

Making Informed Consent an Informed Choice: Training for Health Care Leaders Audio Script

Slide 1/Welcome

Making Informed Consent an Informed Choice: Training for Health Care Leaders

- This course is sponsored by the Agency for Healthcare Research and Quality (AHRQ), Contract No. HHS A290201000031I, Task Order #3.
- The course development and production was a joint effort by AHRQ, Abt Associates, and The Joint Commission.

The course will take approximately 1.5 hours to complete.

Select the next button to begin the course.

Slide 2/Navigation

Before you get started, take a moment to learn how to navigate in this course:

- Select the Next button to move forward.
- Select the Back button to move backward.
- The Progress Bar indicates your progress within a screen. Drag the Progress Bar indicator to move forward or back within a screen.
- Select the Play/Pause button to alternate between controls for viewing screen content.
- Select the Sound On/Off button to turn the audio either on or off for the entire course.
- Select Audio Script On/Audio Script off to view or hide the audio transcript for the course.
- Select the Exit button in the upper right-hand corner to leave the course.
- Select the Menu button in the upper left-hand corner to view the screen menu and move to a specific page.
- Select the Resources Tab located on the left panel of your screen to view additional resources provided with this course. Select “Take the Course” from the left menu when you are ready to return.

Use a combination of ‘Back’ and ‘Next’ to fully repeat a slide. The refresh button will only replay the last function of a slide.

Slide 3/Introduction

Welcome and THANK YOU for your interest in improving the informed consent process for your patients. Informed consent for medical treatment requires clear communication about choices. Informed consent is not a signature on a form; it is a communication process in which a

patient is given information about his or her options for medical tests, treatments, or procedures, and then selects the option that is the best fit for his or her goals and values.

The goal of this course is help you transform informed consent into a process of achieving informed choice in your hospital.

This course is for quality improvement and patient safety leaders, risk management leaders, and unit leaders including physicians, anesthesiologists, nurses, and other clinicians.

Please note that photos throughout this course are for illustration only. Unless otherwise stated the people depicted are models.

Slide 4/Course Scope

Please note that this course focuses on informed consent to medical treatment.

This course does not focus on blanket consent-to-treatment forms that patients sign upon admission to a hospital, because such forms provide very little information to patients.

This course also does not focus on informed consent for research, nor does it focus on advance directives for end-of-life care.

If you wish to learn more about informed consent for research or advance directives, please see the Resources section of this course.

Slide 5/Learning Objectives

By the end of this course, you will be able to:

- Summarize the principles of informed consent in health care.
- Describe strategies and system changes to nurture a hospital culture that supports a high-quality policy of informed consent.
- Launch an Informed Consent quality improvement initiative at your hospital.

Slide 6/Course Contents

Course Contents

The information in this course is organized into the following sections:

Section 1: Principles of informed consent

The purpose of Section 1 is to examine existing problems with the process of informed consent for health care, describe the principles of informed consent, and discuss the implications of a good informed consent process.

Section 2: Crafting and disseminating your informed consent policy

The purpose of Section 2 is to assess current policies, and to develop and disseminate improved policies on informed consent.

Section 3: Building systems to improve the informed consent process

The purpose of Section 3 is to describe systems and resources that need to be put into place to support the effort to improve the informed consent process.

All sections of this activity are required for continuing education credit.

This Web-based training course is classified as an enduring program. You will be able to return to where you left if you cannot complete the entire course in one session.

Slide 7/Benefits of a High-Quality Informed Consent Process

What are the benefits of a high-quality process of 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.

A high-quality process of informed consent has many advantages. It helps patients to make informed decisions, strengthens the therapeutic relationship, and can improve followup and aftercare. When patients and their families understand the benefits, harms, and risks of treatment in advance, they can partner in patient safety. They can better cope with any poor outcomes that may happen as a result of treatment and save money by averting delayed or cancelled surgeries. This understanding makes it less likely for a patient to sue the clinician when a poor outcome occurs.

Slide 8/Why Does Informed Consent Need to be Improved?

Unfortunately, there are many problems with the informed consent process in hospitals today.

Both clinicians and patients often treat informed consent as a nuisance, a formality, and an obstacle on the way to care.

This is a problem for both, because even after signing a consent form, many patients still do not understand basic information about the benefits, harms, and risks of their proposed treatment, including the possibility of poor outcomes. Some patients may also not understand that they can say "no" to a specific treatment.

As a result, informed consent is one of the top 10 most common reasons for medical malpractice lawsuits. Hospitals that ensure patient understanding can generate substantial savings by averting delayed and cancelled surgeries.

Slide 9/Informed Consent Team Roles and Responsibilities

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 of the table 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 table with fellow team members in your unit.

Remember, this is a sample table. 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 and
- A training resource on coaching team members on how to be part of a team

Slide 10/When “informed” consent is NOT informed

Section 1: Principles of Informed Consent

In section 1, we'll learn the principles of informed consent. We'll begin by reviewing some examples of failures to obtain informed consent. One such case is Toni Cordell. Toni had a hysterectomy without realizing the procedure recommended to solve her “woman’s problem” was the removal of her uterus.

Select the image of Toni to learn about her situation.

While Toni’s experience was not recent, failures in the informed consent process happen in hospitals every day.

Toni Cordell: At approximately 30 or 31, I went into the gynecologist and complained about part of this not working correctly. And he said we can repair that.

Great!

I didn’t ask all the right questions. When I showed up 2 weeks later at the admissions office at the hospital, they put enough papers in front of me, I bet there were 5 papers that I needed to sign.

Well, I wasn’t gonna say “Excuse me but I don’t read really well and I certainly don’t read fast and I am concerned with some of these words.”

To me it was lines and circles over sheets and sheets and sheets. And I wasn’t gonna reveal my sense of stupidity so I signed everywhere they told me to sign. Never read it. And then couple weeks later in the follow up office visit the nurse said, “How are you feeling since your hysterectomy?”

Now, I acted as normal as I could. Inside my mouth fell open and I thought to myself, how could I be so stupid as to allow somebody to take part of my body and I didn’t know it.

Slide 11/Ethical Principle of Autonomy

The principle of autonomy gives patients the right to decide what happens to their bodies.

In every State, by law, patients have the right to:

- Make decisions about their care, treatment, and services; and
- To receive adequate disclosure of information about the proposed treatment.

Patients also have the right to:

- Choose among treatment options without any undue influence or coercion,
- Refuse any unwanted medical interventions, and
- Change their minds and withdraw their consent at any time.

Slide 12/It's Not About the Form

Telling patients is not enough for consent to be informed, even if patients sign the form.

A signed consent form implies that prior to the patient's signing it, a process of adequately informing the patient and ensuring understanding has taken place. Yet, many patients sign informed consent forms even when they do not understand the procedure; its benefits, harms, risks; or the alternatives to a specific treatment.

If the patient did not understand the information presented, it becomes a patient safety problem, and your hospital could be sued, even if the patient signed the form.

Courts have held that providing information when the patient doesn't understand does not constitute informed consent. For example, in the Macy versus Blatchford case, the Oregon Supreme Court decided that the physician failed to obtain a patient's informed consent for surgery. In other words, they concluded that it's not explaining unless the patient understands.

Additional information about Macy versus Blatchford case law is located in the Resources section.

Slide 13/Recognizing Patient Capacity for Decisionmaking

To uphold a patient's right to participate in decisions about his or her care, it is important to recognize the patient's capacity for decisionmaking.

The main point to remember is that most patients have the capacity for decisionmaking about their medical care and treatment.

Capacity means both the ability and the right to make a decision. It can change over time, and can depend on the decision to be made.

Each patient should be assessed for their capacity for decisionmaking. If a patient is unable to make decisions the legal designee needs to be identified. You should review your hospital's policy regarding assessing patient capacity and how to identify a legal designee.

Key factors in assessing the patient's capacity are whether the patient:

- Is able to make and communicate a choice.
- Is able to understand key information about his or her condition; the treatment options; and their benefits, harms, and risks; and is not required by law or court order to undergo treatment.

The following are more principles of informed consent. Select each principle for additional information.

Additional information on case law, informed consent of persons with a lack of capacity, and minor's right to consent is located in the Resource section.

Patients do not automatically lack capacity just because they disagree with the care team's treatment plan. Patients may refuse treatment even if it puts their lives in jeopardy.

Some patients cannot speak, or may have an intellectual or physical disability, mental illness, or cognitive impairment, or may be under the influence of alcohol or pain medications. But such situations do not automatically mean that patients lack the capacity to make a decision, though such conditions can make it harder for them to communicate and to make decisions. Later in this course, we will share some communication strategies that can help.

A patient's family and friends often play an important role in the decisionmaking process, but in most cases, the final decision rests with the patient.

There are some exceptions to this rule, namely:

- When the patient lacks decisionmaking capacity,
- When the patient is a minor (although State law and hospital policy may allow mature minors to consent),
- When the patient requests not to be informed, and
- A last exception is a life- or health-threatening emergency which leaves no time to identify or speak with an authorized representative. In that case, the clinician can make a decision in the patient's best interests. But often there is still time to hold a consent discussion in emergency situations.

An authorized representative for minors can be:

- parent or legal guardian.

For adults:

- designated by the patient (health surrogate)
- designated by someone other than the patient who has authority (for example, the hospital policy can establish a hierarchy of authorized representatives in the absence of a proxy, typically spouse first, then adult children, then siblings, then other relatives)

State law defines what constitutes "adequate disclosure"—or what clinicians are required to tell patients.

Adequate disclosure is the duty of the clinician who is providing the treatment. It cannot be delegated to another person. The information to be disclosed must include:

- What the procedure or treatment will involve;
- The anticipated results and probable benefits and harms, such as temporary discomfort;
- Any possible complications, as well as reasonably foreseeable risks. These include very low or remote risks that the outcome will be very severe, such as death, paralysis, disfigurement, or permanent disability.

Finally, adequate disclosure laws require telling patients whether the procedure or treatment is experimental or part of a research study.

Many States have additional requirements.

Slide 14/When to Consult an Authorized Representative

Select the image to hear Cecile's real life story about informed consent in an emergency.

Cecile: "My father was recovering from minor surgery when I noticed he was trying to say something but was having trouble coming up with the words. I called in the nurse practitioner, and he decided to call the stroke team. Well, the stroke team arrived, performed an assessment, and started to wheel my father out the door. "Where are you taking him?" I asked. "To give him medicine to break up the blood clot," they said. I said, "But you haven't gotten consent." "It's an emergency!" they called, halfway out the door. But I was my father's health proxy and I called after them, "You can't give him anything until I consent." That caught them short. "You're right," they agreed. "Can you walk with us while we tell you about this medicine?" And I did. I understand they were in a rush—they had to give him the medicine within 3 hours of his first symptoms, but that didn't mean they didn't have time to get consent."

Slide 15/Making Informed Consent an Informed Choice

Informed consent requires clear communication about choices.

The goal of this course is to help you make informed consent an informed choice for your patients. Let's talk about what that means.

What we often see in informed consent discussions is that a clinician will recommend a treatment, explain the treatment, and then get the patient's consent to deliver the treatment.

This may satisfy the minimum requirements for informed consent, but to make a truly informed choice, patients need clear, unbiased medical information that they can understand about all their treatment options, including what happens if they decide to do nothing.

This is a challenging situation, because clinicians may not always be in a position to provide information about all the options.

In addition to considering all the options, to make an informed choice patients must factor their goals and values into the decision.

Of course, the information about the choices must always be presented in a way that the patient can understand.

On screen is a cartoon image that shows Humpty Dumpty with his cracked shell body sitting in a doctor's office. The doctor is examining Humpty's x-ray and the caption below the picture says "Ok, you can choose regal equine therapy, OR fragment adhesion cranioplasty, which would you prefer?"

Slide 16/Section 2: Crafting and Disseminating Your Informed Consent Policy

Section 2: Crafting and Disseminating Your Informed Consent Policy.

This section will help you to assess your hospital's current policy on informed consent, improve it if need be, and disseminate it better.

You may be asking yourself, "Why should my hospital focus on improving its informed consent policy?"

A recent analysis of The Joint Commission accreditation data suggests that many hospitals could benefit from improving their informed consent policies. Some hospitals were found to be out of compliance with accreditation standards because they did not have a formal written informed consent policy. The most frequent area of concern was a hospital's failure to obtain informed consent in accordance with the hospital's policy and processes. The analysis also revealed that many policies were overly broad and lacked the detail necessary for clinicians to be able to implement the policy.

Slide 17/Section 2: Crafting and Disseminating Your Informed Consent Policy

Judging from the questions asked of The Joint Commission, clinicians need more detailed guidance from their hospital policies on informed consent to answer some of their frequently asked questions.

For example:

- What are the appropriate processes to follow in obtaining informed consent and documenting signatures of physicians, patients, and witnesses?
- How far in advance can we obtain informed consent?
- What are the language requirements on consent forms? For example, is the use of nontechnical terms required? Can English-language forms be used for persons with limited English proficiency (LEP)?
- How should we engage representatives authorized to make decisions on behalf of patients?
- How can we obtain informed consent for children?

- What are the appropriate practices for explaining and documenting the benefits, harms, and risks of treatment alternatives?
- To what extent do patients have the right to refuse care?

Slide 18/Informed Consent Policy Audit Exercise

The next few slides will walk you through the essential elements of an informed consent policy. To get the most out of this section, it will be helpful to have a copy of your hospital's informed consent policy to reference as we discuss each element.

If you believe no policy is available, double check to be sure that this is the case. Most accredited hospitals have a written policy on informed consent. If your hospital truly does not have an informed consent policy, this section can help you to create one.

Informed Consent Policy Improvement Task Force should include:

- Legal
- Risk management
- Medical
- Patients

In addition to obtaining your informed consent policy, please open the accompanying informed consent worksheet. It is available here and in the Resources area of this course. Print a copy or open it in another window, as you will work on it throughout this section.

Policy examples given here are offered for illustrative purposes only, and this exercise is only a starting point. If your assessment shows that there are any deficiencies in your policy, consider working to improve the policy with a task force that includes representatives of your health care facility's legal, risk management, and medical teams, as well as patients. If you are not sure how to engage patients and families, the Resources section of this module includes links to reports from the Institute of Patient- and Family-Centered Care on engaging patients and families in quality improvement.

Select the button to open the Informed Consent Policy Worksheet. A copy of this Informed Consent Policy Worksheet is also available in the Resources area of the course.

Slide 19/Statement of Purpose and Summary of Principles

Hospitals' informed consent policies often start with a statement of purpose and summary of principles.

Select the button to see an example policy from a fictional hospital we will call Wellness Hospital.

Purpose: To ensure that every patient receiving invasive tests or procedures or other medical treatments at Wellness Hospital will be fully informed as to all benefits, harms, foreseeable risks, and alternatives prior to choosing whether to consent.

In addition to the statement of purpose, a general policy may also be provided to outline the key principles of informed consent at the hospital.

Select the button for an example policy from the fictional hospital, Wellness Hospital.

The physician, independent nurse practitioner, or independent physician assistant will ask for consent from the patient or the patient's authorized representative for all surgeries, invasive procedures, or treatments involving risk, such as cardiac catheterizations, lumbar punctures, biopsies, and administration of medicines.

Patients have the right to:

- Make decisions about their care, treatment, and services;
- Receive adequate disclosure of information about the benefits, harms, and risks of the proposed care and alternatives, including the option of receiving no treatment;
- Get answers to all questions;
- Choose among treatment options;
- Refuse unwanted medical interventions; and
- Withdraw consent at any time.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Please note that policy examples given here and on the next several slides are offered for illustrative purposes only. Your hospital's policy should be tailored to your hospital's specific needs and your State's law.

Slide 20/Who can Obtain Informed Consent

Your policy should include a section stating who is responsible for obtaining informed consent.

The physician, independent nurse practitioner, or independent physician assistant in charge who orders a test, prescribes a treatment, or performs a procedure is responsible for the informed consent process. Other staff members can play a supporting role.

If other staff members are playing a support role in your hospital's informed consent process, your policy can clarify who should play what support roles. For example, a nurse can conduct patient education, and support staff can verify that a signed informed consent form is on file before a procedure takes place.

Select the button to see the example policy.

Here is an example from Wellness Hospital:

For all tests, treatments, and procedures offered at Wellness Hospital:

1. The physician, independent nurse practitioner, or independent physician assistant who orders a test, prescribes a treatment, or performs a procedure is responsible for holding an informed consent discussion with the patient and for ensuring that the patient understands

the potential benefits, harms, and risks and chooses the test, treatment, or procedure over alternatives.

2. Anesthesiologists are responsible for holding a separate consent discussion with the patient that is focused on anesthesia.
3. Nurses and residents may prepare a patient for informed consent discussions by holding education sessions with the patient about the patient's condition and what tests, treatments, or procedures the patient can consider.
4. While more than one team member may provide information to the patient about a treatment or procedure, the physician, independent nurse practitioner, or independent physician assistant in charge is responsible for ensuring the coordination and consistency of information given to the patient.

Take a moment and record your answers on your worksheet before continuing with the course.

Slide 21/Procedures that Require Explicit Consent

Certain procedures require explicit consent.

A well-crafted hospital policy on informed consent will list which procedures require explicit consent.

Select the button to see an example policy.

The example of Wellness Hospital's general policy, shown earlier, indicates that all surgeries, invasive procedures or treatments involving risk, such as cardiac catheterizations, lumbar punctures, biopsies, blood transfusion, PICC and central line placement, anesthesia, and administration of medicines, require explicit consent.

Explicit consent requirements can be waived only in emergency situations, such as an unconscious patient requiring lifesaving surgery when surrogate decisionmakers (such as a family member) cannot be consulted in time.

Explicit consent does not always require a patient's signature. For many procedures and treatments, verbal consent can be sufficient. Later on, we will discuss hospital policies regarding how informed consent should be documented.

It is important to review your institution's policy to ensure it addresses other situations that require informed consent such as group practice consents that cover multiple partners in a practice and consent for multiple surgeries or procedures scheduled.

Take a moment to review the Policy Worksheet in the resources section to evaluate your hospital's current policy.

Slide 22/Timing of Informed Consent Discussion

A section of your policy should define when informed consent should be obtained. At a minimum, the policy should state that consent must be obtained before the test, treatment, or procedure is given. Such a detail, while obvious, must be included in any policy.

In addition, you may wish to include a statement of principle about the importance of giving patients enough time to process the information, and to avoid waiting until it is too late to say “no.”

Select the button for an example policy from the fictional hospital, Wellness Hospital.

For example, having the informed consent discussion with a colonoscopy patient after the patient has completed the colon preparation is not considered adequate timing. The Wellness Hospital’s policy makes this explicit. It says:

Informed consent discussions must be held before preparations for tests, treatments, and procedures are begun. Except in emergency situations, discussions should be held well in advance to give patients an opportunity to process the information.

Take a moment to review the Policy Worksheet in the resources section to evaluate your hospital’s current policy.

Slide 23/Content of an Informed Consent Discussion

An informed consent policy should contain information about what to include in an informed consent discussion, so you’ll want your informed consent policy to address this. In many States, the content of informed consent communications is mandated by law.

Select each item for additional information on what a hospital policy should require in an informed consent discussion.

Need

- A description of the patient’s condition and why a test, treatment, or procedure is needed.
- Options
- What other tests, treatments, or procedures should be considered? Often a physician, independent nurse practitioner, or independent physician assistant will want to make a recommendation, but the best practice is to provide information about all feasible options in a neutral way and help the patient make a choice based on the patient’s goals and values.
- The policy should direct physicians, independent nurse practitioners, or independent physician assistants to let patients know that they can choose to have no treatment, and discuss the benefits, harms, and risks related to no treatment.

Who performs?

- The policy should address informing the patient about who will perform the test, treatment, or procedure, including members of the team who will be performing major tasks. In the case of surgery, the National Quality Forum recommends that informed consent discussions should mention about how many times a surgeon has performed a given procedure in the past year and in their lifetime, since that information is critical to assess competence and risk.

Probable benefits, harms, and risks

- The informed consent policy should specify that for each alternative, the physician, independent nurse practitioner, or independent physician assistant should describe what it actually entails and the probable benefits and harms, including:
 - Anticipated results, and the likelihood of getting those results
 - Any temporary discomfort, disability, or disfigurement that can be anticipated during the recovery period
 - What complications the patient is likely to experience, and
 - Any permanent results
- Explain all foreseeable risks, including remote but severe risks.

Questions

- Patients are likely to have many questions. Your hospital's informed consent policy should advise clinicians to let patients know that questions are expected and to make time to answer them.

Check understanding

- Think about including a requirement to check patient understanding, a practice recommended by the National Quality Forum called teach-back. We'll talk more about teach-back later in this course.

Take a moment to review the Policy Worksheet in the resources section to evaluate your hospital's current policy.

Slide 24/Documentation and Verification of Consent

The Joint Commission receives frequent queries about how to document informed consent, suggesting that hospital policies are often insufficiently detailed on this topic.

Therefore, it is important to be sure that your policy should specifically identify the procedures and treatments that are covered by the blanket "consent to treatment" that patients sign upon admission to the hospital, and which procedures and treatments require separate explicit consent.

The policy should specify which procedures and treatments require only verbal consent, documented by a note in the medical record, and which ones require a signed consent form, including signatures by interpreters when used. It should also specify how consent should be documented. Be sure that your policy is consistent with requirements. For example, The Joint Commission's standards require a signed informed consent prior to surgery.

It can also be helpful to specify that a single form can cover recurring treatments such as radiation or chemotherapy.

Because informed consent discussions often take place before the patient gets to the hospital, your policy should address how to document informed consent in those instances.

Select the button for an example policy from the fictional hospital, Wellness Hospital.

Patients at Wellness Hospital sign a blanket consent form for treatment prior to admission. This form documents that the patient has been admitted to the hospital of his or her own accord, and covers non-invasive, routine, minimal-risk procedures such as taking the patient's blood pressure and asking intake questions.

Verbal consent is required for routine treatments and procedures with very low risk, but not minimal risk, such as the administration of most drugs, blood draws, and minor procedures, such as routine X-rays.

A signed written consent is required prior to all surgery, and for any treatments and procedures that involve a significant risk of harm, pain, or discomfort, and/or require sedation or anesthesia. For recurring treatments such as radiation or chemotherapy, a single form can be used to cover multiple sessions.

Qualified interpreters who interpreted an informed consent discussion, or sight-translated the informed consent form, or both, must also sign the form. In the case of telephone interpreters, the physician, independent nurse practitioner, or independent physician assistant conducting the discussion may write the interpreter's name or identification number on the form.

Both verbal and written consent must be documented in the patient's electronic health record. If the informed consent discussion took place outside Wellness Hospital, per this policy the admitting nurse must verify that the physician, independent nurse practitioner, or independent physician assistant performing the procedure obtained informed consent and documented in the patient's electronic health record before treatment occurs.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Slide 25/Exceptions to Informed Consent

Once your policy has outlined the general rules regarding informed consent, it should also note the exceptions.

In brief, the exceptions include certain emergencies, cases in which the patient is incapacitated, most minors, patients whose treatment is required by law or court order, and cases in which a patient asks not to be informed.

Your policy should provide more details on each of these exceptions. We will cover exceptions regarding minors in more depth in the following slides. The Resources section cites a legal reference book by Fay Rozovsky that provides extensive information on this and other informed consent topics.

Slide 26/Exceptions to Informed Consent (Continued)

Your organization's informed consent policy should include what constitutes an emergency, such as if irreparable harm will result if immediate action is not taken. The policy should also provide clear guidance on what to do when exceptions arise. If time allows and treatment is not mandated

by law or court order, it may be possible to identify a surrogate decisionmaker. Laws regarding who can be the patient's duly authorized legal representative vary from State to State. Priority should be given to persons named in health care proxy or power-of-attorney documents, and the hospital may establish a hierarchy of decisionmakers in the event that a health care proxy or power-of-attorney is not available. For example, the spouse or partner may be the first in line, followed by adult children, then siblings, and so forth, with the medical team making decisions as a last resort. This level of detail can help to reduce conflict when the patient is unable to make or express decisions, and relatives disagree on the course of treatment.

You may also wish your hospital policy to include a statement that clinicians should communicate with patients about their treatment even if the patient cannot communicate or consent to care, unless the patient has asked not to be informed. Communicating with the patient can help to alleviate feelings of anxiety and improve cooperation with treatment.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Slide 27/Informed Consent for Minors (Continued)

A hospital's policy should include a section about consent for minors. In most cases, minors cannot legally consent to treatment, and parental consent is required. Nonetheless, in addition to gaining parental consent, you may wish to encourage clinical staff to engage minor patients in their care when possible by providing information about their treatment and, for older children, seeking their assent. Assent is an agreement that implies understanding but does not carry legal power.

In seeking assent, a rule of thumb commonly used by clinicians is that teenagers—typically those age 14 years or older—can process similar information to what is given to their parents or guardian, and younger children—typically those age 7 years or older—can process simple information about what the experience will be, how it may help, how long it will take, and whether it might involve any pain or discomfort.

Select the image to learn about a real-life situation illustrating the importance of seeking assent from minors.

“We received a 14-year-old on our inpatient unit who had a PICC line in place. When talking to her mother regarding her medicines, she learned that the line terminated in her heart and was quite distressed by this. Later that day, the RN went to administer antibiotics and discovered that the patient had pulled the PICC out on her own and hidden it in her gown. That issue might have been avoided with a consenting process that more actively involved the patient, given her age.”

You can prevent issues like this one by involving minors in the consent process.

Slide 28/Informed Consent for Minors (Continued)

A policy should always note whether there are exceptions to the rule that minors cannot give consent. If these exceptions apply in your hospital, they should be noted in your policy.

These exceptions often include mature minors, minor parents, and certain services.

Select each image for additional information.

An image is shown of a young person signing a consent document. Narrator states: Some States allow mature minors to consent to treatment without their parents' involvement. Definitions of "mature minors" vary. If your State allows it (or does not forbid it), your hospital's policy should spell out who can be considered a mature minor. Some State laws define mature minors or the conditions under which a minor can consent. Absent guidance from the law, your definition of a mature minor can be based on age (for example, 14 years or older), on whether the minor is married or has children, or on the minor's cognitive ability and social maturity to understand the information and make an informed decision.

A picture of young parents with a baby is shown. Narrator states: It is generally recognized that minors who are parents have the right to consent to care on behalf of their children.

An image of a teenager looking at medicine with a clinician is shown. Narrator states: Some States allow minors to consent to certain services without involvement by their parents, such as reproductive health care and substance abuse treatment.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Slide 29/Clear Communication Policies

Clear communication policies

Regardless of what patients say or sign, patients have not consented unless they understand the information provided. This is why a hospital's informed consent policy should foster a culture of clear communication with patients. To do this, consider including in your informed consent policy a statement to describe how clinicians can ensure that patient consent is informed. For example you can highlight the importance of plain language; clear and simple forms; the use of high-quality decision aids, graphics, and other educational materials; and teach-back. Teach-back is asking the patient to explain in their own words what they need to know or do, so clinicians can make sure they have explained things well.

A clear communication policy should also address how to make reasonable accommodations to help patients participate in the informed consent process. Accommodations include providing professionally translated forms and language assistance for patients with limited English proficiency, using large print forms as well as magnifier reading glasses for patients with limited vision, and offering to read the form to all patients in case they are embarrassed to admit having difficulties with reading.

Select the button for an example policy from the fictional hospital, Wellness Hospital.

Wellness Hospital is committed to clear communication. To ensure that patient consent is truly informed, we strive to use plain language; clear and simple forms; and high-quality decision aids, graphics, and other educational materials. We also use teach-back to ensure that patients have understood the information that has been presented to them.

For patients with limited English proficiency, clinicians may only conduct informed consent discussions if they have been certified as bilingual by the Office of Interpreter Services or use a qualified medical interpreter. (See Wellness Hospital's Language Access Plan for details on our interpreter services.)

Clinicians should offer assistive devices, such as magnifying readers and audio amplifiers, and ask patients if they would like forms read aloud to them.

Select the image of Magda to hear how she avoided accidental sterilization through the use of clear communication and teach-back.

Magda, a young, non-English-speaking woman, arrived at the holding room for a tubal ligation, which permanently prevents pregnancy. Just to confirm Magda's understanding, the surgeon asked the teach-back question, "What are you having done today?" Magda replied through a medical interpreter that she was having her tubes tied and that 5 years later, when she decided to start her family, she would return to have the tubes untied. The surgeon explained that the procedure was permanent and that there would be no possibility of future pregnancies. With this information, Magda decided not to have the procedure. Without the teach-back and the use of a skilled, certified interpreter, Magda would have likely undergone the procedure and 5 years later would have discovered that it was not reversible.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Slide 30/Compliance and Enforcement

Before you finalize your policy, check with your legal, quality, and safety teams to make sure it complies with Federal, State, and local laws; regulations, such as Medicare and Medicaid rules; as well as accreditation standards.

A last part of your policy should offer a point of contact at the hospital who has overall responsibility for enforcement of the policy. The point of contact should have a clear process for referring complaints for quality improvement or disciplinary action, as appropriate.

Select the button for an example policy from the fictional hospital, Wellness Hospital.

Here is an example:

Questions, Concerns, or Complaints:

Everyone at Wellness Hospital is responsible for following this informed consent policy. If you have questions or concerns, or to report that this policy is not being followed, please call 1.800.xxx.xxxx or visit informedconsent.wellnesshospital.net.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Slide 31/Periodic Review of Informed Consent Policy

All informed consent policies should be periodically reviewed and updated. So, as part of keeping your policy current, you should establish a time frame for periodic review. Designate specific hospital leaders to be responsible for conducting the review. Note in or on the policy document the date when it was last updated, to help ensure that policies are kept current.

Select the button for an example policy from the fictional hospital, Wellness Hospital.

For example, Wellness Hospital's Informed Consent Policy states that the policy shall be reviewed and updated at least every 2 years by the Patient Safety Officer, the Director of Risk Management, and others appointed by the Directors of Quality and Patient Experience. Wellness Hospital also lists the effective date of its informed consent policy at the top of the policy document.

The policy should be evaluated in light of new legal or ethical doctrines, new evidence that changes which procedures are considered risky, and hospital experiences that suggest the policy should be clarified or changed.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Slide 32/Disseminating the Hospital's Policy on Informed Consent

To ensure that your hospital's policy is implemented, both patients and clinicians should be aware of patients' rights with regard to informed consent.

Consider several modes of dissemination to inform patients and clinicians about patients' rights. Common modes of dissemination include posting the informed consent policy on your hospital's Web site, placing posters on walls, and training clinicians and staff members both during orientation and in-service training. Plain-language brochures in multiple languages can be distributed to patients upon admission. The policy can also be disseminated through any patient- and family-centered care networks or online patient social networks your hospital may have.

Take a moment to review the Policy Worksheet in the Resources section to evaluate your hospital's current policy.

Select the Resources button to learn more.

In the Resources section of the course, you will find general and legal references to help you craft your informed consent policy and examples of brochures informing patients of their rights.

Slide 33/Section 3: Building Systems to Improve the Informed Consent Process

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 and patient education materials;
- Removing communication barriers, by:
 - Providing language assistance, such as qualified medical interpreters, and
 - Stocking assistive communication devices;
- Establishing efficient workflows; and
- Training staff at all levels.

As each supportive system is discussed, please review what systems your hospital has and how they could be improved. To do this, open the accompanying Informed Consent Systems Worksheet and complete it as we cover each item in the course. It is available here and in the Resources area of this course. You may print a copy or open it in another window as you will work on it throughout this section.

Select the button to open the Informed Consent Systems Worksheet.

Slide 34/Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms

The first system support that we will talk about is compiling a library of clear and simple informed consent forms. This library should include forms for all the tests, treatments, and procedures that require a signed consent form according to your hospital's informed consent policy.

In addition to serving as documentation, a well-designed informed consent form creates a roadmap for the informed consent discussion. Clear and simple forms help physicians, independent nurse practitioners or independent physician assistants to structure their informed consent discussion and give simple ways of explaining complex concepts.

You will also want to provide forms in the languages commonly spoken by your patients. Make sure to use professional translators. Untrained translators are more likely to make mistakes, which can expose your hospital to liability.

To maximize reading ease and comprehension, forms should follow health literacy principles. These principles include:

- writing in plain language and avoiding medical and technical terms,
- sequencing information logically, and
- breaking the information into chunks with informative headings.

Layout also matters—lots of white space, large easy-to-read fonts, and short line lengths all contribute to readability.

Remember: a signature on a form that the patient does not understand does not serve its purpose, which is to document the patient’s understanding from the informed consent discussion, nor does it protect you or your hospital from liability.

You may be asking yourself, “What does an informed consent that follows health literacy principles look like?” To view an example of how a form can be improved to be reader friendly and easy to understand, select both the Before and After buttons. The Before button displays an original form, and the After button shows the improved form.

A “Before” example from the Iowa Health system is shown that is a document with a high amount of text and readability score of over 16. The text is tightly packed in the document and the words are therefore hard to read.

An “After” example from the Iowa Health system is shown with a document that is easier to read and understand, with a readability score of 7-8.

Slide 35/Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)

To build a library of informed consent forms, you can either use or customize a pre-packaged library, or develop your own consent forms. Regardless of where the forms come from, the key to making sure forms are understandable to your patients is to test them. Check the understanding of both English and translated forms with a diverse group of patients, including patients who are elderly, come from other cultures, or have limited education or vision.

Select both images for additional information.

Select the Resource button to learn more.

Pre-packaged solutions include free online databases of informed consent forms, such as Queensland Health’s online database. A link to this database is provided in the Resources section of this module. There are also commercial products that are available for a fee, and some products are designed to be integrated with electronic health records. Be sure to assess pre-packaged solutions both before and after implementing them, to make sure that the solutions meet the needs of your clinicians and patients. You may be able to build on an existing library of forms and modify or customize those forms to meet your hospital’s needs.

If you are creating your own informed consent forms, you should make sure that your forms follow the health literacy principles that we just discussed. In addition to consulting plain-language writing guides, try to enlist the help of health literacy experts. Be prepared to educate

and collaborate with your hospital's legal counsel or risk managers, or both, to produce clear and simple forms that meet everyone's needs.

It is also important to involve clinicians in the development of forms. That way the forms can be structured to match the flow of the informed consent discussion, and you will get buy-in from clinicians for the new forms.

It is also important to get input from diverse patients and families. Patient and Family Advisory Councils can help identify what is hard to understand and what information patients want to know.

Before you roll out your new forms to the entire hospital, pilot-test them with a few clinicians or in a few units. Get feedback from patients, families, and clinicians, and revise the forms accordingly. Finally, make sure to update your forms on a regular basis. You should modify the forms in your library as you learn of new treatment options or if the expected outcomes or risks change.

In the Resources section of this course, you will find:

- A link to a free online database of consent forms.
- Links to plain language tips and tools that can help you write clearer consent forms.
- A guidebook and toolkit to help you improve your hospital's organizational health literacy.

Slide 36/Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)

Select the image of Mary Ann Abrams to learn how the Iowa Health System developed reader-friendly informed consent forms.

When Iowa Health System leaders noticed that their surgical informed consent forms were complex and hard to read, the leaders worked with clinicians, health literacy experts, and new readers to make their consent forms more reader-friendly. The new forms use simpler language, encourage discussion, and promote teach-back by leaving space for patients to write in what procedure they have agreed to. As a result, an increased number of patients read the form before their procedure; a higher proportion of patients were able to describe the procedure in their own words; patients felt more comfortable asking questions; and patients, families, and nurses reported higher levels of satisfaction with the enhanced form.

In the Resources section of this course, you will find a reference that describes in greater detail this experiment and its results.

Now, it is time to evaluate your hospital's library of informed consent forms and identify areas that need improvement. Take a moment to review the Systems Worksheet in the Resource section to evaluate your hospital's current systems.

Slide 37/Supportive System #2: Maintain a Library of High-Quality Decision Aids and Patient Education Materials

The second supportive strategy is maintaining a library of high-quality decision aids and patient education materials.

While plain-language forms for informed consent can help patients to understand what they are consenting to, many patients need additional help to make an informed choice. Maintaining a library of high-quality decision aids and other educational materials for common tests, treatments, and procedures provides another system to support clinical staff in improving the informed consent process.

A decision aid presents options in an unbiased way to patients so that they can make an informed choice. Decision aids provide information about expected outcomes for each option, as well as the potential benefits, harms, and risks for each option.

Decision aids can be paper-based, audio-visual, multimedia, Web-based, or interactive. Some decision aids are meant for patients to use on their own, while other decision aids are to be used jointly, with the clinician helping the patient process the information and highlighting important points.

Additional information about high-quality decision aids and patient education material is located in the Resources section.

Slide 38/Supportive System #2: Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)

Clinicians often find that using decision aids helps them structure conversations about choices with patients. Research suggests that using decision aids improves patients' knowledge of the options available to them. Patients who use decision aids also have more accurate expectations of possible benefits, harms, and risks of their options. Most importantly, decision aids help patients clarify what matters most to them, makes them more likely to participate in the decisionmaking process and communicate effectively with their providers, and makes them more likely to reach decisions consistent with their goals and values.

And finally, patients whose decisions are fully informed through the use of decision aids are better able to cope with treatment outcomes and adverse events. An added advantage is that in some States, the use of decision aids can serve as evidence that consent was informed.

It is important to remember that decision aids are NOT a substitute for the informed consent discussion. Decision aids are designed to be part of, rather than a replacement for, the informed consent discussion. For example, after a patient has viewed a decision aid, the clinician can use teach-back to make sure the patient understood the information, personalize the information for that patient, encourage and answer questions, and discuss the information in the context of the patient's goals and values.

Select the Resource button to learn more.

In the Resources section of this course, you will find:

- Citations providing evidence on the benefits of decision aids.
- Links to online databases of decision aids.
- Resources to evaluate the quality of decision aids and patient education materials.

Slide 39/Supportive System #2: Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)

Other patient education materials can also help patients to understand and remember information their clinician shares about their conditions and the available options for tests, treatments, or procedures. Unlike decision aids, these materials do not provide comparisons of the options or facilitate decisionmaking. But high-quality decision aids are not always available, and some patients may find single-subject materials easier to absorb.

- Some high-quality decision aids and patient education materials are available for free from reputable sources on the Internet.
- There are also commercial databases of decision aids and patient education materials, some of which can be integrated with your electronic health records.
- Creating your own decision aids and patient education materials is an ambitious undertaking, but some hospitals and health care systems have chosen this path. Follow the suggestions made for creating clear and simple informed consent forms, and be sure to test decision aids with a sample of diverse groups of patients.

Additional information about high-quality decision aids and patient education materials is located in the Resources section in the “Listing of All Resources for Leaders Module” document.

There is an image that links out to the following Web site:

<https://www.effectivehealthcare.ahrq.gov/ehc/decisionaids/osteoporosis/>

Slide 40/Supportive System #2: Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)

There are a lot of decision aids available. Not all of them are high quality. How do you think you might evaluate whether a decision aid is high quality?

Here are some questions to consider when you assess the quality of decision aids:

- Is the organization that made the decision aid experienced in making decision aids?
- Was the decision aid properly tested?
- Is the organization that made the aid free of vested interests in the options presented?
- Does the decision aid include all feasible options and their benefits, harms, and risks, including the option of no treatment?
- Is it based on up-to-date scientific evidence?
- Is there a balanced and unbiased discussion of the options? Decision aids should not steer patients toward a particular choice.

- Is the decision aid easy to understand? Does it use health literacy strategies that were discussed when we talked about clear informed consent forms? If the aid uses audio or video, do the speakers use a moderate pace and speak distinctly? Is the aid available in the languages commonly spoken by your patients?

Finally, a high-quality decision aid will help patients be clear about what matters the most to them and then factor those goals and values into their decisions.

To help you assess and select decision aids, see the standards developed by the International Patient Decision Aid Standards Collaboration and their “Criteria for Judging the Quality of Patient Decision Aids” document; this document and a link to the standards is located in the Resources section of this module.

Once you have identified high-quality decision aids, you still need to check whether they work well for your clinicians or patient population. You may want to pilot-test a decision aid with a small group before making it available hospital-wide. Obtain feedback from both clinicians and a diverse range of patients about how useful and practical a decision aid is.

Slide 41/Supportive System #2: Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)

Someone on your staff will need to maintain your library of decision aids and patient education materials.

You also need to make sure that the decision aids reflect the most up-to-date clinical information. Set up a regular timetable to review materials in your library.

Materials that are too difficult to understand or use or that are no longer accurate should be removed from the library.

Furthermore, new decision aids and patient education materials are being developed all the time, so you should establish a process to scan for, assess, and adopt new materials. You should determine the best way to notify staff about changes to the library and to encourage its use, in order to improve the informed consent process.

Take a moment to review the Systems Worksheet in the Resources section to evaluate your hospital’s current systems.

Slide 42/Supportive System #3: Remove Communication Barriers

The next support strategy that can be used to improve the informed consent process is removing communication barriers. One of the common communication challenges faced by patients is language barriers. Patients with limited English proficiency are at greater risk of not understanding what is in the informed consent forms that they have signed. Hospitals need to develop a language assistance plan to address the needs of patients with limited English proficiency. While developing an entire language access plan is beyond the scope of this course, we will discuss a few of the highlights.

In the Resources section, you will find a Health Care Language Services Implementation Guide that can take you through all the steps for meeting the needs of your patients with limited English proficiency.

If your hospital participates in Medicare or Medicaid, you are required to take reasonable steps to ensure that you are providing equal access to patients with limited English proficiency. Failure to provide language assistance is risky for patients and can serve as the basis for lawsuits.

Select each image for an example of a language barrier.

The family received a \$200,000 settlement from the physician and hospital, and the medical malpractice insurance carrier paid legal fees of \$140,000.

Take, for example, the Tran case. A 9-year-old Vietnamese girl died from a reaction to the drug Reglan. Her parents primarily spoke Vietnamese, yet no competent interpreter was used throughout the girl's encounters with the medical system. Instead, the 9-year-old patient and her 16-year-old brother served as interpreters. Without an interpreter present, the physician could not adequately inform the parents about Reglan's side effects or warnings, or that it was not indicated for pediatric use. The parents also did not understand the physician's instructions to bring their daughter back to the emergency room if side effects arose.

Let's look at one more case. Dai is a young agricultural worker who speaks only Mandarin. He arrived at the hospital with a badly injured arm. The hospital wanted to perform an invasive diagnostic test and gave Dai a poorly translated consent form to sign. Dai signed it, because he thought that if he did not sign, he would not be given a pain reliever.

The Resources section of this course includes references containing evidence to help you make the case and plan for addressing communication barriers in your hospital.

Slide 43/Supportive System #3: Remove Communication Barriers (Continued)

To address your patients' language assistance needs, you will need a system to identify the languages spoken by your patients. As part of this system, all patients should be informed of their rights to a free interpreter, and patients should be asked in which language they would prefer to receive care. These questions can be asked during registration, when scheduling an appointment, upon admission to the hospital, or at all three times. If the patient cannot understand the questions, your hospital can use "I speak" cards or touch-screen registration menus allowing patients to point to their language. In addition, some over-the-phone interpretation services can help to identify the patients' preferred language.

It is very important to remember this caution: never let hospital staff members use patients' friends or family members for interpretation, especially minor children. It is not safe for patients, and could cost your hospital millions in malpractice lawsuits.

There are several options for providing high-quality language assistance to your patients who have LEP.

Select each button to learn more.

One option is to have bilingual staff members provide care in the patient's language. You should establish a system to test and certify that staff members have proficient language skills. Make it clear that clinicians with basic or intermediate language skills should not try to "get by" without an interpreter.

Bilingual staff members can serve as interpreters, but without more training they are more likely to make clinically significant errors than are trained interpreters. If any of your bilingual staff members would like serve as interpreters for other staff members, the bilingual staff members should complete a medical interpreter training course and become certified. Some hospitals have their own interpreter certification system. There are also two national certification systems for medical interpreters in the United States, which are listed in the Resources section of this course. If you use bilingual staff members to interpret for other staff members, consider relieving the bilingual staff from some of their other job demands so they will have time and energy for interpreting.

Hire qualified medical interpreters. If you have a concentration of patients who speak a particular language, you may wish to hire qualified medical interpreters directly. For infrequently spoken languages, language banks and telephone or video medical interpreters are probably your best bet.

Slide 44/Supportive System #3: Remove Communication Barriers (Continued)

Once you have identified your patient language needs, you will need to plan how to meet them.

- In many hospitals, coordinating interpreter services is a full-time job for at least one person. Make sure that your Interpreter Services Coordinator has the resources needed to mobilize qualified interpreters.
- You will also need to train staff members on when and how to request an interpreter. Additionally, training staff members to work with an interpreter as part of a team can increase efficiency and safety.
- If you are using telephone and video interpreting, make sure that you have the equipment you will need readily available. For example, rooms where informed consent discussions take place with telephone interpreters should have telephone or cable jacks or wireless connections, with access to dual-handset or speaker telephones. Similarly, video interpretation requires video conferencing equipment and connections.
- Consider keeping on hand assistive devices for persons with partial hearing loss or vision loss. Such devices include sound amplification devices and magnifying readers. You will need someone to keep an inventory of the devices, make sure the devices are in good working order, and purchase replacements as needed. You will also need places to store the devices where they will be easy to access, and you should notify clinicians about their availability.

The Resources section of this module provides links to several useful trainings.

Now, it is time to evaluate your hospital's language assistance systems.

Take a moment and record your answers on your worksheet before continuing with the course.

Slide 45/Supportive System #4: Improving Workflows

Improving workflows is our fourth supportive strategy.

A workflow map or flowchart can help to clarify and improve the informed consent process. A high-level flowchart can be developed as part of the hospital's informed consent policy to outline the major steps in the informed consent process. Detailed flowcharts can be developed at the unit level to clarify how the process steps fit together and who is responsible for what.

Developing a flowchart is most beneficial when you do it as a group exercise with the people who are involved in the process such as physicians, independent nurse practitioners or independent physician assistants and nurses. First step is to observe the process and to develop your initial flowchart, map the process as it is, not as you think it should be. This mapping will help you to see what needs to be improved. Once you have a flowchart developed, observe the process again and check that the flowchart matches what actually happens; edit the flowchart until it matches what actually happens. Once you've done this, you can work with your diverse clinical team to improve the workflow.

Select the flowchart for a larger view.

The Resources section of this course includes further details on improving workflows.

This outlines a flow chart of the informed consent work flow. The first action is a history and diagnosis, which flows to identify options or develop recommendations or plans. The next asks if explicit consent is needed. If no, the provider notes why explicit consent is not needed. If yes, the provider explains options including what's involved in the treatment, risks, benefits, alternative treatments, and the discussion also includes the option of doing nothing. This flows into a teach-back exercise in which the clinician encourages questions. If the patient understands the treatment, benefits, and risks, the provider determines if they are ready to decide on which option. If the patient doesn't understand treatment benefits and risks, the provider will again explain options. If the patient is ready to decide on options after hearing their options, the provider confirms and documents the discussion. If they are not ready to decide, the provider allows for additional time and provides additional information and resources. The provider will then after some time inquire with the patient if they are ready to decide.

Slide Slide 46/Supportive System #4: Improving Workflows (Continued)

Flowcharts can clarify not only the steps in the process, but also how every team member fits into the process.

If you are a unit lead, consider leading your team through a process map exercise to clarify and improve your workflow for informed consent. This exercise can extend over two team meetings.

Include all people involved in the informed consent process, plus at least one person who is not involved in the process, who can ask questions to clarify the process, and a neutral facilitator who can guide participants through the exercise. Ideally, a patient advocate should be included to ensure that the process is patient-centered.

At the first team meeting, have each person map the part of the process for which they are responsible, and then connect that piece of the diagram to the pieces of other team members.

Use squares to show process steps, diamonds to show decision points, and ovals to mark start and end steps. Arrows connect the steps.

Remember to map the process as it is, not as you think it should be.

Between meetings, observe the informed consent process in your unit; correct the current process map, if needed, to reflect actual practice.

Then, bring your team back together for a second meeting, review the process map, and work together to design a better workflow.

Slide 47/Supportive System #4: Improving Workflows (Continued)

The Joint Commission's Standards Interpretation Group receives many questions each year from hospital staff expressing confusion about who should be responsible for what in the informed consent process. Key questions that can help you improve the workflow of your informed consent process fall into three categories: the big picture, efficiency, and workforce. Select each of the images for additional information then take a moment to review the Systems Worksheet in the Resources section to evaluate your hospital's current systems.

To learn more about the big picture, ask:

- Is the process in line with the hospital's informed consent policy?
- Does the process guard against errors?
- Can we improve the patient experience with this process?
- Are all the critical steps included?
- To learn more about efficiency, ask:
 - Are all steps necessary? Are some duplicative?
 - Is there a more logical way to sequence the steps?
 - Can some steps be performed simultaneously?
 - Is there any technology that would make this process more efficient or easier to perform?
 - Can we learn from other units that have a great informed consent workflow?
- To learn more about the workforce, ask:
 - What skills are necessary to perform each step?
 - Are there any places where it is unclear who is responsible for a particular step?
 - Is each step performed by someone with the right skills?

- Can any of the steps be performed by someone with fewer skills? What training would they need?

Slide 48/Supportive System #5: Address Staff Training Needs

The fifth supportive strategy is addressing staff training needs.

To be successful, hospital staff members at all levels will have to be trained for their roles in the informed consent process.

Everyone from the highest level of management to the administrative staff in the registration offices can benefit from training on the principles of informed consent and hospital policy.

Hospital leaders should take this entire training so they know how to develop the supportive systems needed to make informed consent an informed choice.

Certain skills, such as how best to offer choices and explain the benefits, harms, and risks of all options, are only critical for the clinicians who have the main responsibility for informed consent. But other hospital staff members everyone who interacts with patients, including interpreters can benefit from training in many of the other strategies for clear communication and presenting options. The course you are now taking has a companion course for health care professionals that covers all of those topics.

Additionally, more in-depth training will be required on your hospital's policies, and how to access the resources that you have put in place to support the policies.

The accompanying table shows which training topics are necessary and appropriate for the hospital staff.

Select the chart for a detailed list of training topics and groups to train.

The Resources section of this module provides links to several useful training sessions.

Slide 49/Supportive System #5: Address Staff Training Needs (Continued)

As part of the rollout of your informed consent improvement initiative, you will probably need to use multiple avenues to train staff members.

In-service training can take various forms, such as stand-alone training and Grand Rounds. Think about how the strategies to make informed consent an informed choice can fit into other training you sponsor, such as training on patient safety or patient-centered care, or diversity and anti-discrimination training.

Think creatively. Could a lunchtime session be devoted to building skills, or could informed choice be on the agenda of a departmental or unit meeting? Don't forget to make sure that new staff members also receive the training as part of their orientation.

If your hospital is a teaching hospital, be sure that you train your residents in the hospital's informed consent policy.

In addition, new behaviors can be reinforced through coaching activities such as being a role model for new behaviors, motivating team members to implement the new behaviors, observing performance and providing feedback, and providing opportunities to practice and improve performance.

Now, it is time to evaluate your hospital's informed consent training program.

Take a moment to review the Systems Worksheet in the Resources section to evaluate your hospital's current systems.

Slide 50/Course Summary

Before you go, let us quickly recap the course. We have learned that:

The informed consent process presents multiple challenges. A good process of informed consent goes beyond ethical and legal principles to help patients make an informed choice. To begin to improve the informed consent process, a hospital must:

- Develop, disseminate, and periodically review a clear and detailed policy on informed consent and effective patient communication policies; and
- Provide structure and support to persons in charge of improving the informed consent process.

Improving informed consent will require concerted organization-wide action. The Resources section includes:

- A guide to leading change and developing and implementing an action plan.
- A guidebook to achieving organizational change.
- Other resources related to organizational change to improve the informed consent process.

What will be your next steps to make informed consent an informed choice in your hospital? Please take one last moment as part of this training to note your next steps in your worksheet.

THANK YOU for taking the time to work through this training module for health care leaders on making informed consent an informed choice.

Slide 51/Conclusion

Congratulations!

You have now completed AHRQ's Making Informed Consent an Informed Choice: Training for Health Care Leaders.

To qualify for continuing education credits, please complete the post-training quiz and the course evaluation survey.

You can access the quiz, the course evaluation and resources section using the links in the top left portion of your screen.

Please click “refresh” in the menu on the left to activate the post-training quiz and course evaluation links.

If you have any questions about what you have learned in this course, please email us at HealthLiteracy@AHRQ.HHS.GOV.