to implement improvements to informed consent, and 2) capability—the staff's perceived ability to institute change or, alternatively, the degree to which individual staff feel they can be effective in implementing the informed consent strategies.[3,4]

In the adjacent box we provide a readiness assessment checklist to help you start thinking about whether an informed consent QI initiative is likely to succeed at this time at your hospital. Some of the checklist items were used to assess readiness when selecting hospitals for the pilot test of the training modules. Other items were drawn from a guide for deciding about whether to adopt innovations.[5] (Note: this readiness checklist has not been formally validated.)

Checklist to Assess Hospital Readiness

- ❒ Does your hospital have a strong rationale for improving informed consent?
- ❒ Does improving informed consent further your hospital's goals?
- ❒ Is improving informed consent with these training modules compatible with your hospital's mission, values, and culture?
- ❒ What are the potential costs, benefits, and risks of improving informed consent—and of not improving informed consent?
- ❒ Will hospital leadership support the training and improvements?
- ❒ Are there other competing initiatives or changes that will interfere?
- ❒ How will staff and other stakeholders react to this change?
- ❒ Will your hospital be able to reinforce and/or reward progress?
- ❒ Does your hospital have experience with quality improvement and change management?
- ❒ Does your hospital have the necessary infrastructure to monitor improvements?

Hospital readiness is not a constant. A hospital might not be ready at a given time—for example, because a new electronic health record system is being rolled out—but may then be ready a year later.

You can also work to make your hospital ready for informed consent QI. For example, leadership support is critical to virtually any QI undertaking. Effective approaches to secure and retain leadership support include aligning the change effort with organizational goals, and keeping leadership involved and informed throughout implementation.[6] Resources in the Leader's module, such as the Championing Change presentation and the Practical Guide to Improving Informed Consent,[7] provide guidance in getting leadership buy in.

Quick Starts

If your hospital is not yet ready for a comprehensive QI initiative to shift from informed consent to informed choice, you can still make progress. Review the two Quick Start alternatives below and get started.

Quick Start for Hospital-Level Improvement

- Take the Leaders Module.
- Choose one area for improvement.
- Assemble a work group to develop an improvement plan.
- Test and refine an improvement, for example:
  - Clarify an ambiguity in your informed consent policy.
  - Improve an informed consent form for one test, treatment, or procedure.
  - Assess decision aids used by one department and replace low-quality ones.
  - Arrange for telephone and/or video interpreters for languages not spoken by in-house interpreters and bilingual staff.
  - Require informed consent documentation prior to scheduling surgical procedures.

Quick Start for Unit-Level Improvement

- Take the HCP Module.
- Choose one area for improvement.
- Assemble a work group to develop an improvement plan.
- Test and refine an improvement, for example:
  - Coach clinicians to use plain language.

- Incorporate teach-back into the informed consent discussion.
- Ensure all staff know when and how to call for interpreter services and where equipment for telephone and video interpretation is kept.
- Create an inventory and sign-out sheet for educational and decision aids.
- Institute a check that all patients have been offered options and understand they have the choice to refuse treatment.

Once you've completed a Quick Start improvement, try to leverage your accomplishments. You can:

- Expand on or spread your initial improvement,
- Choose another area for improvement, or
- Re-assess your hospital's readiness to embark on a QI initiative to improve informed consent.

Implementing the Leaders Module

Articulate a Vision

Making informed consent an informed choice has to resonate with staff and feel consistent with the hospital's core values. You will want to articulate a vision that aligns with your mission and strategic goals. For example, if your hospital prides itself on being patient-centered, you can integrate the initiative to improve informed consent into efforts to be patient-centered. If, on the other hand, your hospital has made patient safety its number one priority, the vision for the improvement initiative could emphasize avoiding errors that occur when tests or procedures are performed on patients who, had they understood their choices, would not have consented. For more information on creating a vision, see the Championing Change presentation in the Leaders Module.

Example of a vision statement for making informed consent an informed choice

At our hospital:

- All patients will understand information about treatment options and make informed choices that are consistent with their goals and values.
- All clinicians will have the skills to meet their ethical and legal informed consent obligations and feel protected from lawsuits.

Recruit Change Leads, Executive Sponsors, and Change Team Members

A critical step in rolling out the training modules and making informed consent an informed choice is to identify a change lead. This person will serve as the point person and drive progress. The change lead should have the "authority, expertise, credibility, and motivation necessary to drive a successful initiative."[8] Choose a change lead who can strike a balance between having enough time to expend on the initiative and having the authority to propel implementation. Junior staff may have enthusiasm and time to spend on the initiative, but may garner less respect and lack the clout needed to counter resistance.

One way of lending authority and respect to the change lead is to have executive sponsors of the initiative. Executive sponsors communicate to hospital staff the importance of the initiative and meet regularly with the change lead to get progress reports. Having more than one executive sponsor can be helpful in reinforcing the message that this is a hospital-wide issue, and can protect against disruption should there be turnover in staff.

The change lead could come from a variety of departments, including: accreditation or compliance, patient safety, quality, physician or nursing leadership, patient education, or elsewhere. Table 1 provides some observations on the strengths and weaknesses of change leads from different parts of the hospital. Recruiting two complementary co-leads is an attractive option as the strengths of one co-lead could compensate for the weaknesses of the other. Like having more than one executive sponsor, having co-leads provides a hedge against implementation interruption in the event a change lead departs or transfers to another role in the organization.

Table 1. Strengths and Weaknesses of Change Lead Affiliation

Change lead's affiliation	Strength	Weakness
Accreditation and compliance	Commensurate with role, driven by accreditation standards, seen accreditation review findings	Possible perception from HCP staff: limited on-the-ground understanding of IC practices
Nursing Leadership	Patient education expertise, influence over nursing staff	No oversight of clinicians responsible for obtaining informed consent
Physician Leadership	Influence on clinicians responsible for obtaining informed consent, could introduce in grand rounds and staff meetings (e.g., surgery)	Very limited available time, competing priorities
Quality or Safety	Experience in QI and change management	Possible perception from HCP staff: limited on-the-ground understanding of IC practices
Patient Education	Expertise in improving written and spoken communication	No oversight of clinicians responsible for obtaining informed consent

Note: IC = informed consent

One or two people cannot manage a hospital-wide initiative on their own. Executive sponsors and change leads should recruit a strong change team—a group of individuals who will help roll out the training modules and implement the selected strategies from the training. Consider including representatives from the affected departments (e.g., compliance, accreditation, patient safety, quality, interpreter services, information technology), as well as representatives from the clinical units and different types of staff (e.g., nurses, physicians, residents, nurse educators, interpreters). Having physicians who either have direct lines of authority or hold a lot of sway with their colleagues will be important in achieving improvements in the informed consent discussion.

Executive sponsors and all members of the change team should take both the Leaders Module and the HCP Module. Additional leaders, especially with those whose staff are participating on the change team, may also benefit from taking both training modules. The Joint Commission is offering continuing education credit for completion of the modules on their LMS. You can also host the modules on your own LMS.

Assess Existing Informed Consent Policies and Practices

Your hospital should use your hospital's existing data sources or collect new information to understand what your current informed consent policies are, how well they are being followed, the workflow for the informed consent process and documentation, and the extent to which patients are making informed choices. The assessment results are intended to help your hospital identify opportunities for improvement and potentially set your goals for improvement.

It is important to collect data from multiple sources, since not everyone will share the same perspective. For example, leaders may assume that patient capacity to consent is always assessed, whereas staff may report that there are instances where it is not. Table 2 shows potential sources of information.

Table 2. Assessment Data Sources

Review Existing Data	Collect New Data
Accreditation review findings	Chart audit data[1]
Patient experience survey data on how easy doctors were to understand[2]	Assessments of patient understanding of forms[3]
Malpractice claims and payout data	Inventory and assessments of decision aids and other patient education materials used in informed consent discussions
Compliance review data	Survey data[4]
Interpreter services data	Interview data on familiarity and adherence to your hospital's policies, stories of communication failures, and effective approaches
Data on patient safety events and their impact (e.g., near miss, harm caused).[5]	Patient reports of safety events

[1]See A Practical Guide to Informed Consent[7] for audit tools.

[2]See the Patient Survey provided in Appendixes A and B.

[3]You can collect the informed consent forms used throughout your hospital and test patient understanding (e.g., "Can you tell me in your own words what are the potential risks of the surgery you are having?"[9]).

[4]Use the Health Care Professional Survey in the Appendix C to understand the extent to which physicians, physician assistants, nurse practitioners, and other nurses follow informed consent policy and use best practices. (Also see the survey in Practical Guide to Informed Consent[7]).

[5]For example, a patient safety event could be that no interpreter was involved in conversation with a patient with limited English proficiency, resulting in the patient's misunderstanding the nature of the procedure.

Table 3 provides examples of assessment findings from the pilot test hospitals that identified opportunities to improve informed consent.

Table 3. Examples of Assessment Findings from Pilot Test Hospitals

Area	Opportunities for Improvement
Policy	• Confusion as to whether (and which) residents could independently have the informed consent discussion with patients and sign the consent form. • Unclear who was a legitimate proxy for patient and able to provide consent. • Confusion as to which tests, treatments, and procedures require consent.
Forms	• Complex consent forms not understandable to patients and families. • Group practice consent form needed for Labor and Delivery in which a physician can sign for the entire group, since the on-call physician will be the one delivering a baby and may not necessarily be the patient's doctor or the one that signed the consent form. • Potential need for a separate form for anesthesia consent and blood products. • Lack of forms translated into patients' languages.
Compliance and Workflow	• Failure to adhere to hospital policy. • Consent obtained from patients with limited-English proficiency without qualified language assistance. • Consent not consistently obtained prior to performing bedside tests, treatments, and procedures that required consent. • Physician's offices not getting signed forms to the hospital before the day of surgery. • Outpatient physician practices not using the correct version of the hospital's consent form that was recently revised. • Patients sometimes signing and providing consent AFTER being provided an IV line and/or medications for surgery. • Inconsistency among surgeons in their processes with obtaining consent and getting it to the hospital before surgery. • Failure to obtain a separate signed consent form for each proceduralist responsible for a different aspect of a surgery. • Inconsistency in whether patients had a signed consent form completed in the ICU before surgery.
Communication Supports	• Staff not familiar with all of the interpreter services and resources available to use with patients with limited English proficiency. • Limited use of decision aids.

Select Your Strategies

Based on the results from the assessment described in the previous section, you can select the strategies that your hospital will pursue. It is likely that there will be multiple opportunities for moving your hospital toward making informed consent an informed choice, so avoid taking on more than you can reasonably handle at one time. Overly ambitious QI initiatives can collapse under their own weight.

Consider prioritizing the improvements, starting with one strategy. You may want to start with a strategy that you think you can make quick progress to score an early win. Or you may want tackle a strategy that clearly aligns with other efforts within your hospital, like improving patient and family engagement or surgical patient safety. If you want to push forward on multiple fronts, make sure each implementation team is adequately staffed and there is a plan for how and when staff will pursue each strategy.

Underscore the Importance of Patient Understanding

A rallying cry for your improvement effort could be that patients should understand what they are consenting to. As the Centers for Medicare & Medicaid Services say in the guidelines hospital surveyors use to determine whether a hospital has met Medicare and Medicaid's Conditions of Participation standards, **"Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent."**

Phase In Implementation

The improvements or strategies you select (e.g., use of new forms or improved workflows, accessing interpreter services and other communication aids) do not need to be rolled out hospital-wide, or even across multiple units, simultaneously. Phased implementation will allow you to pass along knowledge and lessons learned from your early adopters to your subsequent implementers. Consider starting with a unit that has:

- A high volume of test, treatments, or procedures requiring informed consent,
- Already identified opportunities for improvement (e.g., accreditation review findings), and/or
- One or more strong champions for improving informed consent processes.

While each unit will have to find its own way of adapting changes to the local environment, there are obvious benefits to providing opportunities for identifying and working out the kinks early in the roll out process.

Take Advantage of Implementation Guidance

Table 4 provides the list of strategies covered in the Leaders Module and suggestions for implementing them.

Table 4. Improvement Strategies and Implementation Suggestions

Improvement Strategy	Suggestions for Implementation
Develop consensus around principles of informed consent	• Reinforce that informed consent must be an informed choice in team huddles, during handoffs, at morbidity and mortality conferences, etc. • Consider providing this part of the training module as part of a staff meeting or in small groups to all staff. • Use safety protocols (e.g., TeamSTEPPS CUS words[1]) to empower staff to intercede if principles of informed consent have not been adhered to.
Write and disseminate a clear and comprehensive informed consent policy	• Set aside time to complete the Policy Worksheet in the Leaders Module. • Review both legality and feasibility of policy revisions. • Obtain feedback from affected staff before formalizing a revised policy.
Build support systems to improve the informed consent process	• Engage the affected departments (e.g., interpreter services) and units. • Set aside time to complete the Supportive Systems Worksheet in the Leaders Module.
Compile a library of clear and simple informed consent forms	• Assess the quality of the informed consent forms being used in your hospital. • Use plain language and health literacy specialists to improve forms. • If patient and family members on hospital advisory committees all have high levels of education, recruit community members with limited literacy to test forms. • Promote standardization, using the same form for each test, treatment, or procedure throughout the hospital.
Maintain a library of high-quality decision aids and other patient education materials	• Create an inventory of and assess decision aids and patient education materials used. Identify duplication and purge lower-quality materials. • Prioritize topics (e.g., common or complex procedures) and create or purchase high-quality materials. • Test with representatives that reflect the diversity of your patient population.
Remove communication barriers	• Assess the adequacy of language assistance, and advocate for increasing the numbers of bilingual clinicians and access to qualified interpreters if necessary. • Clarify policies on meeting language assistance needs relating to: » Who may communicate with patients and families in a language other than English without an interpreter. » What constitutes a qualified interpreter. » Release from duties to serve as a qualified interpreter for other staff. » Use of telephone or video interpreters versus in-person interpreters • Establish a system to track the inventory of communication aids (e.g., reading glasses, video interpreter consoles).

[1]The TeamSTEPPS assertive statements: I am Concerned!, I am Uncomfortable, This is a Safety issue!

Table 4. Improvement Strategies and Implementation Suggestions Cont'd

Improvement Strategy	Suggestions for Implementation
Improve workflows	• Map out the workflow to identify inconsistencies with policy and inefficiencies. • Allow staff (e.g., nurses in pre-operative areas) to generate ideas on how the workflow could be improved. • Test improvements in one area before spreading changes.
Address staff training needs	• Determine which staff (or units) are unaware of policies, resources, or best practices and train staff. • Use different modes to train staff or reinforce training material (e.g., emails, newsletters, postings, staff meetings). • Invest in getting the training right from the beginning. Poorly designed training will sour staff on the initiative. • Recruit and train influential staff (e.g., department chiefs) to serve as training facilitators. • Pick the low-hanging fruit—train volunteers first. They may be able to serve as peer coaches for others. • Create incentives for units that meet training goals. • Make training a credentialing requirement for non-employee clinicians who have hospital privileges.

For your hospital to make informed consent an informed choice, changes made at the hospital level must cascade down to the unit level. Staff need to be informed of and act on new policies, use new forms and decision aids, and avail themselves of resources to overcome communication barriers. You may find some of the topics covered in the next chapter, Implementing the Health Care Professionals Module, helpful as you activate staff to respond to the changes you have made.

Define Measurable Objectives, Monitor, and Report

A critical part of any QI effort is to develop a written action plan with clear objectives and a realistic timeline, and to use that action plan to ensure that progress can be monitored and measured. Results of interim monitoring and measurement efforts should be reported back to leadership and staff, and used to adjust the action plan where necessary or appropriate. You will want to define SMART objectives (Specific, Measurable, Attainable, Relevant, and Time bound)[10] to track your progress toward your goals. Table 5 provides examples of SMART objectives.

Table 5: Examples of SMART Objectives for Hospital-level Improvements

Topic	Objective
Process	• All members of the change team will have completed both the Leaders and HCP Modules by [date]. • X percent of change team members will attend each meeting. • Each change team member attends X percent of team meetings.
Assessment	• Audits of X charts will be completed by [date]. • X interviews of staff concerning perceptions of informed consent policy and practice will be completed by [date]. • X clinicians will have completed the Health Care Professional Survey by [date].
Policy	• A new informed consent policy will be drafted by [date]. • Executive review will be completed by [date]. • Clarity of the new policy will be tested with X unit leaders and Y team leaders by [date]. • The new policy will be finalized by [date]. • Informed consent will be the topic of leadership rounds X times a year. • X percent of patients having tests, treatments, or procedures will report that clinicians complied with policy by describing other options by [date].
Forms and Decision Aids	• X percent of informed consent forms will be understandable by culturally diverse patients by [date]. • X new decision aids that meet International Patient Decision Aid Standards will be added to the patient education library by [date].
Communication Supports	• Wait times for in-person interpreter services will be reduced to X minutes by [date]. • X percent of bilingual clinicians will be tested for language proficiency by [date]. • X bilingual staff members will be trained as interpreters by [date]. • X mobile video remote interpretation stations will be installed in [hospital units] by [date].
Workflow and Documentation	• X percent of informed consent forms for elective surgeries are received in the hospital at least 2 days before the scheduled surgery by [date]. • X percent of tests, treatments, and procedures requiring informed consent will have complete documentation of informed consent by [date].
Training	• X percent of physicians, nurse practitioners, and physician assistants will have completed the HCP training course on making informed consent an informed choice by [date]. • Residents will be trained in clear communication skills within X days of the beginning of their residency.

You will need to determine the best method for monitoring your hospital's progress toward achieving the goals. The same data sources that informed your assessment of informed consent practice in your hospital can help you track your progress (e.g., chart audits, surveys of health care professionals and patients). You may want to track data by unit, so you know which areas in the hospital are speeding ahead and which are falling behind. Routine monthly data collection may be important for tracking progress on some goals, while spot checks might be sufficient for others.

Some goals may need to be broken down into some intermediate steps in order to monitor progress. For example, if your goal is improve the understandability of your informed consent forms, you might want to track the percentage of informed consent forms assessed, the percentage of forms revised, and the percentage of revised forms tested with diverse patients.

To ensure accountability, monitoring achievement of SMART objectives should be accompanied by reporting. Consider how frequently the Change Team, Executive Sponsors, and other hospital leadership should receive monitoring reports.

Implementing the Health Care Professionals (HCP) Module

Regardless of whether or not your hospital implements strategies from the Leaders Module, implementing strategies from the HCP Module will move your hospital closer to making informed consent an informed choice. The selection of which strategies from the HCP Module may be made by hospital leadership for hospital-wide implementation, or by leaders at the unit level for implementation within their own units. For the purposes of this section of the guide, we will assume that you are a unit leader who either has been given discretion over which strategies to implement, or are pursuing informed consent improvement in the absence of a hospital-wide initiative. The guidance in this section will help you implement the strategies presented in the HCP Module for communicating clearly, presenting choices, documenting progress, and working effectively as a team.

Identify Champions

Your first step toward implementing change should be to identify Champions to support your efforts. Champions are "individuals who dedicate themselves to supporting, marketing, and 'driving through' a [change effort],"[11] and to "overcom(ing) indifference or resistance."[6] Champions often strongly believe in the initiative and actively support it during implementation.[6]

Form an implementation team of champions to promote informed choice in your unit. You may want to recruit a variety of champions to help with different tasks, such as:

- Ensuring staff take the HCP module.
- Selecting strategies to be implemented.
- Writing a plan for implementing the selected strategies and developing SMART objectives.

- Leading implementation by modeling new behaviors and mentoring others.
- Monitoring the improvement initiative's progress.

Effective champions:

- Are influential—well-liked and well respected
- Stay passionate and persistent
- Have managerial skills—build consensus, set realistic goals, use authority sensibly
- Possess interpersonal skills—are good listeners and good communicators
- Act strategically—are politically aware, can anticipate and counteract resistance
- Solve problems—think flexibly, negotiate, mobilize resources

Engage Staff

Target Key Trainees

We recommend that *all clinicians who must obtain informed consent* (e.g., physicians, independent physician assistants, and residents if applicable) take the entire HCP Module. This will provide them with a broad knowledge base and inform them about the full range of available strategies. Minimally, a group of senior clinicians can take the entire HCP training. This leadership team can then select which strategies to implement, and limit training for all remaining staff to the strategies that have been selected. For example, at our pilot hospitals, nursing staff whose roles do not include obtaining informed consent gave us feedback that some of the modules (e.g., Presenting Choices) did not pertain to them. Thus, you might want to consider having only nursing managers take the full module while other nursing staff skip this section.

Encourage Participation

Busy clinicians are likely to tell you that they don't have time to take the training. Or, they may express an intention to do so but then have trouble getting around to it. You may feel like you have little leverage over clinicians who are not employees of the hospital. Be resourceful in thinking how to make it a priority for them.

- Establish a sense of urgency. For example, you could frame the initiative as being critical to accreditation review preparation.
- Appeal to their sense of professionalism. Clinicians care about their patients and often don't realize that patients don't always understand their choices.
- Point out the personal advantages. They can receive continuing education credit and potentially reduce their malpractice exposure.
- Gain consensus that there's a problem. Conduct an assessment of your unit's informed consent practices. Discuss the issues that surfaced.
- Humanize the problem. Tell a compelling story about a patient's struggle to make an informed choice. If you can't come up with a story from your unit, use one from the module.
- Use peer pressure. Post a list of who has and who hasn't taken the training module in the hallway.
- Set deadlines. Set a date by which everyone is expected to complete the module. Or ask each clinician to set his or her own deadline and then follow up on that date.
- Engage in decisionmaking. Announce a meeting at which decisions will be made about which improvement strategies to pursue and make completion of the module a prerequisite to attending the meeting.
- Negotiate. Perhaps there is something you can temporarily take off their plates to make it easier from them to take the module.
- Assign employees (e.g., hospitalists, residents) to complete the module. Monitor and enforce completion. Provide release time to complete the training. This also communicates that this is a priority activity.

What Makes Them Tick?

Think about what motivates each clinician in your unit. Is he a stickler for the rules? Is he altruistic? Is she competitive? Does she dislike being told what to do? The tactic to get clinicians to take the module will likely differ depending on their personalities and positions.

Malpractice as a Motivator

Washington became the first state to enact legislation establishing increased legal protection to physicians whose patients sign an acknowledgement that patient decision aids were used during informed consent.

Select Your Strategies

When choosing the topic for your initial improvement efforts, you'll want the benefits of an assessment of the informed consent practices in your unit. Please review the earlier section on Assess Existing Policy and Practice for sources of assessment data (p.12).

In addition to letting the assessment data drive your decision, the attitudes of clinicians in your unit may influence the choice. For example, if clinicians have expressed frustration when trying to communicate with patients and families who have limited English proficiency, they might be especially receptive to the strategies for removing communication barriers. Alternatively, they may have heard of teach-back from other sources and be interested in trying it in the context of informed consent. You may decide to prioritize strategies that you think will offer protection to your most vulnerable patients, or strategies that will affect the largest number of patients. Regardless of whether leadership or staff select the strategies for your unit, you'll want to take capitalize on their affinities with particular topics.

Follow These Implementation Tips

Implement Gradually

Don't make too many changes at one time. And don't feel that you have to have the entire unit implement a change for all patients at once. In QI work we talk about "small tests of change." Here are some ways you might think about gradually implementing the strategies in the HCP module:

- Ask a couple of volunteers to try a strategy.
- Ask staff to try a strategy with 1 patient a day.
- Try the strategy for only one test, treatment, or procedure.

It is important that staff learn from their tests, refine their approaches, and share what they've learned with their colleagues. Set a timetable for steadily expanding implementation until everyone has made the change with all patients.

Reinforce the Training

Taking one online training module is unlikely to result in widespread behavior change. Seek and use opportunities to reinforce the guidance provided in the training module. For example:

- Review training module content in staff meetings or in other communications with staff (e.g., email, newsletters, postings).
- Use case presentations, grand rounds, morbidity and mortality conferences, and other teaching techniques to support the strategies taught in the module.
- Present audit findings or stories from a patient safety review on informed consent.
- Present and discuss a video from the module at a Lunch and Learn session.
- Make informed choice the theme of leadership rounding.
- Provide opportunities to role play.
- Identify helpful resources in the module and share them across the unit.
- Engage members of your hospital's Patient and Family Advisory Council.
- Provide self-assessment forms for self-reflection on progress.
- Recognize staff who have mastered a strategy and invite observation.
- After rounding, huddle on ways to improve implementation of a strategy.
- At a staff meeting, ask staff how they think things are going with implementing a specific strategy and what could be done to improve it.

Think Creatively

Implementation strategies can be deceptively simple. For example, one hospital had a problem with central lines being placed without any documentation of informed consent. That changed after the central line kits were locked behind the nursing station. No one could get a central line kit without first presenting the signed consent form to a nurse.

No one has a monopoly on creative thinking. If your implementation team is stymied by a problem, open up the discussion for wider input. You could even start a contest for the best idea.

What would you do?

Your unit recently got video interpretation consoles. They're great, but they're constantly being left in patients' rooms. Staff sometimes aren't bothering to chase down the consoles when they have to talk to a patient or family with limited English proficiency. How might you solve this problem?

Define Measurable Objectives and Monitor Unit Improvements

As with any quality improvement initiative, it is important to establish SMART objectives to track progress. Table 6 contains examples of SMART objectives for each of the topics in the HCP module.

Table 6: Examples of SMART Objectives for Unit-level Improvements

Topic	Objective
Assessing capacity	X percent of informed consent documentation will include documentation of the assessment of patient's capacity to consent by [date].
Preparing for the discussion	X percent of patients will report the person who conducted the informed consent discussion spent enough time with them by [date].
Use health literacy universal precautions	X percent of patients will report that explanations of what was likely to happen and what might go wrong were easy to understand by [date].
Remove language barriers	X percent of informed consent documentation for patients preferring a language other than English will include documentation of use of a qualified interpreter by [date].
Teach-back	X percent of informed consent documentation will include documentation of asking the patient to describe his/her understanding of what would likely happen if he/she had the test, treatment, or operation by [date].
Offer choices	X percent of patients will report they were given options and felt free to choose any of the options by [date].
Engage patients, families, friends	X percent of patients will report they were encouraged to ask questions by [date].
Elicit goals and values	X percent of patients will report they were asked what mattered most in choosing what to do by [date].
Show high-quality decision aids	X percent of records of patients who underwent tests, treatments, or procedures for which a high-quality decision aid was available will include documentation of use of the aid by [date].
Explain benefits, harms, and risk of all options	X percent of patients will report that the description of other options was easy to understand by [date].
Help patients choose	X percent of patients will report that they were very satisfied with their experience discussing the options and making a decision by [date].

Table 6: Examples of SMART Objectives for Unit-level Improvements Cont'd

Topic	Objective
Team roles	X percent of staff not conducting informed consent discussion will agree or strongly agree with the statement that, "Staff feel free to question the decisions or actions of those with more authority" by [date].
Documentation	X percent of tests, treatments, or procedures requiring informed consent will have a signed consent form or chart notes documenting verbal consent. X percent of informed consent forms will have been completed prior to day of scheduled surgery by [date].
Workflow	Percentage of procedures delayed because of incomplete documentation of informed consent will be reduced to X percent by [date].

Data sources for monitoring progress on your objectives can come from the same sources as were used to assess hospital policies and practices (e.g., chart audits, the Health Care Professional Survey, the Patient Survey).

When thinking about sample size and frequency, remember that you're not necessarily looking for proof of statistically significant improvement. You're collecting data to gain confidence that progress is being made in implementing agreed upon changes.

- Look for "sentinel nodes." Figure out if there are key behaviors that will be indicative that the mindset of informed choice is taking hold, and monitor them.
- Check for weak links. Decide where the process is most likely to break down and focus attention on that area.
- Value qualitative data. Talking to a few people can give you key insights into implementation snags and how to fix them.

Troubleshooting Implementation Challenges

Effective implementation "requires changes in professional norms in addition to changes in individual clinicians' knowledge and beliefs."[3] There are many potential challenges and barriers to implementing improvements. Table 7 provides a list of these challenges, many drawn from the experiences of the pilot hospitals, as well as possible solutions for mitigating or addressing these challenges.

Table 7. Potential Solutions to Address Implementation Challenges

Implementation Challenges	Potential Solutions
Low priority on improving informed consent	• Align the effort with important current initiatives, like patient safety or patient engagement. • Coordinate initiative with accreditation surveys.
Limited resources for improving informed consent practices	• Leverage existing infrastructure (e.g., EHR) and processes (e.g., current chart audits) to assess current practices and support even small improvements.
Physicians are not employees of the hospital limiting the ability to enforce training	• Require training as part of credentialing process for granting physicians hospital privileges. • Have the chief/chair of a unit encourage completion at their staff meetings/grand rounds. • Coordinate with the medical school that the physicians are associated with to encourage participation and completion of the training.
Staff turnover	• Ensure new staff are trained in a timely manner. • Create a process to notify change lead of staff changes.
Physicians, independent nurse practitioners, and independent physician assistants see little need to improve their informed consent discussions with patients	• Conduct an assessment of patients' understanding of the consent discussion. Share results with clinicians who conduct consent discussions. • Explore whether malpractice insurance carriers would provide a discount for clinicians who take the training and implement the strategies. • Invite a representative from a facility that makes informed consent an informed choice to meet with key leaders.

References

1. Institute for Healthcare Improvement (IHI). How to Improve. http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx
2. Aarons GA, Horowitz JD, Dlugosz LR, Ehrhart MG. The Role of Organizational Processes in Dissemination and Implementation Research. In: Brownson RC, Colditz GA, Proctor EK, editors. Dissemination and Implementation Research in Health: Translating Science to Practice. New York: Oxford University Press, Inc.; 2012. p. 128–53.
3. Weiner B, Amick H, Lee S-Y. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Medical Care Research and Review. 2008. PMID:18511812.
4. Wise CG, Alexander JA, Green LA, Cohen GR, Koster CR. Journey toward a patient-centered medical home: readiness for change in primary care practices. Milbank Q. 2011;89(3):399–424. PMID: 21933274.
5. Brach C, Lenfestey N, Roussel A, Amoozegar J, Sorensen A. Will It Work Here? A Decisionmaker's Guide to Adopting Innovations. Prepared by RTI International under Contract No. 233-02-0090. Agency for Healthcare Research and Quality (AHRQ) Publication No. 08-0051. Rockville, MD: AHRQ; September 2008.
6. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4(1):50. PMID: 19664226.
7. Fleischer L RS, Miller SM, Partida Y, Martin-Boyan A, Soltoff C, et al. A practical guide to informed consent. Philadelphia: Temple University Health System. 2008. http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html.
8. Agency for Healthcare Research and Quality (AHRQ). TeamSTEPPS Implementation Guide. http://www.ahrq.gov/teamstepps/instructor/essentials/implguide.html.
9. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): a new measure of understandability and actionability for print and audiovisual patient information. Patient Educ Couns. 2014;96(3):395–403. PMID: 24973195.
10. National Academies. SMART Objectives. http://www.nationalacademies.org/hmd/About-IOM/Making-a-Difference/Community-Outreach/Smart-Bites-Toolkit/~/media/17F1CD0E451449538025EBFE5B1441D3.pdf.
11. Greenhalgh T, Robert G, Bate P, Macfarlane F, Kyriakidou O. Diffusion of innovations in health service organisations: a systematic literature review: John Wiley & Sons; 2008.

Appendix A: Patient Survey to Assess Informed Consent—English Version

The following survey is intended to obtain feedback from patients immediately following an informed consent discussion to provide evaluative or quality improvement information to hospitals to assess and improve their informed consent processes using strategies described in AHRQ's Making Informed Consent an Informed Choice Training Modules.

Instructions on How to Administer the Survey

Aim: This survey can be used in a quality improvement or evaluation effort after improvements to the informed consent process are implemented to measure informed consent explanations and associated patient understanding. This survey can also be used to identify weaknesses in the informed consent discussion, specifically if key components of informed consent are explained to patients and whether they understood the explanations.

Content: This survey can be given to patients or their family members who are asked to provide consent to tests, treatments, or procedures. This survey asks patients or surrogate decisionmakers to determine whether key components of a comprehensive informed consent discussion were explained and whether the explanations were easy for patients to understand. It also asks about unanswered questions, overall satisfaction with the consent discussion, and the consent form.

IRB: If appropriate per hospital policy, the hospital IRB should approve use of this survey before administering it to patients.

Patients to exclude: Patients and surrogate decisionmakers should be excluded if completing the survey might present undue burden at a very stressful time in their hospital stay or if they decline to complete the survey, or for other reasons deemed appropriate.

Timing of administration: The baseline survey should be administered to patients before an intervention to improve informed consent discussions (e.g., training) is implemented in a hospital unit. The followup survey should be administered to patients after the improvements to the informed consent discussion have been systematically and consistently implemented across the unit. The survey should be given to patients immediately following an informed consent discussion whether or not consent was given.

Interpreters and readers: The survey is available in English and Spanish. Administrators should offer to read the survey to patients.

Survey

We are doing this study to understand how to improve the informed consent process to treatment—a process by which a patient is told about the risks and benefits of proposed tests, treatments, or procedures, as well as alternatives, and makes a decision based on that information.

We are asking you to answer the following questions based on the talk you just had with the doctor or nurse about having a test, treatment, or operation. Your answers will help the hospital understand what information patients get before giving consent for tests, treatments, or operations. That will let the hospital make improvements.

Before you take this survey you should know the following:

- Your participation is voluntary.
- It should only take you 5 minutes to complete this survey.
- This survey does not collect any personal or health information about you.
- You do not have to complete this survey.
- Your medical care will not change in any way if you do not take this survey.
- Your relationship with your health care providers or the hospital will not change if you do not take the survey.
- If you decide to take this survey, you can stop answering the questions at any time.
- There is no cost to you for taking this survey.
- The principal risk of this survey is a small risk of loss of confidentiality. The survey team has many procedures in place to reduce this risk.

Who Spoke with You.

Who was the main person who spoke with you about having a test, treatment, or operation?

1 ❒ My personal doctor

2 ❒ A doctor from the hospital

3 ❒ A nurse from the hospital

4 ❒ I don't know

5 ❒ No one spoke to me about a test, treatment, or operation.

6 ❒ Other: _____

1. An interpreter is someone who helps you talk with others who do not speak your language. Did you use an interpreter to speak with that person?

   1 ❒ No, I speak English very well.

   2 ❒ No, we spoke in English although I do not speak English very well.

   3 ❒ No, that person spoke my language very well (for example, we both speak Spanish very well).

   4 ❒ No, that person spoke my language a little.

   5 ❒ Yes, we spoke with the help of an interpreter provided by the hospital.

   6 ❒ Yes, we spoke with the help of my friend or family member.

Explanations about the Main Test, Treatment or Operation.

Think about the main test, treatment, or operation you talked about.

2. Did the main person who spoke to you explain what would likely happen if you had the test, treatment or operation?

   1 ❒ Yes

   2 ❒ No ⟶ If no, go to Question 7

3. Was the explanation about what would likely happen if you had the test, treatment, or operation easy to understand?

   1 ❒ Yes, definitely

   2 ❒ Yes, somewhat

   3 ❒ No

4. Did that person ask you to describe your understanding of what would likely happen if you had the test, treatment, or operation?

   1 ❒ Yes

   2 ❒ No

5. Did that person explain what might go wrong and how likely it was that something would go wrong?

   1 ❒ Yes

   2 ❒ No ⟶ If no, go to Question 7

6. Was the explanation about what might go wrong and how likely it was easy to understand?

   1 ❒ Yes, definitely

   2 ❒ Yes, somewhat

   3 ❒ No

Other Possible Tests, Treatments, or Operations.

7. Did the main person who spoke to you describe your other options, such as having a different test, treatment, or operation or having no test, treatment, or operation?

   1 ❒ Yes

   2 ❒ No ⟶ If no, go to Question 9

8. Was the description of your other options easy to understand?

   1 ❒ Yes, definitely

   2 ❒ Yes, somewhat

   3 ❒ No

9. A decision aid provides information and helps you think about your options for tests, treatments, or operations. A decision aid can be on paper or be a video, audio tape, or computer program. Did anyone show you a decision aid or give you a decision aid to use?

   1 ❒ Yes

   2 ❒ No ⟶ If no, go to Question 11

10. Did you find the decision aid helpful in deciding whether to have a test, treatment, or operation?

    1 ❒ Yes

    2 ❒ No

    3 ❒ I didn't use it

About the Discussion.

11. Did the main person who spoke to you listen carefully to you?

1 ❒ Yes

2 ❒ No

12. Did that person spend enough time with you?

1 ❒ Yes

2 ❒ No

13. Did that person ask you what matters most to you in choosing what to do?

1 ❒ Yes

2 ❒ No

14. Did that person encourage you to ask questions?

1 ❒ Yes

2 ❒ No

15. After the discussion, did you have any questions that were not answered?

1 ❒ Yes

2 ❒ No ⟶ If no, go to Question 17

16. Why were your questions not answered?

1 ❒ I asked, but I didn't get an answer.

2 ❒ I asked, but the response didn't answer my questions.

3 ❒ I asked, but the response was hard to understand.

4 ❒ There wasn't enough time to ask questions.

5 ❒ I didn't feel that I could ask questions.

6 ❒ Other:_____

17. Did you feel like you had enough information about all the options to make a decision?

    1 ❒ Yes

    2 ❒ No

18. Did you feel free to choose any of the options, including the choice of not having any test, treatment, or operation?

    1 ❒ Yes

    2 ❒ No

19. Overall, how satisfied are you with the experience you had discussing the options for tests, treatments, or operations and making a decision?

    1 ❒ Very unsatisfied

    2 ❒ Somewhat unsatisfied

    3 ❒ Somewhat satisfied

    4 ❒ Very satisfied

The Consent Form.

20. Was the consent form you were asked to sign for the test, treatment, or operation in a language you read very well?

    1 ❒ Yes, it was in English and I read English very well.

    2 ❒ Yes, it was in my language (not English) and I read my language very well.

    3 ❒ No, it was in English and I do not read English very well.

    4 ❒ No, it was in my language (not English) and I do not read my language very well.

    5 ❒ I did not look at the form

    6 ❒ I was not asked to sign a form → Go to Question 23

21. Did anyone help you read the form?

1 ❒ Yes, someone from the hospital read it to me in English.

2 ❒ Yes, someone from the hospital read it to me in my language (not English).

3 ❒ Yes, a friend or family member read it to me in English.

3 ❒ Yes, a friend or family member read it to me in my language (not English).

4 ❒ No, I read it myself.

5 ❒ No, no one helped me read the form and I did not read it

22. How easy was the form to understand?

1 ❒ Very hard to understand

2 ❒ Somewhat hard to understand

3 ❒ Somewhat easy to understand

4 ❒ Very easy to understand

Person who Completed Survey.

23. Please select the option that best describes the person who answered these questions.

1 ❒ I am the patient.

2 ❒ I am the parent, legal guardian, or health care proxy of the patient.

3 ❒ I am a family member or friend of the patient.

4 ❒ Other

Appendix B: Patient Survey to Assess Informed Consent—Spanish Version

The following survey is intended to obtain feedback from patients immediately following an informed consent discussion to provide evaluative or quality improvement information to hospitals to assess and improve their informed consent processes using strategies described in AHRQ's Making Informed Consent an Informed Choice Training Modules.

Instructions on How To Administer the Survey

Aim: This survey can be used in a quality improvement or evaluation effort after improvements to the informed consent process are implemented to measure informed consent explanations and associated patient understanding. This survey can also be used to identify weaknesses in the informed consent discussion, specifically if key components of informed consent are explained to patients and whether they understood the explanations.

Content: This survey can be given to patients or their family members who are asked to provide consent to tests, treatments, or procedures. This survey asks patients or surrogate decisionmakers to determine whether key components of a comprehensive informed consent discussion were explained and whether the explanations were easy for patients to understand. It also asks about unanswered questions, overall satisfaction with the consent discussion and the consent form.

IRB: If appropriate per hospital policy, the hospital IRB should approve use of this survey before administering it to patients.

Patients to exclude: Patients and surrogate decisionmakers should be excluded if completing the survey might present undue burden at a very stressful time in their hospital stay or if they decline to complete the survey, or for other reasons deemed appropriate.

Timing of administration: The baseline survey should be administered to patients before an intervention to improve informed consent discussions (e.g., training) is implemented in a hospital unit. The followup survey should be administered to patients after the improvements to the informed consent discussion have been systematically and consistently implemented across the unit. The survey should be given to patients immediately following an informed consent discussion whether or not consent was given.

Interpreters and readers: The survey is available in English and Spanish. Administrators should offer to read the survey to patients.

Encuesta Para Pacientes

Estamos haciendo este encuesta para entender cómo mejorar el proceso de consentimiento informado para los tratamientos médicos—un proceso por el cual se le explica a un paciente los riesgos y los beneficios de tratamientos o procedimientos médicos ofrecidos y de sus alternativas, y con esa información, el paciente toma su decisión.

Le estamos solicitando que responda las siguientes preguntas basándose en la conversación que acaba de tener con el médico o enfermera (o) sobre la necesidad de hacerse a una prueba, un tratamiento o una operación. Sus respuestas ayudarán al hospital a entender qué información obtienen los pacientes antes de otorgar su consentimiento para pruebas, tratamientos u operaciones. Eso ayudará al hospital a hacer mejoras.

Antes de que complete este formulario, debe saber lo siguiente:

- Su participación es voluntaria.
- Completar esta encuesta generalmente durará menos de 5 minutos.
- No está obligado a completar esta encuesta.
- Esta encuesta no recopila información personal de usted o de su salud.
- No habrá ningún tipo de cambio en su atención médica si no participa en esta encuesta.
- Su relación con sus proveedores médicos o de salud no cambiará si no participa en esta encuesta.
- Si decide participar en la encuesta, puede dejar de responder las preguntas en cualquier momento.
- No hay ningún costo para completar la encuesta.
- El riesgo principal de este estudio es un pequeño riesgo de pérdida de confidencialidad. El equipo de investigación tiene muchos procesos para reducir este riesgo.

Quién habló con usted.

¿Quién fue la persona principal que habló con usted sobre la necesidad de realizarse una prueba, un tratamiento o una operación?

1 ❒ Mi médico personal

2 ❒ Un médico del hospital

3 ❒ Una (o) enfermera (o) del hospital

4 ❒ No sé

5 ❒ Nadie habló conmigo sobre la necesidad de realizarme una prueba, un tratamiento o una operación

6 ❒ Otro: _____

1. Un intérprete es alguien que le ayuda a comunicarse con otras personas que no hablan su mismo idioma. ¿Utilizó el servicio de un intérprete para hablar con esa persona?

   1 ❒ No, hablo muy bien Inglés.

   2 ❒ No, hablamos en Inglés aunque yo no lo hablo muy bien.

   3 ❒ No, la persona hablaba mi idioma muy bien (por ejemplo, los dos hablamos muy bien español).

   4 ❒ No, esa persona habló un poco en mi idioma.

   5 ❒ Sí, hablamos con la ayuda de un intérprete proporcionado por el hospital.

   6 ❒ Sí, hablamos con la ayuda de un amigo mío o familiar.

Explicaciones sobre la prueba, el tratamiento o la operación principal.

Piense en el tratamiento, la prueba o la operación principal sobre la que hablaron.

2. ¿La persona principal que habló con usted le explicó lo qué probablemente sucedería si se realiza la prueba, el tratamiento o la operación?

   1 ❒ Sí

   2 ❒ No ⟶ Si la respuesta es no, pase a la pregunta 7

3. ¿Fue fácil de entender la explicación sobre lo que probablemente sucedería si se realiza la prueba, el tratamiento o la operación?

   1 ❒ Sí, definitivamente

   2 ❒ Sí, más o menos

   3 ❒ No

4. ¿Esa persona le pidió que describiera lo que entendió sobre lo que probablemente sucedería si se realiza la prueba, el tratamiento o la operación?

   1 ❒ Sí

   2 ❒ No

5. ¿Esa persona le explicó qué podría salir mal y qué probabilidad había de que algo saliera mal?

   1 ❒ Sí

   2 ❒ No ⟶ Si la respuesta es no, pase a la pregunta 7

6. ¿Fue fácil de entender la explicación sobre qué podría salir mal y qué probabilidad había de que sucediera?

   1 ❒ Sí, definitivamente

   2 ❒ Sí, más o menos

   3 ❒ No

Otras pruebas, tratamientos u operaciones posibles.

7. ¿La persona principal que habló con usted le describió sus otras opciones, como el realizarse una prueba, un tratamiento o una operación diferente o no realizarse ninguna prueba, tratamiento ni operación?

   1 ❒ Sí

   2 ❒ No ⟶ Si la respuesta es no, pase a la pregunta 9

8. ¿Fue fácil de entender la descripción de sus otras opciones?

   1 ❒ Sí, definitivamente

   2 ❒ Sí, más o menos

   3 ❒ No

9. La asistencia para decisiones brinda información y le ayuda a pensar en sus opciones de pruebas, tratamientos u operaciones. La asistencia para decisiones puede ser en papel o en un video, una grabación de audio o un programa de computadora. ¿Alguien le mostró o le dio alguna asistencia para decisiones para que la usara?

   1 ❒ Sí

   2 ❒ No ⟶ Si la respuesta es no, pase a la pregunta 11

10. ¿Le fue útil la asistencia para decisiones para decidir si realizarse o no a una prueba, un tratamiento o una operación?

   1 ❒ Sí

   2 ❒ No

   3 ❒ No la usé

Acerca de la conversación.

11. ¿La persona principal que habló con usted lo (a) escuchó atentamente?

   1 ❒ Sí

   2 ❒ No

12. ¿Esa persona pasó suficiente tiempo con usted?

   1 ❒ Sí

   2 ❒ No

13. ¿Esa persona le preguntó qué era lo más importante para usted al decidir qué hacer?

   1 ❒ Sí

   2 ❒ No

14. ¿Esa persona lo alentó a que hiciera preguntas?

   1 ❒ Sí

   2 ❒ No

15. Después de la conversación, ¿tuvo alguna pregunta que no fuera respondida?

1 ❒ Sí

2 ❒ No ⟶ Si la respuesta es no, pase a la pregunta 17

16. ¿Por qué no obtuvo respuestas a sus preguntas?

1 ❒ Pregunté, pero no obtuve una respuesta.

2 ❒ Pregunté, pero la respuesta no respondió mis preguntas.

3 ❒ Pregunté, pero fue difícil entender la respuesta.

4 ❒ No hubo suficiente tiempo para hacer preguntas.

5 ❒ No sentí que pudiera hacer preguntas.

6 ❒ Otro:_____

17. ¿Cree que recibió suficiente información sobre todas las opciones para tomar una decisión?

1 ❒ Sí

2 ❒ No

18. ¿Se sintió con libertad de elegir alguna de las opciones, incluida la decisión de no realizarse ninguna prueba, tratamiento u operación?

1 ❒ Sí

2 ❒ No

19. En general, ¿qué tan satisfecho está con la experiencia de haber conversado sobre las opciones de pruebas, tratamientos u operaciones y tomar una decisión?

1 ❒ Muy insatisfecho

2 ❒ Un poco insatisfecho

3 ❒ Un poco satisfecho

4 ❒ Muy satisfecho

El formulario de consentimiento.

20. ¿El formulario de consentimiento que se le solicitó que firmara para la prueba, el tratamiento o la operación estaba en un idioma que usted lee muy bien?

    1 ❒ Sí, estaba en Inglés y yo leo muy bien en Inglés.

    2 ❒ Sí, estaba en mi idioma (que no es el Inglés) y yo leo muy bien en mi idioma.

    3 ❒ No, estaba en Inglés y yo no leo muy bien en Inglés.

    4 ❒ No, estaba en mi idioma (que no es el inglés) y yo no leo muy bien en mi idioma.

    5 ❒ No vi el formulario

    6 ❒ No se me solicitó que firmara un formulario →

    ⟶ Pase a la pregunta 23

21. ¿Alguien le ayudó a leer el formulario?

    1 ❒ Sí, alguien del hospital me lo leyó en Inglés.

    2 ❒ Sí, alguien del hospital me lo leyó en mi idioma (que no es el Inglés).

    3 ❒ Sí, un amigo o familiar me lo leyó en Inglés.

    4 ❒ Sí, un amigo o familiar me lo leyó en mi idioma (que no es el Inglés).

    5 ❒ No, lo leí yo solo.

    6 ❒ No, nadie me ayudó a leer el formulario y no lo leí →

    ⟶ Pase a la pregunta 23

22. ¿Qué tan fácil fue de entender el formulario?

    1 ❒ Muy difícil de entender

    2 ❒ Algo difícil de entender

    3 ❒ Algo fácil de entender

    4 ❒ Muy fácil de entender

La persona que completó la encuesta.

23. Seleccione la opción que mejor describe a la persona que respondió estas preguntas.

1 ❒ Soy el paciente.

2 ❒ Soy el padre, la madre, el tutor legal o el representante en cuestiones de atención médica del paciente.

3 ❒ Soy un familiar o un amigo del paciente.

4 ❒ Otro _____

Appendix C: Health Care Professional Survey to Assess Informed Consent

Instructions on Administration of the Survey

The health care professional survey can be administered via paper or through an online survey platform that will automatically total the results. Below are the details of the survey's administration.

Aim: By measuring staff knowledge, learning, and attitudes, this survey can be used to: 1) assess your current informed consent to treatment processes, or 2) evaluate whether quality improvements to the informed consent process have been implemented.

Content: This survey asks about what role the staff member plays in providing consent, what the current process of informed consent is for their unit, the effectiveness of informed consent at their institution, their ability to complete the teach-back process, their attitudes about informed consent, and general background information on the staff member. The post-survey can be used after the completion of a QI project, and thus also asks questions about the impact of the informed consent training.

IRB: If appropriate per hospital policy, the hospital IRB should approve use of this survey before administering it to staff.

Staff to exclude: Any staff member who is not eligible to participate in the health care provider training module.

Timing of administration: The first iteration of the survey will be administered to staff before the staff complete the training on informed consent is implemented in participating hospital units. The followup survey will be administered to staff about 2-3 months after the improvements to the informed consent discussion and process have been systematically and consistently implemented across participating units.

Interpreters and readers: The survey is available only in English.

Survey

We are surveying you to understand how to improve the informed consent process[1] —a process by which a patient is told about the risks and benefits of proposed tests, treatments, or procedures, as well as alternatives, and makes a decision based on that information.

If you agree to participate in this survey, we will:

- Ask you questions about your hospital's informed consent policies and processes, your self-reported use of evidence-based practices described in the health care professional training module, a self-assessment of your informed consent process effectiveness, and your attitude regarding patients' rights in informed consent.
- Ask you about your experiences, to capture how learning and strategy implementation affected behavior, and/or yielded results.

Before you take the survey you should know the following:

- Your participation is voluntary.
- This survey should only take you 20 minutes to complete.
- You do not have to complete this survey.
- If you decide to take this survey, you can stop answering the questions at any time.
- There is no cost to you for taking this survey.
- You can refuse to take part in this survey without any effect on your professional relationship with your hospital.

[1]When using the survey to monitor progress in improving informed consent processes you can change the wording to, "We are surveying you to track improvement of the informed consent process."

Role in Informed Consent.

1. Which best describes your typical role in informed consent for tests/treatments/procedures (check all that apply):

   - ❒ I am not involved in informed consent, and I am unaware when or whether it is done.
   - ❒ I am not involved in informed consent, but I am aware when or whether it is done.
   - ❒ I provide information on the test/treatment/procedure, risk/benefits, and alternatives to patients for informed consent.
   - ❒ I conduct the informed consent discussion with patients.
   - ❒ I show decision aids to patients.
   - ❒ I obtain signatures on the consent form (paper or electronic).
   - ❒ I confirm that patients have provided consent.
   - ❒ I am focused on informed consent for the hospital because of my safety or quality role.
   - ❒ Other (please describe): _____

Current Informed Consent Policy.

2. To what extent do you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
a) I know which tests, treatments, and procedures require written consent.					
b) I know which tests, treatments, and procedures require verbal consent.					
c) I know which members of the clinical team are permitted to conduct the informed consent discussion.					
d) I know when and how to assess a patient's capacity to consent.					
e) I know what the witness who signs the informed consent form is testifying to.					
f) I know the exceptions to informed consent requirements.					

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
g) I know how to handle cases when informed consent was obtained before the patient came to the hospital.					
h) I am clear about my role in the informed consent process.					

Current Informed Consent Process.

3. For tests/treatments/procedures that require informed consent, how frequently do clinicians in your unit do the following when obtaining informed consent?

Check "DK" (Don't Know) if you don't know what clinicians do in your unit.

	Never	Sometimes	Usually	Always	DK
a) Assess patients' decisionmaking capacity					
b) Allocate ample time in private space					
c) Use health literacy universal precautions					
d) Call for qualified interpreters when conducting a consent discussion with a patient who speaks a different language					
e) Offer choices, including the option of doing nothing					
f) Engage patients, family, and friends in the consent discussion					
g) Elicit goals and values					
h) Encourage questions					
i) Use high-quality structured patient decision aids (e.g., tool to help a patient understand the benefits, harms, and risks of a test, treatment, or procedure and make a decision)					
j) Neutrally explain the benefits, harms, and risks of all options					
k) Use teach-back techniques to check patient understanding					
l) Better document the informed consent discussion					
m) Ask patients to confirm consent immediately before test, treatment, or procedure when consent has been given in advance					

4. For tests/treatments/procedures that require informed consent, how frequently do you do the following when obtaining informed consent?

Check "NA" (not applicable) if the statement does not apply to your responsibilities or you don't know what the statement is referring to.

	Never	Sometimes	Usually	Always	DK
a) Assess patients' decisionmaking capacity					
b) Allocate ample time in private space					
c) Use health literacy universal precautions					
d) Call for qualified interpreters when conducting a consent discussion with a patient who speaks a different language					
e) Offer choices, including the option of doing nothing					
f) Engage patients, family, and friends in the consent discussion					
g) Elicit goals and values					
h) Encourage questionh					
i) Use high-quality structured patient decision aids (e.g., tool to help a patient understand the benefits, harms, and risks of a test, treatment, or procedure and make a decision)					
j) Neutrally explain the benefits, harms, and risks of all options					
k) Use teach-back techniques to check patient understanding					
l) Better document the informed consent discussion					
m) Ask patients to confirm consent immediately before test, treatment, or procedure when consent has been given in advance					

Informed Consent Process Overall Effectiveness.

5. On a scale from 1 to 10 where 1 is the worst and 10 is the best, how well does **your unit** ensure patients are making an informed choice?

- ❒ 1 – Worst
- ❒ 2
- ❒ 3
- ❒ 4
- ❒ 5
- ❒ 6
- ❒ 7
- ❒ 8
- ❒ 9
- ❒ 10 – Best
- ❒ DK – Don't know

6. On a scale from 1 to 10 where 1 is the worst and 10 is the best, how well do **you** ensure patients are making an informed choice?

- ❒ 1 – Worst
- ❒ 2
- ❒ 3
- ❒ 4
- ❒ 5
- ❒ 6
- ❒ 7
- ❒ 8
- ❒ 9
- ❒ 10 – Best
- ❒ N/A – I'm not involved in the consent process

Teach-Back Self Efficacy

Teach-back is a way to check that you have explained to patients what they need to know in a manner that they understand. Patient understanding is confirmed when they are able to explain it back to you in their own words.

7. On a scale from 1 to 10, how confident are you in your ability to use teach-back in an informed consent discussion? (1 = "not at all confident", 10 = "very confident")

- ❒ 1 – not at all confident
- ❒ 2
- ❒ 3
- ❒ 4
- ❒ 5
- ❒ 6
- ❒ 7
- ❒ 8
- ❒ 9
- ❒ 10 – very confident
- ❒ N/A – I'm not involved in the consent process

Attitudes about Informed Consent

8. To what extent do you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
a) Clinicians should encourage patients to talk about their values when deciding whether to consent to a test, treatment, or procedure.					
b) Clinicians are in a better position than patients to decide which tests, treatments, or procedures patients need.					
c) Clinicians should not present alternatives that are demonstrably less effective.					
d) Refusing a life-saving treatment or procedure demonstrates that the patient is not capable of making a sound decision.					

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
e) Clinicians are responsible for ensuring that patients understand all their options before making a decision.					
f) Getting the patient's signature on a consent form is the most critical part of the informed consent process.					
g) Lack of patient understanding of benefits, harms, and risks of treatments is a serious patient safety problem.					
h) The informed consent process is worth the time it takes.					
i) The chief purpose of informed consent processes is to comply with regulations and be protected from lawsuits.					

Background Information.[1]

This information will help in the analysis of the survey results.

9. How long have you worked in this hospital?

❒ a. Less than 1 year
❒ b. 1 to 5 years
❒ c. 6 to 10 years
❒ d. 11 to 15 years
❒ e. 16 to 20 years
❒ f. 21 years or more

10. How long have you worked in your current hospital work area/unit?

❒ a. Less than 1 year
❒ b. 1 to 5 years
❒ c. 6 to 10 years
❒ d. 11 to 15 years
❒ e. 16 to 20 years
❒ f. 21 years or more

[1]Questions taken from the AHRQ Hospital Survey on Patient Safety Culture

11. What is your staff position in this hospital? Select ONE answer that best describes your staff position.

- ❒ a. Registered Nurse
- ❒ b. Physician Assistant/ Nurse Practitioner
- ❒ c. LVN/LPN
- ❒ d. Patient Care Asst/ Hospital Aide/Care Partner
- ❒ e. Attending/Staff Physician
- ❒ f. Resident Physician/ Physician in Training
- ❒ g. Pharmacist
- ❒ h. Dietician
- ❒ i. Unit Assistant/Clerk/Secretary
- ❒ j. Respiratory Therapist
- ❒ k. Physical, Occupational, or Speech Therapist
- ❒ l. Technician (e.g., EKG, Lab, Radiology)
- ❒ m. Administration/Management
- ❒ n. Other, please specify:

12. How long have you worked in your current specialty or profession?

- → ❒ a. Less than 1 year
- → ❒ b. 1 to 5 years
- → ❒ c. 6 to 10 years
- → ❒ d. 11 to 15 years
- → ❒ e. 16 to 20 years
- → ❒ f. 21 years or more

13. In your staff position, do you typically have direct interaction or contact with patients?

- → ❒ a. YES, I typically have direct interaction or contact with patients.
- → ❒ b. NO, I typically do NOT have direct interaction or contact with patients.

14. In which hospital unit do you primarily work?

- ❒ [insert other participating units]
- ❒ [insert other participating units]
- ❒ [insert other participating units]

AHRQ Publication No. 17-0016-1-EF
January 2017