

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

Slide 1/Welcome

Welcome to:

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

- 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 physicians, nurse practitioners, physician assistants, nurses, and other clinical staff.

Although this module talks directly to the clinician responsible for obtaining informed consent, it is important that everyone on the team understands the process and be able to make sure it unfolds as planned. The topic of Informed Consent Team Roles and Responsibilities is addressed in greater detail toward the end of this course.

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:

1. Describe the principles of informed consent.
2. Describe strategies for clear communication about choices during the informed consent process.
3. Describe strategies for presenting choices, such as showing structured decision aids and encouraging questions.
4. Describe appropriate ways to document and confirm informed consent, and to work as part of a team.

Slide 6/Course Content

This information in this course is organized into 4 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.

Informed consent requires clear communication about choices, so in Sections 2 and 3 of this course, we will discuss strategies for clear communication and presenting choices. When you have completed those sections, you will have learned 10 strategies to make informed consent an informed choice.

Strategies for clear communication include preparing for the informed consent discussion, using health literacy universal precautions, removing language barriers, and using teach-back.

Strategies for presenting choices include offering choices; engaging patients, families, and friends; eliciting the patient's goals and values; showing high-quality decision aids; explaining the benefits, harms, and risks of all options; and helping patients to think through their options and choose.

Finally, in Section 4, we will talk about how to confirm and document informed consent, and what roles various healthcare team members can play in 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/Section 1: Principles of Informed Consent

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.

There is a video of Toni Cordell showing her story that outlines the following:

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 10/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 11/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 12/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.

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.

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

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 13/When to Consult an Authorized Representative

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

On screen is a picture of Cecile. She recounted this story. Cecile says: "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 14/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 15/Section 2. Strategies for Clear Communication

Section 2: Strategies for Clear Communication

The second section of this course describes four strategies for ensuring clear communication during the informed consent process.

The first strategy is to prepare for the informed consent discussion by gathering all the information you will need and giving some thought to the way you will organize the discussion.

The second strategy is to use health literacy universal precautions, such as using plain language with all patients.

The third strategy is to identify and remove language barriers that arise when patients have limited English proficiency, including those patients with hearing impairments.

The fourth strategy is to use teach-back to make sure you have explained the choices in a way that patients and their families and friends have understood.

Slide 16/Strategy 1: Prepare for the Informed Consent Discussion

The first strategy is to prepare for the informed consent discussion. To get ready, you will need to attend to several details.

Make sure that you have the results of any relevant diagnostic tests available. When possible, share easy-to-understand results with your patients ahead of time.

Ask your patients whether there are people whose opinions are important to them, or whose support they would like to have during the discussion. If other people are expected, plan to hold the discussion in a room that is large enough to include everyone comfortably.

The space should also be private enough so that others outside the space will not overhear confidential information about the patient.

Scheduling is important, as well. Schedule a time when everyone who should be there can attend.

Think about whether it is the right time to have an informed consent discussion. A patient who has just been told a diagnosis may not be ready to talk about the treatment options. Similarly, if your patient is impaired by alcohol, medicines, or anxiety, and if immediate treatment is not required, you should wait until your patient is better able to hear the choices.

Consider how long the discussion is likely to take, and plan enough time for the discussion. Think about whether you might need more than one discussion session.

Select the image to learn how one clinician handled the situation when a discussion went longer than anticipated.

Tanya: My husband and I were close to reaching a decision with my husband's doctor about a procedure she would perform the following week. The doctor thought we were done and was making for the door. But I still had lots of questions. So I said, "Look, I know that this is a routine procedure for you. But it isn't for us. We have questions that we'd like to get answered before we proceed." She looked uncomfortably at the door, and I knew she was thinking of the patients in her waiting room. She said, "I'll tell you what. I've got two more patients to see. If you can wait, I'll come back and we can talk more." So we waited for half an hour. Then true to her word, she came back and answered all our questions.

Slide 17/Strategy 1: Prepare for the Informed Consent Discussion (Continued)

Informed consent requires good communication between clinicians and patients, but effective communication can be a challenge for both. Many factors can contribute to the challenges.

During the informed consent discussion, patients are rarely at their best. They may be feeling ill, scared, or stressed. They may feel intimidated by people in white coats. They may not be able to hear everything you are saying, instead tending to focus on the negative aspects of the choices you are presenting—the harms and risks—without giving equal weight to the benefits.

Language can also be a barrier. As clinicians, we often use medical terms that most patients will not understand. Even when we use simple language, sometimes the concepts are difficult to understand. For example, many Americans have trouble understanding numerical expressions of risk.

Patients who are not proficient in English face additional language barriers. According to the U.S. Census, almost 9% of the U.S. population has limited English proficiency. If you are not certified as being proficient in your patient's preferred language, then there is a language barrier between you. Translated forms alone cannot remove that barrier, because not all patients can read the language that they speak, and a form alone cannot take the place of an informed consent conversation. There also may be cultural differences between you and your patient. Without realizing it, you may be talking past each other.

Some patients face additional challenges, such as limited health literacy. More than a third of U.S. adults—77 million people—are estimated to have difficulty with common health tasks, such as following directions on a prescription drug label or understanding a chart showing a childhood immunization schedule. These patients often hide their difficulties with reading or understanding. And because they come from every walk of life, you cannot anticipate these difficulties from their appearance.

Being deaf or hard of hearing is another communication barrier. Vision impairments can also make it difficult or impossible for patients to read consent forms.

Learning style matters, as well. Visual learners learn best from written materials and pictures, auditory learners learn best when they hear an explanation, and kinesthetic learners learn best when they can touch or experience something related to what is being said.

Patients with cognitive impairment or intellectual disabilities often have the capacity for decisionmaking and should not automatically be treated as incompetent.

The final challenge is the time pressure we all face. While we would all like to be generous with our time, the truth is that spending more time than scheduled with one patient often means that you may have to short-change another patient. Fortunately, with practice you can learn to remove communication barriers efficiently.

Slide 18/Strategy 2: Use Health Literacy Universal Precautions

Many communication barriers can be removed by our second strategy, adopting “health literacy universal precautions.” These are techniques to communicate clearly with and check understanding for every patient or family member involved, because everyone, no matter how well educated, is at risk of misunderstanding sometimes.

Clinicians often use medical jargon without even realizing it. It is how we were trained to speak. But your patients will not follow what you’re saying if you use unfamiliar terms. Try to use language that you would use while talking to your uncle in your living room. The simpler the words, the better. Do not worry that your patients will feel insulted, as if you are talking down to them. No matter how well educated, everyone appreciates clear and simple explanations.

Speaking slowly is another important aspect of health literacy universal precautions. Your patients’ processing speed may decrease because they feel unwell or are afraid, or because of cognitive impairments or intellectual disabilities. Even under the best of circumstances, the new concepts that you are introducing may sound like a torrent of words unless you make an effort to slow down and speak at a comfortable pace. And for patients who can only handle a little bit of information at a time, you may need to break up the conversation into several sessions.

In addition to explaining the information, you should use visuals to help get your point across. Visuals can be as simple as a picture that you draw. Use clear and uncluttered illustrations. Think about whether there is anything you can let patients touch or experience, such as a computer touch-screen, a 3-D model of the body parts you’re talking about, a piece of equipment that will be used for their procedure, or a brief tour of the operating room in settings where that is practical.

Repeating key points gives your patient a second chance to take in important information. Be as specific and concrete as you can be to reinforce the information that you have shared.

Some patients may be hard of hearing but usually get by without a hearing aid. Because you want your patients to hear every word of the informed consent discussion, you should politely offer assistive listening devices to all patients you suspect may have hearing difficulties. You may also try to find a quieter space for the informed consent discussion, and be sure to face the patient when you talk.

Similarly, for patients with low vision, you can offer magnifying readers, make sure that the lighting is strong enough for the patient to read, and offer to read forms aloud.

Lastly, check that your patient understands. Teach-back is a useful technique that we will discuss in more detail a little later in this course.

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

- The AHRQ Health Literacy Universal Precautions Toolkit,
- A paper on the attributes of a health literate organization,
- CDC resource “Everyday Words for Public Health Communication,” and
- A list of medical terms and their everyday substitutes.

Slide 19/Strategy 3: Remove Language Barriers

Our third strategy to ensure clear communication is to remove language barriers. Your hospital probably has a policy that guides communicating with patients with limited English proficiency, including those patients who use sign language instead of English.

Make sure that you are familiar with your hospital’s policies. Remember, failure to use interpreters is risky for patients and can also serve as the basis for lawsuits!

Select each image to hear their stories regarding language barriers.

The first image is that of Gayle Tang. Gayle’s story is the following:

I am bilingual in English and Cantonese, a Chinese dialect. I was the principal architect in the design and implementation of language access programs, including trainings for health care interpreters and bilingual staff. But when I was faced with a health condition, I lost my English. In a time of stress, I reverted back to my primary language, Chinese. It wasn’t until I was able to speak to a doctor in Cantonese that I felt relieved, reassured, and cared for.

Dai is the second story and is the following:

Dai is a young agricultural worker who speaks only Vietnamese. 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.

In the Resources section of this course, you will find additional information on why, when, and how to use a medical interpreter.

Slide 20/Strategy 3: Remove Language Barriers (Continued)

Here are some important do and don’t guidelines to follow when communicating with patients with limited English proficiency and regarding interpreters.

- Do explain that it is the hospital's policy to use qualified medical interpreters and not to use family members or friends.
- Do let patients know that they can get an interpreter for free. Do not ask the patient if they brought someone who can interpret for them.
- Do face the patient, not the interpreter, when talking and listening to the patient.
- Do brief the interpreter on the patient's situation, and ask the interpreter to let you know if anything is unclear.
- Do offer video sign language interpreters if a qualified in-person interpreter is not available. Do not offer paper and pen to patients who are deaf or hard of hearing so they can communicate with you.
- Don't ask the interpreter to obtain consent for you.
- Don't speak rapidly without a pause or ask the interpreter not to interrupt you. Interrupting is OK if patient understanding is at risk.
- Don't use your foreign language skills to conduct the discussion, even if you speak that patient's language well.
- Don't have forms on hand that have been translated by bilingual staff members.
- Don't expect patients to read and understand a translated form on their own.
- Do not defer to the patient's wishes that friends or family members interpret for you.

Select each guideline for more information.

Be sensitive to the fact that a patient's language skills can diminish under stress, so even if he or she has spoken English well in the past, you may still need a qualified medical interpreter for the informed consent discussion.

Using unqualified interpreters—especially minor children—is risky for both patients and clinicians.

Also, if your hospital receives any Federal funding, including Medicare and Medicaid payments, your patients must be offered the option of having a qualified medical interpreter. You will not know whether patients want an interpreter unless you ask them. Furthermore, some patients may say their English is fine when you are having difficulty understanding them, and you believe they are having difficulty understanding you, as well. If you have any doubt as to whether your patient's English is really proficient, call in a qualified interpreter. It is your responsibility to make sure that you and your patient understand each other. And be sure to note your patient's preferred language and need for interpreter services in his or her chart, so that others will know as well to call for an interpreter.

Patients with limited English proficiency may refuse interpreters because they think they will have to pay for it. Let your patients know that interpreters are available at no cost to them.

You should always look at your patient when you are talking and when your patient is talking, not at the interpreter. Direct your empathy and response in English toward the patient. The qualified medical interpreter will provide the verbal translation of your words. However, you should still engage in nonverbal communication. Explore whether training on working with interpreters is available in your area.

This video shows a physician briefing her interpreter. First few seconds of video:

<http://www.ahrq.gov/teamstepps/lep/videos/briefing/index.html>

Video remote interpreting (VRI) has been used to comply with the Americans with Disabilities Act's requirement to ensure effective communication with deaf persons. A patient who is deaf or hard of hearing may, however, decide that VRI does not provide effective communication and may refuse to use it.

Keep in mind that writing does not lend itself well to interactive communication. Furthermore, the average reading level of deaf high school graduates in the United States is roughly at the fourth-grade level. Always offer a qualified interpreter to patients who are deaf or hard of hearing. Call for a qualified interpreter if you have any difficulty understanding the patient's speech. Chances are that the patient is having difficulty understanding you, as well.

Additional information on how to communicate with patients who are deaf or hard of hearing is located in the Resources section.

Do not catch yourself saying, "Could you please consent this patient for me?" It is your job to have the informed consent discussion with your patient. Never ask an interpreter to do that for you.

Interpreters are more likely to make errors if you speak very rapidly and cover lots of information without a pause to allow for interpretation. Take it slow, and break down the information into manageable chunks.

If you try to speak a language other than English, you must be able to speak it VERY well and you must be certified to practice medicine in that language. Do not try to "get by" in another language if you are not proficient in that language.

It is best to use informed consent forms that have been professionally translated into languages commonly spoken by patients. But if you do not have a translated form, ask a qualified interpreter to "sight translate"—that is, read the form out loud in the patient's language. Forms can be designed to leave room for interpreters to write down their sight translations. Do not ask a patient to sign a form in English that they cannot read and that has not been translated by a qualified translator.

Just like English-proficient patients, not all patients with limited English proficiency can read in their preferred language. Do not rely on their being able to learn what they need to know about their choices from a form. Whether patients are literate or not literate, remember this: a form does not take the place of an informed consent discussion.

The patient has a right to have a friend or family member interpret for them. But you also have the right to use an interpreter of your choice—a qualified medical interpreter. So instead of deferring to a patient's wish that friends or family members interpret, have both interpreters in the room during the informed consent discussion.

Slide 21/Strategy 4: Use Teach-Back

Our fourth strategy is to use teach-back, a method for confirming that you explained things clearly. You do that by asking them to tell you—in their own words—the important information you've shared with them.

Do not wait until the end of the informed consent discussion to initiate teach-back. Employ the “Chunk and Check” process by which you ask your patient to teach back each chunk of information as you go along. It is very important that patients teach-back in their own words. If they simply parrot the exact words you said, you do not know whether they actually understood the meaning.

Teach-back is not a memory test. Patients can look over the Informed Consent form or other materials you have shared with them as they teach-back. But watch out for verbatim quotes that do not reveal whether your patient understands or does not understand.

If your patient is unable to teach-back correctly, explain again in a different way. Repeating the exact same thing probably will not increase your patient's understanding. Try a new approach by using different words, and then ask your patient to teach-back again in his or her own words.

You need to repeat the teach-back process until your patient can correctly teach all the information back. If your patient cannot demonstrate understanding, then he or she may be unable to give informed consent.

When the patient has correctly taught back everything you wanted to be sure they understood, be sure to document your use of the teach-back and the patient's response in the medical record.

Slide 22/Strategy 4: Use Teach-Back (Continued)

Why use teach-back?

- Evidence shows that teach-back is associated with improved understanding during the informed consent process.
- The National Quality Forum (NQF) named teach-back for informed consent as a patient safety practice in 2003 and again in 2006 and 2010. NQF advises clinicians to:

“Ask each patient or legal surrogate to “teach back,” in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.”

Slide 23/Strategy 4: Use Teach-Back (Continued)

Why do you think teach-back is a widely used technique to check for understanding during the informed consent process?

Think about your answer, and when you are ready, select the Answer button to compare your answer with ours.

Teach-back is a great way to check patient understanding because you are:

- asking patients to explain in their own words what they were told during the informed consent discussion;
- providing a chance for the clinician to check the patient's understanding and reteach information, if needed; and
- checking on clarity, or how well the clinician explained what the patient needs to know. You are not testing the patient.

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

- A link to teach-back training resources and
- A list of articles that demonstrate the benefits of teach-back

Slide 24/Strategy 4: Use Teach-Back (Continued)

There are several tips recommended from the “Always Use Teach-Back Toolkit” that you can use to help use teach-back most effectively.

A link to the Always Use Teach-Back! Toolkit, from which these tips were adapted, can be found in the Resources section.

These tips include the following:

- Use a caring tone of voice and attitude.
- Display comfortable body language and make eye contact.
- Use plain language.
- Emphasize that the responsibility to explain clearly is on you, the clinician.
- Ask your patients to explain back, by using their own words.
- Use non-shaming, open-ended questions.
- Don't ask questions that can be answered with a simple yes or no.
- Use easy-to-understand print materials to support learning.
- If the patient is not able to teach-back correctly, explain in a different way and then recheck.
- Document the use of teach-back and the patient's response to teach-back.

Slide 25/Strategy 4: Use Teach-Back (Continued)

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

Select each image of a health care worker for some examples of teach-back questions and phrases.

“Just to make sure that I explained things well, can you tell me in your own words what will happen if you choose to have this procedure done?”

“It’s my job to explain things clearly. To make sure I did, can you please tell me in your own words what good results you expect from this treatment? How likely do you think it is that you will get those results?”

Is there any downside to this treatment? To prompt the patient further about this, you can say:

- “Do you expect to experience any pain? For how long?”
- “Will you be limited in your activities? For how long?”

“Every treatment has some risks. Can you tell me in your own words about the risks of this procedure?” To prompt the patient further about this, you can say:

- “What about the possible side effects we discussed?”
- “What could go wrong in surgery?”
- “Remember how we talked about allergic reactions?”

“We have talked about some other treatments you could choose. Can you tell me what are some of the pros and cons of these alternative treatments?”

“What if you choose not to get any treatment? Can you tell me in your own words what might happen?”

Slide 26/Strategy 4: Use Teach-Back (Continued)

Here are some frequently asked questions about teach-back.

Select each question to view the answer.

Question: Why do teach-back for every patient? Why not just do it for patients with limited health literacy?

Answer: All patients making medical decisions are at risk of misunderstanding and can benefit from teach-back. More than one-third of the U.S. population is estimated to have limited health literacy. Even people with proficient health literacy are at risk of misunderstanding when they are sick, stressed, or scared.

Question: Won’t teach-back take too much time?

Answer: A randomized controlled trial on elective surgery by Fink and colleagues showed that teach-back improved patient understanding and took an average of 4 minutes. Another study by Schillinger and colleagues suggested that patient visits with teach-back took no longer than those visits without teach-back. In addition, teach-back can save time and money by reducing cancelled or delayed surgeries.

Question: Won’t patients be annoyed when they are asked to do a teach-back?

Answer: Patients may feel insulted if you make the teach-back seem like a test. Let your patient know that you are checking how clear you were by using phrases such as, “just to make sure I explained it well...” before asking your teach-back questions, so that the patient understands it is not a test of his or her abilities.

Question: Isn't teach-back mostly useful for patient discharge and self-management? Why do it for informed consent?

Answer: Teach-back is useful whenever it is important to make sure that patients understand. You have not obtained informed consent if you are not sure that your patient has understood the information presented and the available choices.

Slide 27/Knowledge Check

Can you identify which of the following statements are examples of teach-back?

Remember, teach-back is asking the patient to describe, in his or her own words, what the patient understands from your conversation with him or her.

Examples of teach-back include:

Can you tell me in your own words what will happen if you choose to have this procedure done?

What good results do you expect from this treatment?

Examples that are Not Teach-Back include:

Are you clear about the procedure we discussed?

Do you understand the benefits of this treatment?

Slide 28/Section 3. Strategies for Presenting Choices

Section 3: Strategies for Presenting Choices

In this third section of the course we will describe six strategies for presenting choices. Since we have already described four strategies in Section 2, we will keep track of these new strategies by numbering them from 5 to 10.

Strategy 5 is to offer choices. Patients always have a choice among alternatives, even if that choice is to do nothing.

Strategy 6 is to engage patients and their families and friends by putting them at ease and enhancing their confidence to participate in the informed consent discussion.

Strategy 7 is to ask patients about their goals and values so you can help them understand how well different options might work for them.

Strategy 8 is to select and show high-quality decision aids.

Strategy 9 is to explain the benefits, harms, and risks of all options, not just the option you recommend.

Strategy 10 is to help patients deliberate and choose the option that is the best fit with their goals and values.

Additional tools, factsheets, and references regarding these strategies are located here and in the Resources area of the course.

Slide 29/Strategy 5: Offer Choices

Strategy 5 is to present all the options available and offer choices. It is important that the patient understand that there are always choices, even if the only alternative is to do nothing.

It can be very difficult to offer options when you have a strong opinion on what the best choice is. It may help to keep in mind that what we clinicians think is the best treatment is often colored by what those around us are doing. For example, in your community, most doctors may treat stable angina with angioplasty, while in another community, bypass surgery is the most common treatment. Medical management is the most frequent treatment in yet another community. The fact that practice patterns differ around the country shows that it is not patients' clinical circumstances, or their preferences, that is driving much of medical decisionmaking.

Ultimately, it should be the patient's decision. Their decisions will depend on such things as how much pain they are in, how much activity limitation they have, what they are willing to put up with, how risk-adverse they are, and what their short-term and long-term plans are. What seems best to you may not be the best choice for your patient, depending on his or her goals and values.

Cost may be a consideration for your patient. But do not omit options just because they are not covered by the patient's insurance or would be expensive. You will not be able to tell a patient exactly what the out-of-pocket costs will be, but you may be able to give the patient a sense of the relative costs of alternative treatments. Encourage your patients to consult with their insurance companies to find out what their coverage is and how much the alternatives they are considering will cost them.

You may wish to dispel the idea that you are putting out options because you lack expertise and do not know what to do. You might try saying, "There is good information about the differences between these treatments that I'd like to discuss with you."

Here are two examples of situations where health care workers offered choices to patients as part of obtaining that patient's informed consent.

Select the image of each patient to learn their story.

The first image is of Robert. Robert is an 88-year-old man with advanced prostate cancer. He was responding well to hormone treatment, but his prostate became so large that he developed a blockage. We had to insert a catheter. I increased his dose of doxazosin in the hopes of shrinking his prostate, but after several weeks Robert was still unable to urinate.

In the informed consent discussion, I told Robert and his family about two choices: have surgery to remove part of his prostate or live with a catheter. I thought the surgery would be the best choice, but I knew that Robert was afraid of anesthesia and of getting an infection while at the hospital. We talked through the benefits, harms, and risks of both options. Robert was pleasantly surprised that the surgery is usually done without general anesthetic and was less happy about

the prospect of living with a catheter when he learned it would likely restrict his ping-pong playing. To my surprise, he chose to have the surgery. I think that if I had not gained his trust by being a neutral source of information, Robert might not have been willing to undergo the surgery.

The second image is of Marie. Marie is a 32-year-old patient who reported having heard a “popping” sound and having severe knee pain. An MRI revealed a medium-sized, bucket-handle tear of her meniscus in the red zone. After looking at her test results and condition, I presented 3 options to Marie. She could try home management and physical therapy, she could have her meniscus repaired, or she could have the torn part of her meniscus removed.

I then asked her to watch a decision aid that describes the options and to schedule another visit to discuss them further.

When Marie returned, I explained that her chances for a repair are good, since the tear is not too large and is in an area that has good blood flow to promote healing. I also told her my estimates for recovery times, and checked that she understood the benefits, harms, and risks of the options, including the increased risk of future arthritis with a partial removal of the meniscus.

Marie was in so much pain that she didn’t think she could manage without surgery. Her chief concern was to get back to work quickly, and she was worried about the long period of time she would be rehabilitating her knee after a repair. Despite knowing that she’d be more likely to develop arthritis in that knee than if she had the repair, she decided to have the partial removal of her meniscus. It wouldn’t have been my choice, but she has different priorities.

Slide 30/Strategy 6: Engage Patients, Families, and Friends

Strategy 6 is to engage patients, families, and friends. Research shows that patients who are involved in decisionmaking are more satisfied with their care.

But many patients lack confidence that they can make important decisions about their health. That is why our sixth strategy is engaging patients, their families, and their friends.

Do you know why many patients and their families and friends lack confidence when making decisions about their health?

Think about it and when you are ready, select the Answer button to compare your answer with ours.

There are several reasons why patients may feel at a disadvantage.

First, they don’t have the expert knowledge that the clinician has. The patients may be vulnerable due to the physical and emotional effects of their illnesses, including possible impairment, disability, fatigue, pain, mental stress, etc. They may also be used to clinicians who tell them what to do rather than ask them to join in the decisionmaking. Or they may come from a culture where it’s customary to defer to doctors, and asking a question would be considered rude.

Many people may be involved in informing the patient, but if you are the clinician who is in charge of ordering a test or treatment or performing a procedure, there are some things you have to do yourself.

Your job is to

- Put your patients at ease and show that you respect their values and opinions.
- Draw them into the informed consent discussion and enable them to be active participants in the decisions they are facing.

You can start by acknowledging their expertise.

Patients have unique knowledge about their lives, emotions, culture, social supports, experiences, wants, goals, and more. Listen to them carefully and you will learn a lot. You can let them know that you are listening by asking followup questions.

That way you can find out what specific information they need further clarity on before they can make a decision. For example, you could say: “I hear you’re worried about not being able to walk much this summer. Let’s talk a bit more about what to expect.”

Slide 31/Strategy 6: Engage Patients, Families, and Friends (Continued)

Part of engaging the patient, and their family and friends, includes putting everyone at ease and showing respect. You can start doing this by encouraging your patients to have a trusted family member or friend with them during the informed consent discussion to support them as they get information and make decisions. A patient who is stressed about their condition is more likely to misunderstand the information given. A support person can lower the stress, help the patient to process the information, and ask questions.

There are other things you can do to put patients and their family and friends at ease. To show them that they are important and respected, you should:

- Be courteous;
- Sit down so you are at the same level as your patients;
- Make eye contact with your patients;
- Always listen to your patients, and try not to interrupt them;
- Use a caring tone of voice;
- Display comfortable body language;
- Be attentive to your patient’s personal comfort during the discussion;
- Don’t rush the discussion. Let your patients know that you have time to make sure they have the information they need and to discuss their concerns. And don’t rush them to make a decision. Rarely will taking a little extra time make a clinical difference; and
- Be sure to encourage the patient to ask questions.

You can also create an environment of psychological safety by encouraging questions and signaling your openness. Psychological safety means that patients are not afraid to share what they think, wonder, and feel, because they feel accepted and respected.

Slide 32/Strategy 6: Engage Patients, Families, and Friends (Continued)

Many patients and their families and friends will need your encouragement to become active participants in the informed consent discussion. To draw them into the conversation, try starting with their areas of expertise: their experience with their health problem.

Select each image to learn about using open-ended questions, acknowledging patients' expertise, and asking specific questions as ways of stimulating a conversation.

You may need to help them get started. It helps to use open-ended questions that cannot be answered with yes or no. Here are some questions that can help get them talking.

- “The last time I saw you was a month ago. How is your knee condition affecting you now?”
- “What worries you most about that?”

Be sure to address the patient's specific concerns. This step will also indicate that you are listening and will encourage them to share further.

Always acknowledge that the patient is an expert about himself or herself, and encourage them to ask and share information about their treatment expectations, concerns, and understanding of their condition. For example, you might politely say,

- “You know your body better than I do,” or,
- “You're in the best position to judge.”

One way to acknowledge the patient as an expert about himself or herself is to ask specific questions related to the patient's role in his or her care and treatment. You might, for example, ask the patient:

- “How do you cope when the pain gets bad?”
- “What has made you feel better?”
- “What doesn't seem to be working well?”

Additional resources are available in the Resources section of this course to help draw your patients into informed consent discussions. These resources include worksheets to help patients think through their options, and the Web site of the Informed Medical Decisions Foundation.

Slide 33/Strategy 6: Engage Patients, Families, and Friends (Continued)

Patients often have unanswered questions about their choices. They may be ashamed to ask questions, perhaps fearing they will seem foolish. Or they might just be shy by nature. So you'll need to encourage them to ask questions, which is our sixth strategy.

Why do you think patients might need some additional encouragement to ask questions?

Patients may think that you do not have enough time to answer their questions. Or, they may not be able to process the information quickly enough to be able to come up with questions.

Patients may simply be overwhelmed with the amount and flow of information. Or they may have forgotten their questions by the time you finish presenting information on all the choices. Patients may also have a perception that the provider is not listening or is preoccupied.

Here are some suggestions for how you can encourage your patients to get the information they need to make informed decisions.

- Invite questions with your body language. Lean forward. Look expectantly. Signal that you have the time and want to listen to their questions.
- When they do start asking questions, do not interrupt them. It may take a little while until they get to what is on their mind. Wait until they get their questions out rather than trying to anticipate questions.

Do not wait until the end of the discussion to solicit questions. Chunk out the information—give it out in chunks—and ask for questions after each piece of information. Creating multiple opportunities to ask questions increases the likelihood that patients will speak up.

Slide 34/Strategy 6: Engage Patients, Families, and Friends (Continued)

Another way you can encourage patients to ask questions is to create the expectation that they have questions by saying something like, “I know I’m giving you a lot of information. Let me pause here so you can tell me what questions you have.”

This is better than simply asking, “Do you have any questions?”

Roberta has an example of what can happen if a practitioner does not act in a way that encourages questions.

Select the image of Roberta to learn about this.

My doctor just seemed like he was in a hurry. I read his body language. He’d ask if I had any questions, and I said no, and he’d walk out the door. I could have asked him this and that, but he couldn’t even give me a chance. It was, “Any questions?” and out the door he went before I could even think.

Remember, patients pick up on the cues you send, so be sure to act accessible and encourage questions!

Slide 35/Strategy 7: Elicit Goals and Values

Strategy 7 is to elicit goals and values. Patients don't all want the same things. Treatments have different consequences, and some will matter more to one patient than another. By using Strategy 7, you will help your patient figure out what is important to him or to her.

To get at your patients' treatment goals and values, you might try asking this: "What matters to you most?" You may need to probe a bit further, by asking about specific outcomes such as minimizing pain, getting back to work or school quickly, and being able to participate in a favorite activity. Some goals may be long-term, such as reducing the risk of future injury or illness, or living as long as possible.

Treatment choices may be influenced by concerns about the treatments themselves. Again, you may have to probe to find out what is really on your patients' minds. Is it the side effects? Or are they worried about being dependent on others, or on medicines? Or about possible complications? Or perhaps they are concerned about whether the treatment is likely to be successful.

Patients may ask you, "What would you do?" Remember that what a person chooses depends on their goals and values, and your patient's goals and values may be different from your own. It's tempting to jump in with your recommendation, but try to help your patients to think about what is important to them.

Slide 36/Strategy 8: Show High-Quality Decision Aids

Strategy 8 is to show high-quality decision aids. A decision aid presents the various options in an unbiased way to a patient so that he or she can make an informed choice. Using a decision aid is another great strategy you can use to help present choices to a patient.

Decision aids provide information about:

- The various options available for a specific medical problem or screening procedure;
- Expected outcomes for the various options; and
- Potential benefits, harms, and risks.

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 have more accurate expectations of the possible benefits, harms, and risks of their options. More 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.

Additional information about interventions to promote informed consent is located in the Resources section.

Slide 37/Strategy 8: Show High-Quality Decision Aids (Continued)

When you are suggesting use of a decision aid, consider how your patient best learns. Is your patient one who likes to read information, or would they rather see and listen to it?

Decision aids can be paper-based, audiovisual, 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 someone helping the patient process the information and highlighting important points. If a multimedia resource is being recommended, make sure that your patient has the right equipment to view it. And if the decision aid is available on a Web site, make sure your patient is comfortable with Internet. You may need to make arrangements to show the decision aid to the patient in your office, and offer adaptive software for people with low vision or other disabilities.

Additional information on evaluating patient decision aids and educational materials is located in the Resources section of this course.

Slide 38/Strategy 8: Show High-Quality Decision Aids (Continued)

It is important to remember that decision aids are NOT a substitute for the informed consent discussion, even if offered as part of a high-quality computerized informed consent system.

Decision aids are designed to complement, rather than replace, 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, can personalize the information for that patient, can encourage and answer questions, and can discuss the information in the context of the patient's goals and values.

When you seek to locate high-quality decision aids, keep in mind that:

- Your hospital may have a library of decision aids for use in the informed consent process, and
- Some decision aids are available for free from reputable sources on the Internet.

Please see the Resources section of this course for details.

Slide 39/Strategy 9: Explain Benefits, Harms, and Risks of All Options

Strategy 9 is explaining benefits, harms, and risks of all options.

Don't just describe the option you recommend. And remember, "all options" includes the option of doing nothing.

For informed consent to be an informed choice, your explanation must be neutral.

This takes a certain effort, because there's often an unconscious tendency to lead the patient toward the option you recommend.

You also want to acknowledge that there's often uncertainty regarding the outcomes of the options. Don't be afraid to share the limitations for the evidence.

For example, you might say, "Some research shows this treatment is effective, and some shows it's not effective. We don't know how effective it will be for you."

Some benefits and harms will be time limited. Be specific about how long you expect a benefit or harm to last. For example, you might say, "You won't be able to drive for a month."

You also want to be complete. Don't leave out little things. For example, you might tell your patient, "Your skin around the area we cut will be tender."

When there's a risk of harm rather than a virtual certainty, it can be challenging to explain.

Try to avoid subjective terms, such "very likely." If you only say that the result is very likely, your patient may think the chances are 95%, or 60%. This may affect the patient's decision, so it's important to use actual numbers.

When you present numbers, frame the information in a balanced way, giving both the positive and negative consequences.

For example, you could say, "16% of patients had this complication, and 84% did not." But not everyone will understand percentages.

People process information differently, so try presenting information in more than one way.

For example, in addition to giving percentages, you could give the same information as the frequency, saying "That means 1 in 6 patients got this complication and 5 in 6 did not."

It's also helpful to show a visual.

Slide 40/Strategy 9: Explain Benefits, Harms, and Risks of All Options (Continued)

Select each image for additional information on explaining options.

It is important to state clearly when your patient is more or less likely than the average patient to experience particular benefits, harms, or risks. For example, if your patient has diabetes, she needs to know that her healing time may be longer than that of the average patient.

How experienced the clinician is can affect the risks of an option, so be sure to tell your patient how many years and how many times you've done this. Particularly for surgical procedures, the National Quality Forum recommends telling patients how many times a surgeon has performed the procedure in the past year, and how many times in his or her lifetime. You should also inform patients whether other members of the team will be performing major tasks, and what their experience levels and qualifications are.

You want to let your patients know they not only have a choice of treatments, but they also have a choice about who provides the treatment.

Let your patient decide what benefits, harms, and risks are important. Don't minimize harms or risks just because they seem minor to you, such as losing your hair or not being able to drive. They may be important to your patient.

Your patients may come from different countries or ethnic groups, and they may think differently from you about benefits, harms, and risks. For example, a Hispanic patient may be more likely to be fatalistic about outcomes. Or a Navajo patient may believe that negative words and thoughts about one's own health become self-fulfilling. You cannot be familiar with every group's health beliefs and practices, but you can bring in cultural brokers to help bridge the gap. Cultural brokers, such as interpreters or traditional healers, are people who can help you frame the discussion in a way that is appropriate in the patient's culture.

It may be appropriate to encourage your patients to consult with other clinicians to help them make their decisions.

You may not know all the benefits, harms, and risks of all the options. For example, if surgery is an option and you're not a surgeon, your patient will need to talk to a surgeon to seriously consider that option.

So rather than being insulting, sending your patient for a second opinion shows that you're secure in your knowledge.

Furthermore, it gives patients confidence that they're making the right choice for them.

Slide 41/Strategy 10: Help Patients Choose

Once you have described the options, the final step is to help patients make their choices.

You can start by asking patients what they are thinking about the options. Based on what they share with you, you can answer any additional questions, and offer information that is relevant to their goals and values. Patients may also need your help to assess the feasibility of each option, including which options are offered at your facility, how soon it can be done, who could do it, how much it will cost, what support needs they will have, and how much time they will likely need to take off from work.

Patients may need help thinking about the trade-offs involved. You can ask them to describe the pros and cons of the different alternatives from their perspectives. Ask them to reflect back on other considerations that they raised earlier in the conversation. Finally, help patients choose the options that best fit their goals and values.

Additional information on shared decision-making is located in the Resources section of this course.

Slide 42/Knowledge Check

Indicate which of the following practices are examples of engaging patients and their families and friends.

Encouraging questions, listening to your patients and their families and friends without interrupting, and acknowledging that patients have choices and expertise about themselves and are in the best position to make the decision about their own health care, are all examples of engaging your patients and their families and friends. Telling patients what you think is the best treatment option does not engage those patients or families and friends in making a decision.

Slide 43/Putting it All Together (A Model Informed Consent Conversation)

Putting it all together

Adrian is a 14-day-old boy who was brought to the hospital on his 6th day of life for lethargy. He was admitted for hypoxia and diagnosed as having meningitis. Several attempts were made, unsuccessfully, to perform a lumbar puncture to confirm the diagnosis.

As a precautionary measure, Adrian has been receiving a course of intravenous antibiotics for the past 8 days, but all of his visible veins have been damaged by the treatment. There are 2 days of treatment to go, and there is no way to place another intravenous line.

Slide 44/Putting it All Together (A Model Informed Consent Conversation Continued)

Adrian's mother is very tired and stressed out. She goes to sit with the doctor to discuss her choices.

Doctor: Ms. Jenson, unfortunately the treatment has damaged Adrian's veins.

Mom: I know, the nurse told me that.

Doctor: So we need to talk about what your choices are right now. Is there anyone you'd like to have with you while we discuss this?

Strategy used: Engaging patients, families, and friends.

Mom: Yeah. My sister Ana. She just went out to get us sandwiches.

Doctor: It's important that we make some decisions pretty quickly. Can you call her and ask her to come back?

Mom: Sure.

Course narrator's voice: When Adrian's aunt Ana returns.

Doctor: Let's step over here where we can talk privately.

Strategy used: prepare for the informed consent discussion find a private space to talk.

Doctor: I was just telling your sister that Adrian's veins have been damaged and we can't put another needle in the veins we've already used to give Adrian more medicine.

Aunt Ana: OK.

Strategy used: health literacy universal precautions: use plain, nonmedical language. Speak slowly and use visual aids.

Doctor (speaking slowly, with pauses): Adrian should get another 2 more days of medicine. Since we can't put a needle into the veins that we can get to easily, we could use what's called a central line to give him the rest of his medicine. The central line gets the medicine to a vein inside his body. Let me show you what the central line looks like.

It's a very thin and long tube that we insert in this vein here (show picture with subclavian vein like the one shown here). We then thread it all the way to the heart. This will allow us to give Adrian the rest of his medicine and the heart will pump it throughout his body. This is pretty technical, and I want to make sure I explained that properly. Can you tell me what you understood about what a central line is and why we'd use one?

Strategy used: Use teach-back, chunking and checking the information

Mom: It's a tube that goes into his chest, all the way to his heart. And you want to use it to give him the rest of his medicine.

Doctor: Right. If we give him medicine for another 2 days, we'll be sure the meningitis is gone. If he doesn't finish the medicine, the meningitis could come back even worse than before.

Mom: I sure don't want that.

Doctor: Now, I have to tell you that there are risks in using a central line. In this hospital, about 1%—that's one of every 100 patients—winds up with a life-threatening infection as a result of using a central line.

Strategy used: Explain benefits, harms, and risks of all options (offer information in more than one way)

Mom (sounding scared): Can't we just stop his treatment now, since we're only 2 days short, and he seems to be doing fine? We're not even sure that he has meningitis.

Doctor: You absolutely could choose to do that.

Strategy used: Offer choices; affirm that it's the mother's choice.

Doctor: But I have to tell you, there are risks of not giving him the rest of his medicine, too. If Adrian stops the medicine now, it's possible the meningitis will come back...assuming he has meningitis. I can't tell you how likely it is that the meningitis will come back since it's very unusual not to finish the medicine. But if the meningitis does come back, Adrian could die. About 25% of newborns with meningitis—that's 1 out of 4 babies—don't make it. And of those

that live, about a third have problems later on like seizures and learning disabilities. I wish could be more precise about what the odds are, but there's just a lot of uncertainty.

Strategy used: Explain benefits, harms, and risks of all options, including the option of no treatment.

Mom: Wow. That's really scary.

Doctor: I know. And I'm not sure I explained it that well. Can you tell me what you think will happen if we don't give Adrian any more medicine?

Mom: There's a 25% chance he'll die.

Doctor: Well, there's a 25% chance he'll die if he has meningitis and if the meningitis comes back. We don't know exactly how likely it is to come back if we don't give him 2 more days of medicine. But the chances are greater than if we give him the rest of the medicine. So let's see if I explained that more clearly. Can you tell me what you think will happen if we don't give Adrian the last 2 days of medicine.

Strategy used: Use teach-back (re-teach using different words, re-check after re-teaching)

Mom (a little uncertain): He's more likely to get meningitis again... if he has it now. And if he gets it again, there's a 25% chance he'll die. Is that right?

Doctor: That's right. And what about if we do give him the medicine using the central line? What might happen then?

Mom: It should make him better and prevent the meningitis from coming back.

Doctor: Yes. And what else could happen?

Aunt Ana: He could get an infection.

Mom: An infection that could kill him.

Doctor: Yes...that could unfortunately happen. But meningitis is a lot riskier than a central line, if he has meningitis. I've given you a lot of information and you've got a hard decision to make. Now I'm sure you have some questions you'd like to ask me. What more can I tell you?

Strategy used: Encourage questions.

Mom: How sure are you that Adrian has meningitis?

Doctor: It's hard to say. As you know, we weren't able to get the fluid we needed to do the tests to be absolutely sure. The fact that he was inactive when you brought him in and he's responded to the medicine makes it pretty likely that he has meningitis. If I had to put a number on it, I'd say that I'm 80% sure that he has meningitis.

Strategy used: Explain the benefits, harms and risks of all options; acknowledge uncertainty.

Aunt Ana: That's pretty sure.

Doctor: But I'm NOT certain; I'm NOT 100% sure. What else is on your minds?

Aunt Ana: What are the chances Adrian will die if he gets an infection from the line?

Doctor: The chances of his dying from an infection from the central line are very small—only 2 out of 1,000 babies who get a central line die of an infection. What other questions do you have?

Strategy used: Engage patients, friends and families; encourage questions.

Mom (sobbing slightly): I can't think of any more. My poor Adrian! He's been through so much already.

Doctor: He really has. Poor little guy.

Why don't you take a little time to think about it and talk with your sister?

Mom: Yes...I need time to think.

Doctor: Of course. Then I'll leave you with these notes and let you two talk. I'll come back in an hour. And if you have any more questions before then, have the nurse page me. How does that sound?

Mom: That sounds good.

Strategy used: schedule multiple sessions for the informed consent discussion if needed.

Course narrator's voice: One hour later...

Doctor: Hi, Ms. Jenson. Have you had a chance to think about the central line for Adrian?

Mom: Yes, but I'm still having a hard time deciding.

Doctor: OK. It's a tough decision. When you think about making this decision, what are you thinking about? What are your main concerns?

Strategy used: Elicit goals and values.

Mom: I just want to take him home. I want to get out of this hospital and get back to a normal life. My other kids are going to drive my mother to an early grave. We can't go on like this much longer.

Doctor: I hear how much you'd like to go home and get back to the rest of your family. It can be so hard being pulled in different directions.

Strategy used: Engage patients, families and friends by showing respect, listening, and using a caring tone.

Mom: Yes, Dr. Tabor, I am.

Aunt Ana: You know, I think Mom can handle the kids for another 2 days. And I can help too.

Doctor: That's great. So, Ms. Jenson, now that you've heard what your sister had to say, what are you most worried about?

Strategy used: Help patients choose.

Mom: Adrian's having meningitis. But I'm also worried that he could get an infection from the central line.

Doctor: That could happen. But if you're just comparing risks, having meningitis is a lot riskier than having a central line.

Mom: I don't think I could forgive myself if he wound up dying of meningitis because we didn't finish the treatment. OK. Let's do the central line.

Slide 45/Confirming Understanding

Section 4: Confirming and Documenting Informed Consent and Being Part of a Team

In this last section we will talk about confirming consent that took place earlier, how to document informed consent, and about what roles various members of the health care team can play in the informed consent process.

Informed consent discussions can occur days or weeks ahead of a test, treatment, or procedure. It is therefore critical to verify consent at the hospital, whether the form has already been signed or not yet signed. Check whether patients truly understand what is going to happen and the associated benefits, harms, and risks. Patients may have misunderstood or forgotten what you told them. They may have gotten conflicting information from other health care professionals, or may have gotten misinformation from the Internet, or otherwise may have become confused.

Slide 46/Confirming Understanding (Continued)

As a safety precaution, you should check that your patient has understood and agreed to the test, treatment, or procedure right before it is done. The teach-back method that you learned earlier can help you confirm that your patient understands. You can ask these questions:

- What are you having done today?
- How do you expect to feel afterwards?
- What results do you expect?
- How likely is it that you will get those results?
- What are the risks? How likely are they to happen?

If a patient cannot answer these questions correctly, STOP the line; that is, halt any activity that could cause harm. Even if all forms have already been signed, do not proceed with the test, treatment, or procedure.

Select the image of Magda to learn about how one surgeon's dedication to obtaining informed consent was able to avert a serious medical error by asking confirming questions.

A picture of a young woman, Magda highlights her story. Magda, a young woman who did not speak English, arrived for a tubal ligation. Just to confirm the patient's understanding of the procedure, her surgeon asked her through an interpreter, "What are you having done today?" Magda replied 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 carefully explained that the procedure was permanent and that there would be no possibility of future pregnancies. After hearing this information, Magda decided not to have the procedure performed.

Slide 47/Documenting Consent

If you have followed the process described in this training, you have had an informed consent discussion with your patient, presented choices clearly, and verified those choices were understood.

Now your patient has made a decision, and the final step is to document the informed consent conversation and decision.

There are different ways in which informed consent is documented, based on the nature of the treatment and the proposed urgency of care.

Non-invasive routine care, such as taking blood pressure, is usually covered by the blanket consent form patients sign when admitted to the hospital.

In general, signed written consent is obtained for each major therapeutic and diagnostic procedure.

A separate written consent is obtained for anesthesia by the clinician administering it. Sometimes, treatments or procedures require only verbal consent.

Usually, documentation of the consent discussion and verbal consent is required in the patient's record.

Policies can differ, so be sure to consult your hospital's policies on documenting informed consent.

Slide 48/What to Include

When you document informed consent, make sure your documentation is complete. If you have used an interpreter during the informed consent discussion, make a note in the record and have the interpreter sign the informed consent form if one is being used.

Document the choices that you presented to the patient, any decision aids you shared, and your use of teach-back to verify that your patient understood the benefits, harms, and risks of each alternative.

Finally, document the patient's decision, even when patients choose not to have a treatment or procedure.

For both the patient's protection and your own, consider documenting every informed consent discussion in the patient's record, even if it is not required by hospital policy. If a lawsuit is brought against you or the hospital, such documentation could be helpful. Documentation will also supply critical information to auditors who check to see whether a hospital's informed consent policies are being followed.

Slide 49/Appropriate Documentation

While documentation policies are often hospital-specific and relate to local and State laws, examples of appropriate documentation and verification practices include the use of reader-friendly consent forms, and chart notes which can be used either as a complement to, or, in some cases, as a substitute for the forms.

Select each image to view examples of a reader-friendly consent form and an informed consent chart note.

Slide 50/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 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 51/Understanding Team Roles

Every team member has a responsibility for safety. This video tells you about using “CUS” words. The acronym “CUS” stands for Concerned, Uncomfortable, and Safety. CUS words are used to raise issues respectfully about the informed consent process, or any other aspect of care with other team members.

In this video, an interpreter uses these words to bring up a concern with the clinician about her use of complex language and the patient’s understanding. If your hospital uses TeamSTEPPS, this tool will be familiar, since it came from the TeamSTEPPS Patient Safety system.

See video at <http://www.ahrq.gov/teamstepps/lep/videos/cuswords/index.html>

Slide 52/Course Summary

Before you go, let’s quickly recap what we have covered in this course.

- Patients have the right to decide what happens to their bodies. Clinicians are responsible for helping patients to make informed choices about their medical care, which can be a challenge. Several strategies can help you to help your patients make informed choices about their medical care.
- We have gone over four clear communication strategies. These strategies are:
 - Strategy 1: Prepare for the Informed Consent Discussion
 - Strategy 2: Use Health Literacy Universal Precautions
 - Strategy 3: Remove Language Barriers
 - Strategy 4: Use Teach-Back
- We have also gone over six strategies for presenting choices. These strategies are:
 - Strategy 5: Offer Choices
 - Strategy 6: Engage Patients, Families, and Friends
 - Strategy 7: Elicit Goals and Values
 - Strategy 8: Show High-Quality Decision Aids
 - Strategy 9: Explain Benefits, Harms, and Risks of All Options
 - Strategy 10: Help Patients Choose

And finally, in Section 4, we learned that confirming patients' understanding and appropriately documenting the informed consent process can help to protect both patients and clinicians.

We also learned about the importance of confirming consent that has been obtained earlier, and of appropriate documentation of the informed consent discussion and the decision made. In addition, we saw that while the clinician performing a procedure or prescribing a treatment is responsible for obtaining informed consent, multiple team members may be involved in helping patients make an informed choice.

Slide 53/Congratulations!

Congratulations!

You have now completed AHRQ's Making Informed Consent an Informed Choice: Training for Health Care Professionals, a module in the course titled "Improving Hospital Informed Consent with an Informed Consent Toolkit."

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 the resources section using the links in the top left portion of your screen.

Thank you for your commitment to improving the informed consent process for patients at your hospital.

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

If you have questions about this course, please email us at: HealthLiteracy@AHRQ.HHS.GOV