Making Informed Consent an Informed Choice:

Training for Health Care Professionals

Sponsored by:

Agency for Healthcare Research and Quality (AHRQ)
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The development and production of this course was a joint effort by AHRQ, Abt Associates, and The Joint Commission.

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The authors of this module are responsible for its content. No statement may be construed as the official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Select the next button to begin the course.

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 the Audio Script On/Off button to turn the audio script either on or off for the entire 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. 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.

Introduction

Informed Consent requires clear communication about choices.

It is not a signature on a form.


Informed Consent

Informed Choice

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 towards the end of this course.

Course Scope

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
- Informed consent for research
- Advance directives for end-of-life care

References regarding those topics are located in the Resources area of this course.

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 (e.g., showing structured decision aids, encouraging questions), and
4. Describe appropriate ways to document and confirm informed consent, and to work as part of a team.

Course Content

Section 1: Principles of Informed Consent

Purpose: 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: Strategies for Clear Communication

- 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

Section 3: Strategies for Presenting Choices

- 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

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

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.

Benefits of a High Quality Informed Consent Process

What are the benefits of a high-quality process of informed consent?

A high-quality process of informed consent can:

- Help patients make informed decisions
- Strengthen the therapeutic relationship
- Improve follow-up and after-care
- Engage patients and families
- Enhance patient safety
- Save money by averting delayed or cancelled surgeries
- Help to prevent lawsuits

Why Does Informed Consent Need to be Improved?

Informed consent is often treated as a nuisance and a formality.

Even after signing a consent form, patients often do not understand:

- The benefits, harms, and risks of treatment
- The possibility of poor outcomes
- Their option to say 'no'

Did You Know?

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.

Section 1: Principles of Informed Consent

When "informed" consent is NOT informed

Select the image of Toni to learn about her situation. (Not a model)

Video (from the health literacy kit) - Copyright 2007 American Medical Association Foundation and American Medical Association

Section 1: Principles of Informed Consent:

Ethical Principle of Autonomy

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

Patients have the right to:

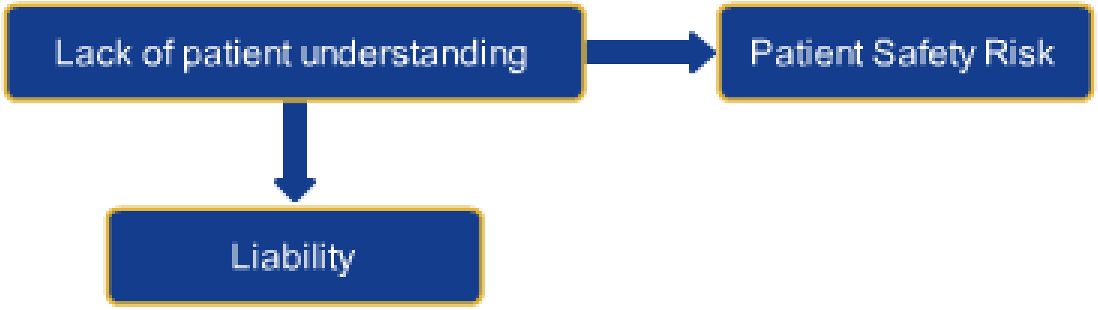
- Make care decisions
- Receive adequate disclosure
- Choose treatment options
- Refuse medical intervention
- Withdraw consent

Section 1: Principles of Informed Consent:

It's Not About the Form

Signed Form ≠ Informed Consent

- The consent form exists to document that the patient has been provided information, has understood the information, and has agreed to a particular treatment or procedure.
- Many patients sign informed consent forms even when they do not understand the procedure.



Courts have held that providing information when the patient doesn't understand does not constitute informed consent.

Explain = to make plain or understandable

Section 1: Principles of Informed Consent:
Recognizing Patient Capacity for Decision-Making

Most patients have the capacity for decision-making

Capacity:

- Means both the ability and the right to make a decision, and
- Can change over time and can vary depending on the decision to be made.
- Every person should be assessed for capacity
    - If there is a lack of capacity → legal designee should be identified

Key criteria for patient capacity:

- Ability to make and communicate a choice
- Ability to understand key information about:
    - His or her condition
    - Options for treatment
    - Benefits, harms, and risks of treatment
- No law or court order requiring treatment

Lack of Capacity | **Authorized Representative** | **Adequate Disclosure**

Select each principle for additional information.

Section 1: Principles of Informed Consent:

Recognizing Patient Capacity for Decision-Making

What is a lack of capacity?

incapacity ≠ disagreement

Patients may refuse treatment even if it puts their lives in jeopardy.

The following conditions do not automatically mean patients lack capacity:

- Inability to speak
- Intellectual disability
- Physical disability
- Mental illness
- Cognitive impairment
- Intoxication

Incapacity ≠ having conditions that make it harder to communicate or make decisions

Select each principle for additional information.

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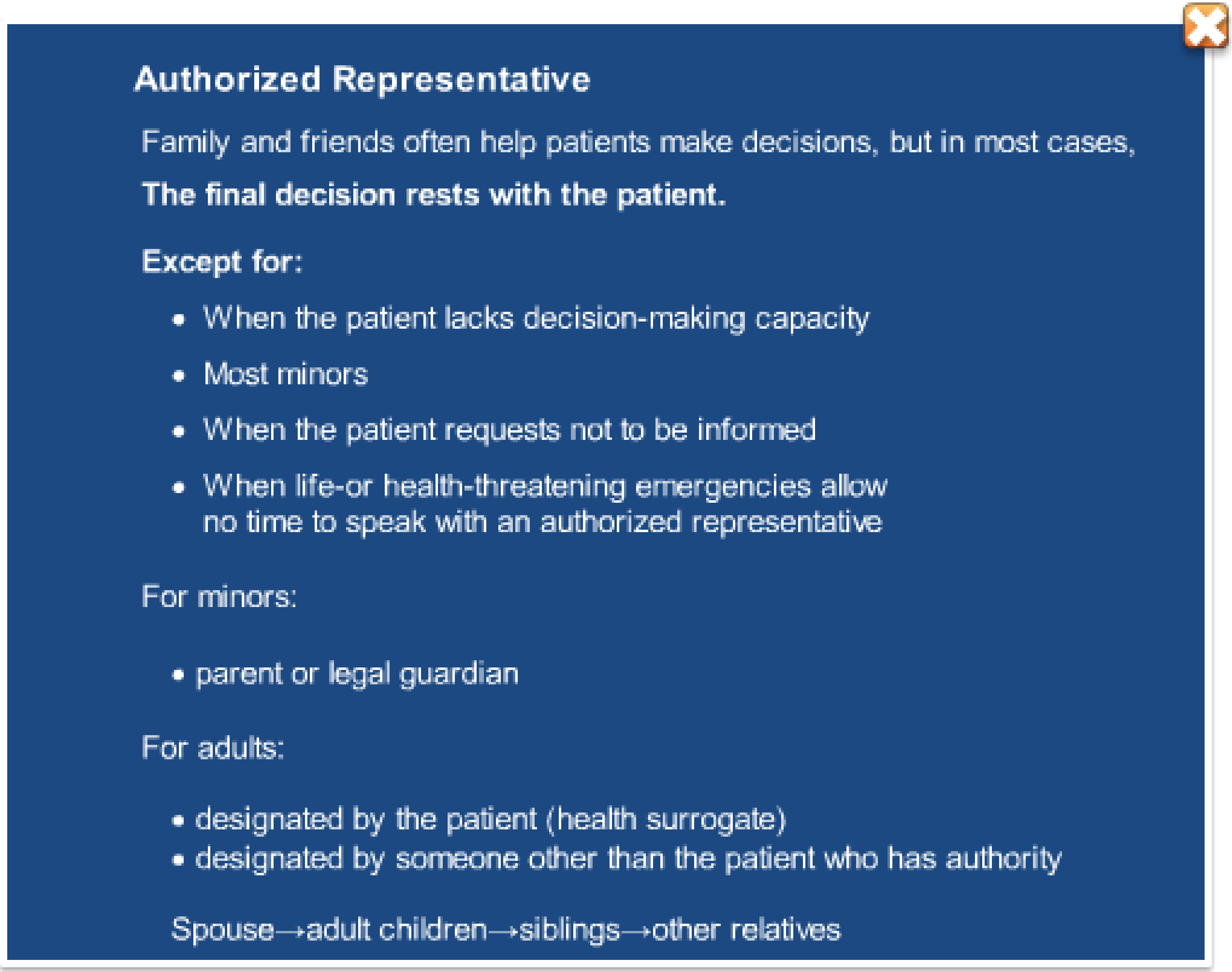


Authorized Representative

Family and friends often help patients make decisions, but in most cases,

The final decision rests with the patient.

Except for:

- When the patient lacks decision-making capacity
- Most minors
- When the patient requests not to be informed
- When life-or health-threatening emergencies allow no time to speak with an authorized representative

For minors:

- parent or legal guardian

For adults:

- designated by the patient (health surrogate)
- designated by someone other than the patient who has authority

Spouse→adult children→siblings→other relatives

Sel

Section 1: Principles of Informed Consent:

Recognizing Patient Capacity for Decision-Making

Adequate Disclosure

"Adequate Disclosure" is a non-delegable duty of the clinician providing the treatment.

To meet the legal standard, Adequate Disclosure must include explaining:

- What is involved with the treatment
- Anticipated results, benefits, and harms of the treatment
- Possible complications and foreseeable risks
- Whether the procedure is experimental

Lack of Capacity

Authorized Representative

Adequate Disclosure

Select each principle for additional information.

Section 1: Principles of Informed Consent:

When to Consult an Authorized Representative

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

Cecile

An article from Health Affairs, which provides a cautionary tale about obtaining informed consent in an emergency, is located in the Resources section.

Section 1: Principles of Informed Consent:

Making Informed Consent an Informed Choice

Informed Consent requires clear communication about choices.

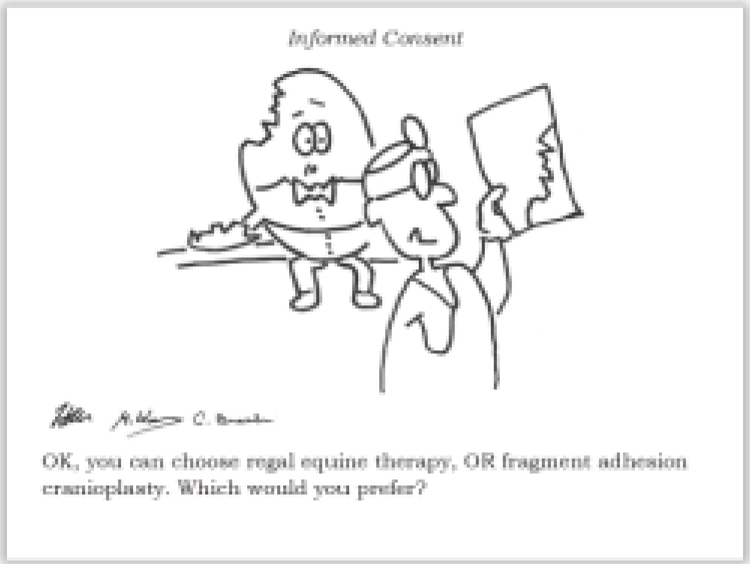
Informed Consent

Informed Choice

Informed choice requires:

- Clear, unbiased information about **all** treatment options.
- An answer to the question: What if I do nothing?
- Knowing how the options align with the patient's goals and values.

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



Informed Consent

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

Click on the image to enlarge.

Informed Consent

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

Section 2: Strategies for Clear Communication

- 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

Section 2: Strategies for Clear Communication:
Strategy 1: Prepare for the Informed Consent Discussion

- Share test results
- Include all important parties
    - Enough space
- Ensure privacy
- Schedule:
    - At a convenient time
    - When patients and families are ready to listen
    - Enough time
    - Multiple sessions?

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

Section 2: Strategies for Clear Communication:

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

Challenges to effective communication

- Feeling ill, scared, or stressed
- Feeling intimidated
- Tendency to focus on harms and risks instead of benefits
- Complex language or medical terminology
- Limited English proficiency
- Differences between cultural values of patient and clinician
- Limited health literacy and numeracy
- Hearing or vision impairments
- Differences in learning styles
- Cognitive impairment or intellectual disability
- Time pressures

Section 2: Strategies for Clear Communication:
Strategy 2: Use Health Literacy Universal Precautions

- Everyone is at risk of misunderstanding.
- Use plain, non-medical language
- Speak slowly
- Present information over several sessions
- Use visual aids
- Repeat key points
- Offer assistive listening and reading devices
- Check for understanding

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

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Most hospitals have policies that guide communicating with patients with limited English proficiency.

Important !

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!

Gayle Tang

Dai

Select each image to hear their stories regarding language barriers. (Not a model)

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

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

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Gayle Tang

- Vietnamese speaker
- Painful arm
- Invasive diagnostic test
- Poorly translated consent form

Dai

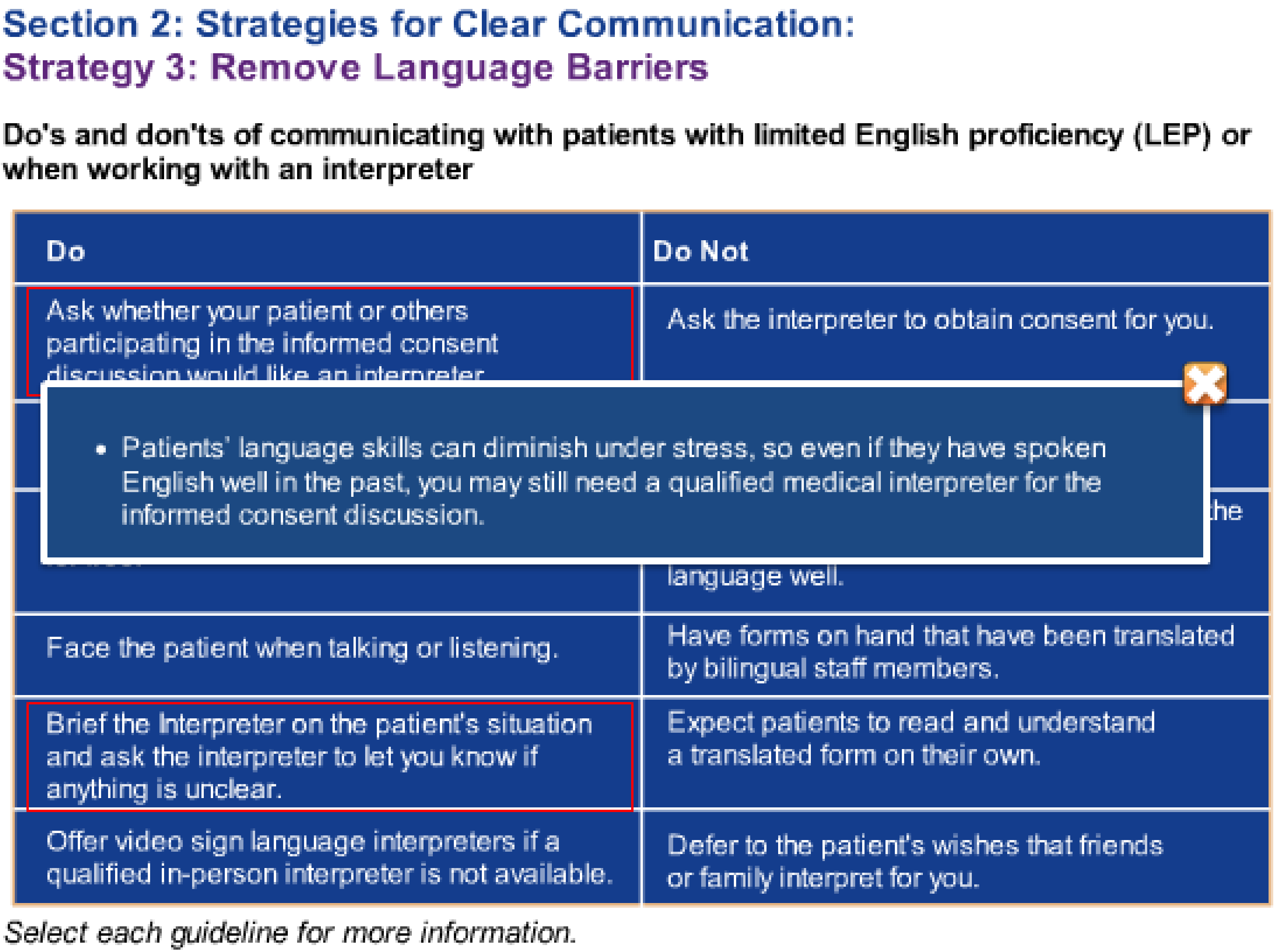
Select each image to hear their stories regarding language barriers. (Not a model)

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or when working with an interpreter

Do	Do Not
Ask whether your patient or others participating in the informed consent discussion would like an interpreter.	Ask the interpreter to obtain consent for you.
Explain that it is the hospital's policy to always use a qualified medical interpreter.	Speak rapdily without a pause or ask the interpreter not to interrupt you.
Let patients know they can get an interpreter for free.	Use your foreign language skills to conduct the discussion even if you speak that patient's language well.
Face the patient when talking or listening.	Have forms on hand that have been translated by bilingual staff members.
Brief the Interpreter on the patient's situation and ask the interpreter to let you know if anything is unclear.	Expect patients to read and understand a translated form on their own.
Offer video sign language interpreters if a qualified in-person interpreter is not available.	Defer to the patient's wishes that friends or family interpret for you.

Select each guideline for more information.



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- Patients' language skills can diminish under stress, so even if they have spoken English well in the past, you may still need a qualified medical interpreter for the informed consent discussion.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

- 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.
- Some patients may say their English is fine when you are having difficulty understanding them, and you believe that they are having difficulty understanding you, too.
- **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.**
- Make sure to note your patient's preferred language and the need for interpreter services in his or her chart.

Brief the Interpreter on the patient's situation and ask the interpreter to let you know if anything is unclear.	Expect patients to read and understand a translated form on their own.
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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.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or when working with an interpreter

- Always look at your patient when you are talking and when your patient is talking. Do not look 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.
- Engage in nonverbal communication.
- Seek training on working with interpreters.

Do	Do Not
	the
	ed by bilingual staff members.
Brief the Interpreter on the patient's situation and ask the interpreter to let you know if anything is unclear.	Expect patients to read and understand a translated form on their own.
Offer video sign language interpreters if a qualified in-person interpreter is not available.	Defer to the patient's wishes that friends or family interpret for you.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

This video shows a physician briefing her interpreter.

anything is unclear.	
Offer video sign language interpreters if a qualified in-person interpreter is not available.	Defer to the patient's wishes that friends or family interpret for you.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or wh

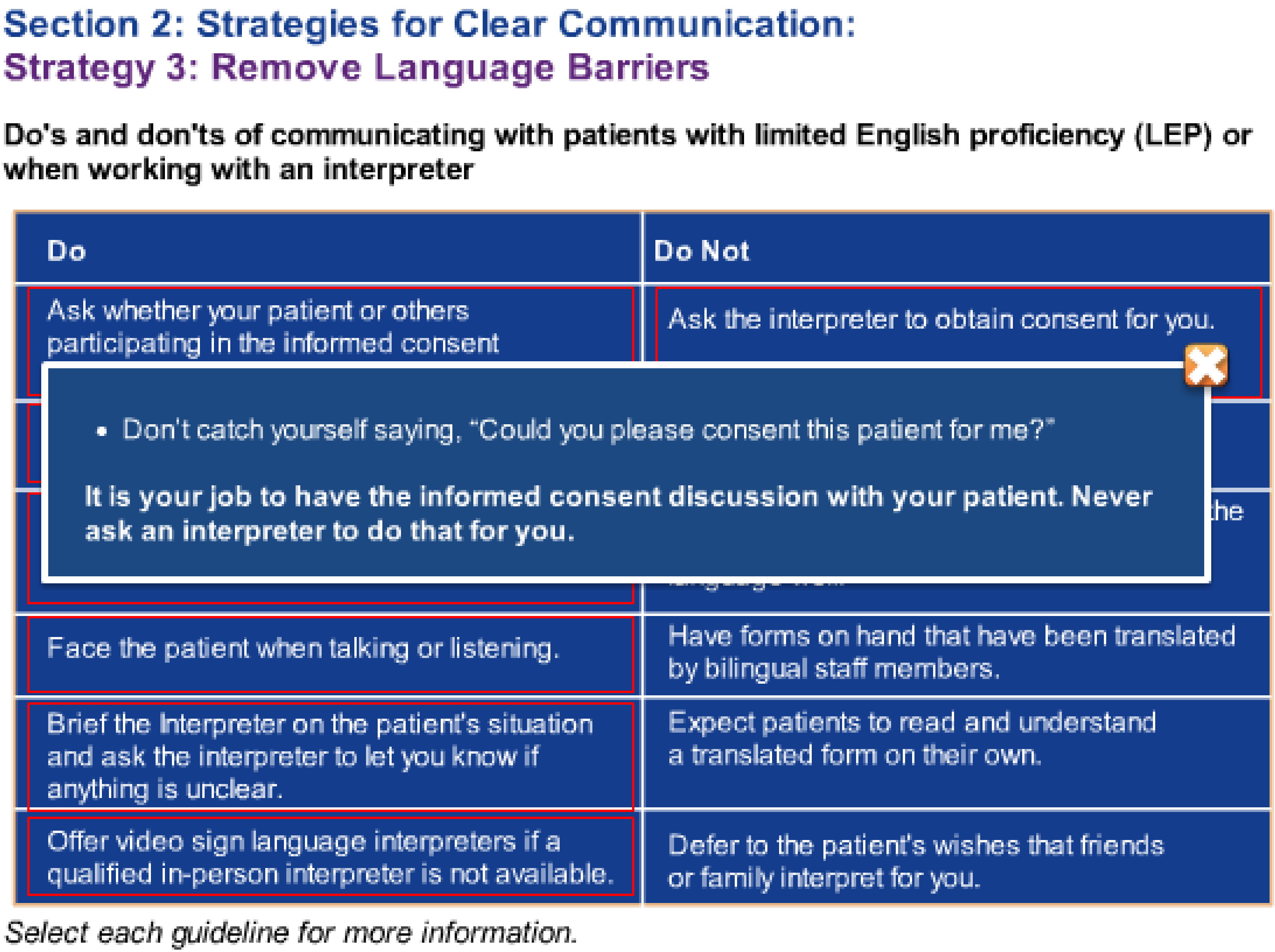
Video remote interpreting (VRI) has been used to comply with the Americans with Disabilities Act's requirement to ensure effective communication with deaf persons. A patient who is deaf or hard of hearing may, however, decide that VRI does not provide effective communication and may refuse to use it.

Keep in mind that

- Writing does not lend itself well to interactive communication.
- The average reading level of deaf high school graduates in the United States is roughly at the fourth-grade level.
- You should always offer a qualified interpreter to patients who are deaf or hard of hearing.
- You should call for a qualified interpreter if you have any difficulty understanding a 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.

Select each guideline for more information.



Section 2: Strategies for Clear Communication:

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Offer video sign language interpreters if a qualified in-person interpreter is not available.	Defer to the patient's wishes that friends or family interpret for you.

- Don't 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.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or when working with an interpreter

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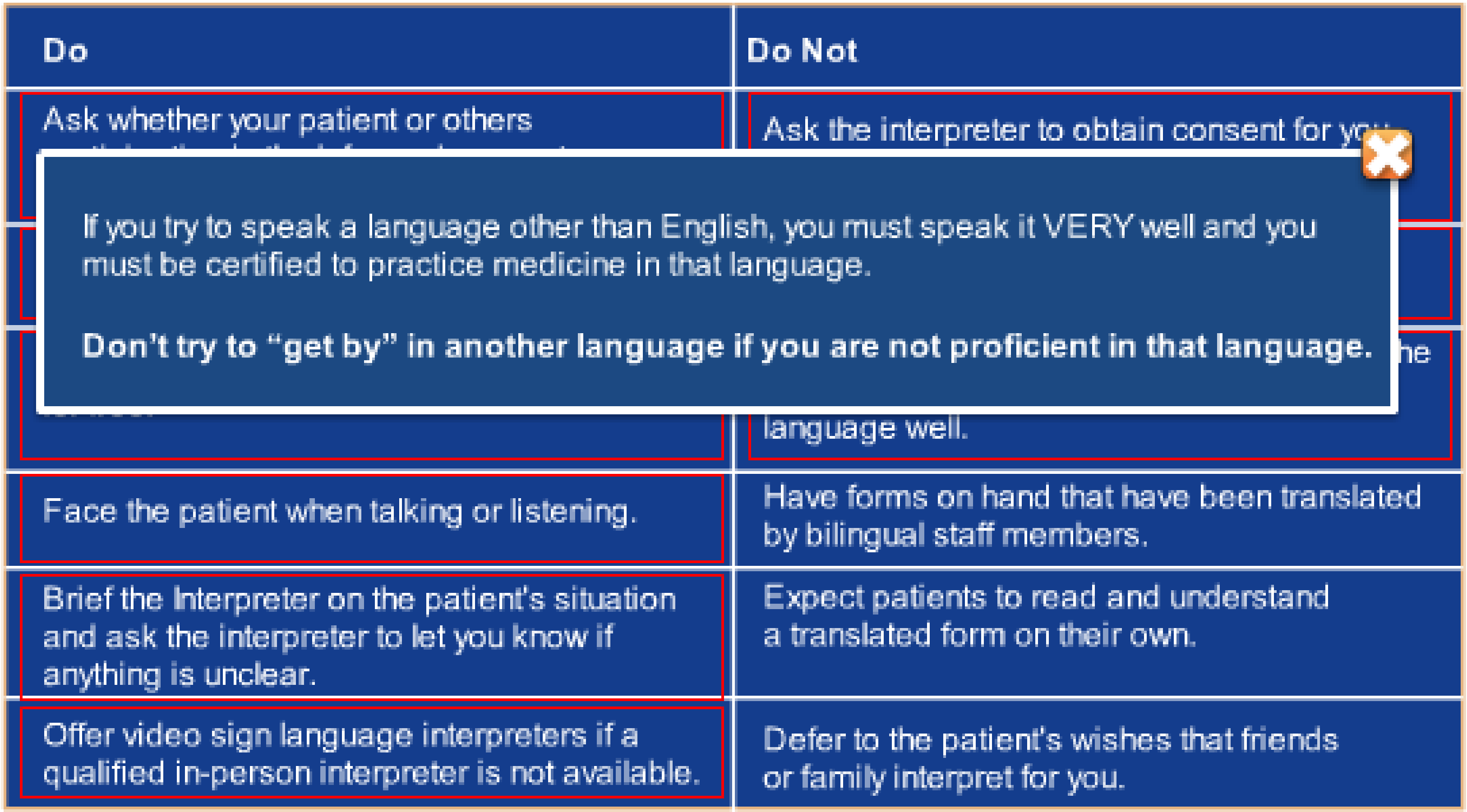
Interpreters are more likely to make errors if you speak very rapidly and cover lots of information without a pause to allow for interpretation. Take it slow, and break down the information into manageable chunks.

Interrupting is OK if patient understanding is at risk.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or when working with an interpreter



If you try to speak a language other than English, you must speak it VERY well and you must be certified to practice medicine in that language.

Don't try to "get by" in another language if you are not proficient in that language.

Do	Do Not
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Strategy 3: Remove Language Barriers

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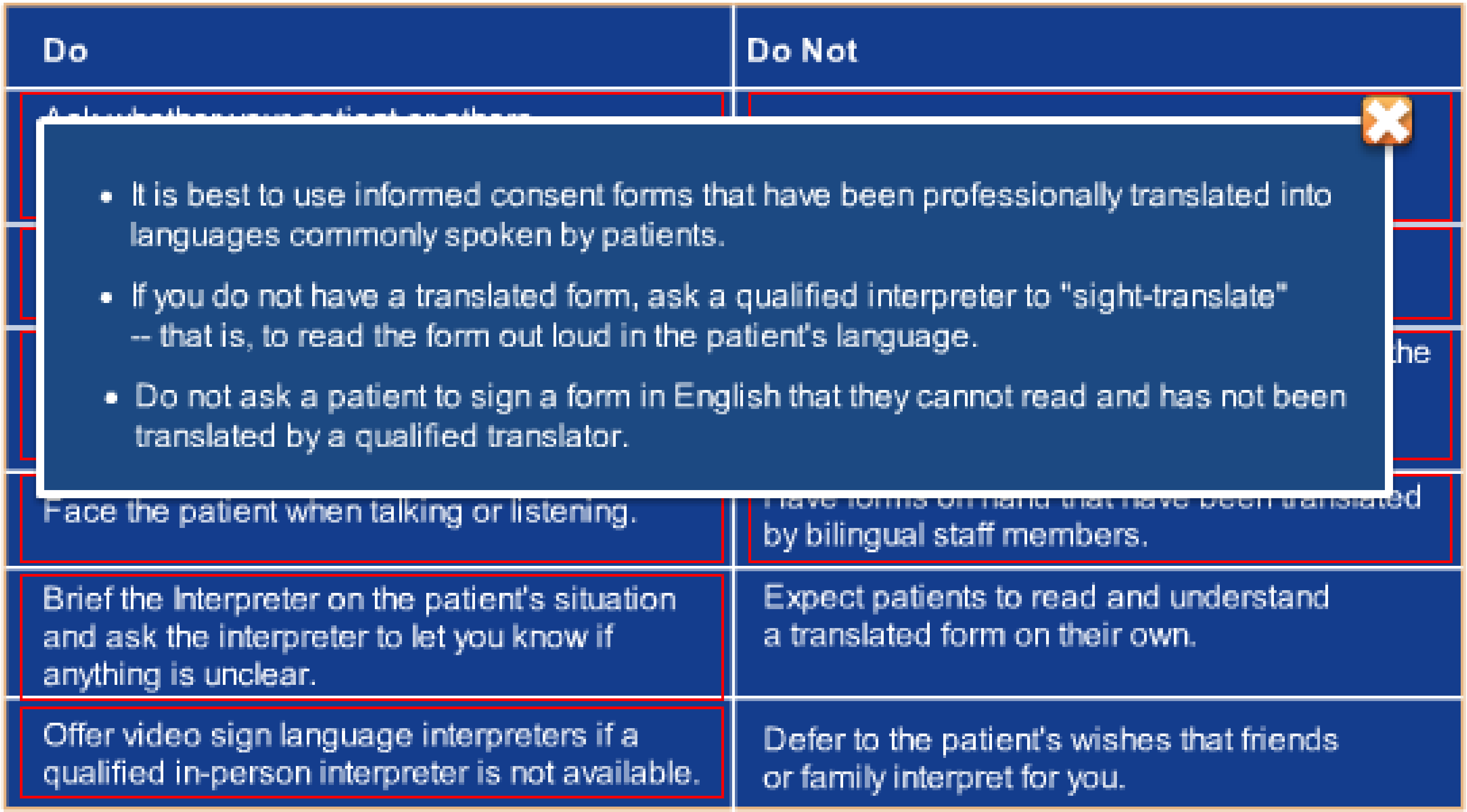

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- It is best to use informed consent forms that have been professionally translated into languages commonly spoken by patients.
- If you do not have a translated form, ask a qualified interpreter to "sight-translate" -- that is, to read the form out loud in the patient's language.
- Do not ask a patient to sign a form in English that they cannot read and has not been translated by a qualified translator.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or when working with an interpreter

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- Not all patients with LEP can read in their preferred language.
- Do not rely on patients being able to learn what they need to know about their choices from a form.

A form does not take the place of an informed consent discussion.

Select each guideline for more information.

Section 2: Strategies for Clear Communication:
Strategy 3: Remove Language Barriers

Do's and don'ts of communicating with patients with limited English proficiency (LEP) or when working with an interpreter

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.

Do	Do Not
Ask whether your patient or others participating in the informed consent	Ask the interpreter to obtain consent for you
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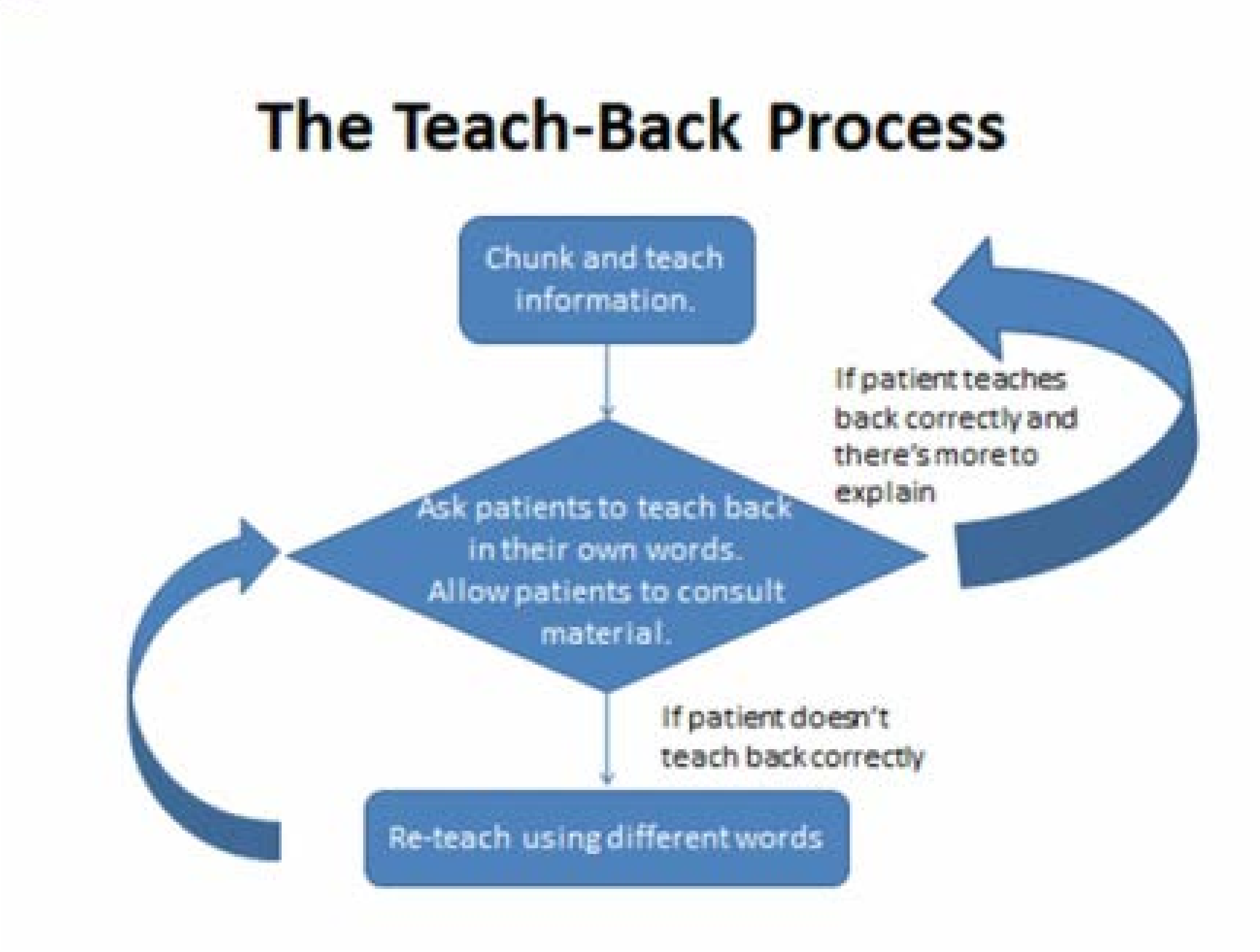
Section 2: Strategies for Clear Communication:
Strategy 4: Use Teach-Back



The Teach-Back Process

Chunk and teach information.

Ask patients to teach back in their own words. Allow patients to consult material.

If patient teaches back correctly and there's more to explain

If patient doesn't teach back correctly

Re-teach using different words

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

Why use Teach-Back?

- Teach-Back **improves understanding!**
- Teach-Back for informed consent is a **patient safety practice**

National Quality Forum (NQF) Patient Safety Practice:

> "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."

References

- NQF Safe Practices for Better Healthcare 2010 Update

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

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

Teach-Back is a great way to check patient understanding and confirm the clarity of your communication because you are:

- Asking patients to explain in their own words what they were told during the informed consent discussion;
- Providing a chance to check understanding and reteach information; and
- Checking the clarity of the clinician's explanation.

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.

Section 2: Strategies for Clear Communication:

Strategy 4: Use Teach-Back (Continued)

Tips on conducting teach-back effectively.

You should:

- 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 patient's response to it.

References

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

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

Teach-back Questions and Phrases

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

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

Teach-back Questions and Phrases

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

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

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

Teach-back Questions and Phrases






- "It's my job to make sure I explained 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?"

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

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

Teach-back Questions and Phrases

- 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?"

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

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

Teach-back Questions and Phrases

- "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?"

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

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

Teach-back Questions and Phrases

- "We've talked about some other treatments you could choose. Can you tell me what are some of the pros and cons of these alternative treatments?"

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

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

Teach-back Questions and Phrases

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

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

Section 2: Strategies for Clear Communication:

Strategy 4: Use Teach-Back (Continued)

Frequently asked questions about teach-back:

- Why do teach-back for every patient? Why not just do it for patients with limited health literacy?
- Won't teach-back take too much time?
- Won't patients be annoyed when they are asked to do a teach-back?
- Isn't teach-back mostly useful for patient discharge and self-management? Why do it for informed consent?

Select each question to view the answer.

Section 2: Strategies for Clear Communication:

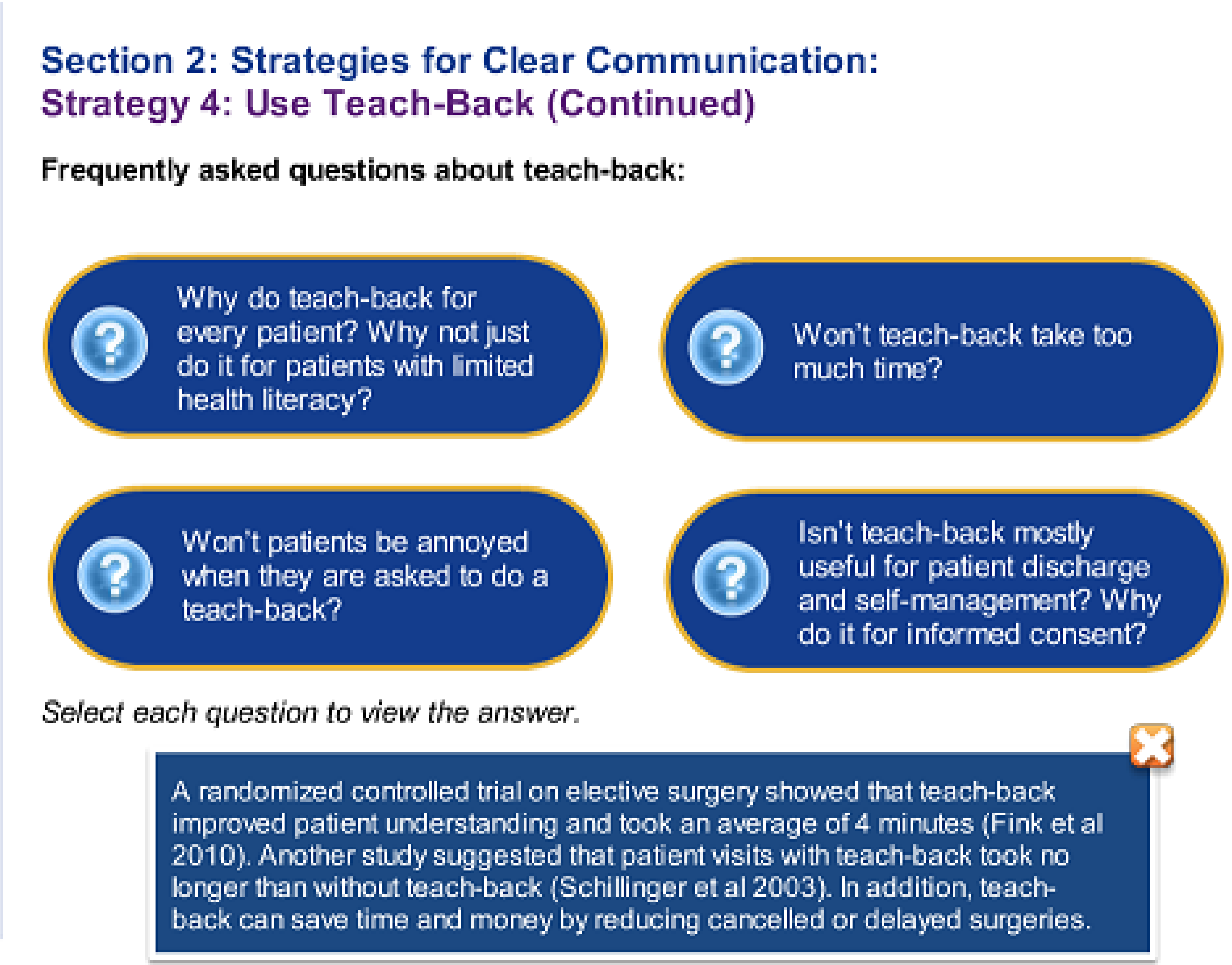
Strategy 4: Use Teach-Back (Continued)

Frequently asked questions about teach-back:

- Why do teach-back for every patient? Why not just do it for patients with limited health literacy?
- Won't teach-back take too much time?
- Won't patients be annoyed when they are asked to do a teach-back?
- Isn't teach-back mostly useful for patient discharge and self-management? Why do it for informed consent?

Select each question to view the 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.



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

Frequently asked questions about teach-back:

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

Won't teach-back take too much time?

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

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

Select each question to view the answer.

A randomized controlled trial on elective surgery showed that teach-back improved patient understanding and took an average of 4 minutes (Fink et al 2010). Another study suggested that patient visits with teach-back took no longer than without teach-back (Schillinger et al 2003). In addition, teach-back can save time and money by reducing cancelled or delayed surgeries.

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

Frequently asked questions about teach-back:

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

Won't teach-back take too much time?

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

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

Select each question to view the answer.

Patients may feel insulted if you make the teach-back seem like a test. To minimize that risk you can use the phrase, "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.

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

Frequently asked questions about teach-back:

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

Won't teach-back take too much time?

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

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

Select each question to view the answer.

Teach-back is useful whenever it is important to confirm a patient's understanding. You have not obtained informed consent if you are not sure that your patient has understood the information presented and the available choices.

Section 2: Strategies for Clear Communication

Knowledge Check

Which of the following statements are examples of Teach-back?

DROP HERE

DROP HERE

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

For a text-only version of the exercise, **click here**

Section 2: Strategies for Clear Communication

Knowledge Check

Which of the following statements are examples of Teach-back?

Teach-Back Examples	Not Teach-Back Examples
Can you tell me in your own words what will happen if you choose to have this procedure done?	Are you clear about the procedure we discussed?
What good results do you expect from this treatment?	Do you understand the benefits of this treatment?

Section 3: Strategies for Presenting Choices

- 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

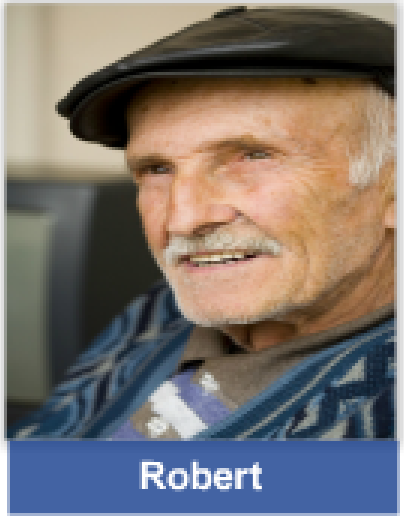
Additional tools, factsheets, and references regarding these strategies are located here and in the Resources area of the course.

Section 3: Strategies for Presenting Choices:

Strategy 5: Offer Choices

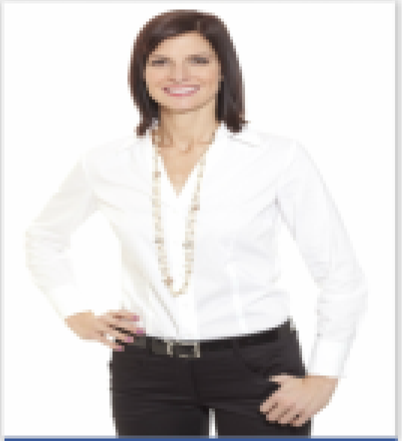
Always present **all** the options and offer choices.

- There are always choices.
- One of the choices is to do nothing.
- You can make recommendations, but remember: it is your patient's choice.
- Community practice patterns often drive medical decisions, not clinical circumstances or patient preferences
- Talk about cost, but do not limit choices on the basis of insurance coverage or cost.
- Even though the choice is theirs, you have expertise to share.



Robert

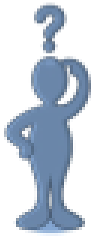
Select the image of each patient to learn their story.



Marie

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends

Patients involved in decision-making are more satisfied with their care. Engaging family and friends helps the patient in the decision-making process. Yet patients, their families, and their friends often lack confidence to make important decisions about their health.



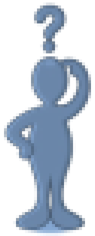
Do you know why many patients and their families and friends lack confidence when making decisions about their health?

Answer

Section 3: Strategies for Presenting Choices:

Strategy 6: Engage Patients, Families and Friends

Patients involved in decision-making are more satisfied with their care. Engaging family and friends helps the patient in the decision-making process. Yet patients, their families, and their friends often lack confidence to make important decisions about their health.



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

Answer

Many patients and their families and friends lack confidence when making decisions about their health because they:

- Lack expertise: "The doctor knows more than I do";
- Are ill: "I'm in no shape to make decisions";
- Respond by a habit: "I'm used to being told what to do"; or
- Feel deference: "It would be rude to question the doctor".

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

To help put patients, families, and friends at ease and show respect, you should:

- Encourage patients to include a trusted family member or friend;
- Be courteous;
- Sit down so you are at the same level as your patients;
- Make eye contact with your patients;
- Listen to your patients without interrupting;
- 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;
- Encourage questions; and
- Create psychological safety.

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

Draw patients into discussion with conversational prompts


Use open-ended questions


Acknowledge patient's expertise

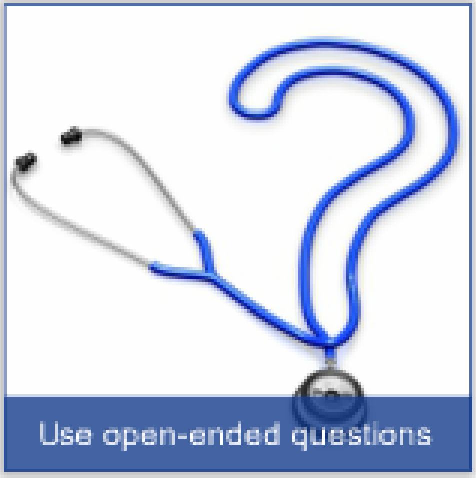

Ask specific questions

Select each image for additional information about each conversational prompt.

Section 3: Strategies for Presenting Choices:

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

Draw patients into discussion with conversational prompts



Use open-ended questions

Acknowledge patient's expertise

Ask specific questions

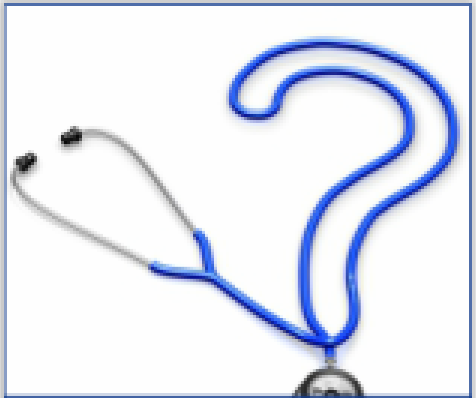
Select each image for additional information about each conversational prompt.

Use open-ended questions.

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

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

Draw patients into discussion with conversational prompts



Use open-ended questions

Acknowledge patient's expertise

Ask specific questions

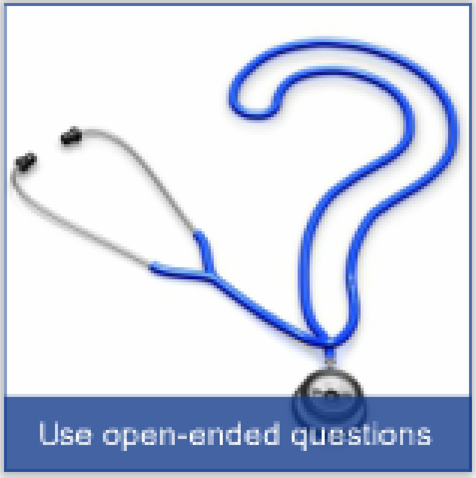
Select each image for additional information about each conversational prompt.

Acknowledge the patient as his or her own expert.

- "You know your body better than I do."
- "You're in the best position to judge."

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

Draw patients into discussion with conversational prompts


Use open-ended questions


Acknowledge patient's expertise


Ask specific questions

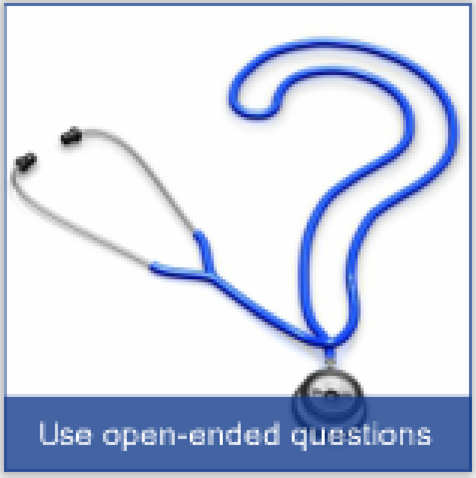
Select each image for additional information about each conversational prompt.

Ask specific questions related to the patient's role in his or her care and treatment.

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

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

Draw patients into discussion with conversational prompts


Use open-ended questions


Acknowledge patient's expertise


Ask specific questions

Select each image for additional information about each conversational prompt.

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 website of the Informed Medical Decisions Foundation.

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

Encourage Questions

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

Patients might not want to ask questions because they:

- Perceive that there are time constraints,
- Are still processing the information or have information overload,
- Just don't remember, or
- Have a perception that the provider is not listening or is preoccupied.

You can encourage patients to ask questions by:

- Inviting questions with body language,
  - Lean forward
  - Look expectantly
- Not interrupting, and
- Soliciting questions at multiple intervals.

References

AHRQ Health Literacy Universal Precautions Toolkit: 2nd edition. January 2015. Tool 14: Encourage Questions. Agency for Healthcare Research and Quality, Rockville, MD.

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

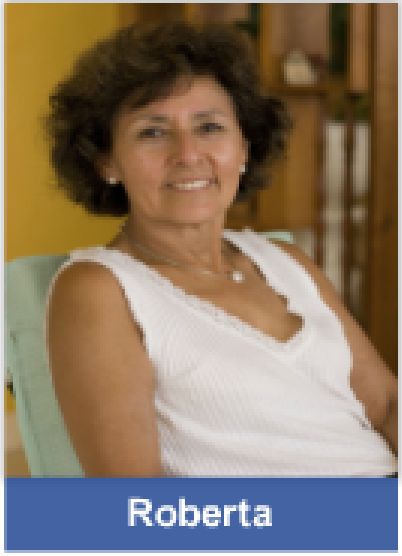
When you encourage questions, you create the expectation that the patient has questions.

SAY:

"I know I'm giving you a lot of information. Let me pause here so you can tell me what questions you have."

DON'T SAY:

"Do you have any questions?"



Select the image of Roberta for an example.

Section 3: Strategies for Presenting Choices:
Strategy 6: Engage Patients, Families and Friends (Continued)

When you encourage questions, you create the expectation that the patient has questions.

SAY:

"I know I'm giving you a lot of information. Let me pause here so you can tell me what questions you have."

DON'T SAY:

"Do you have any questions?"

Important !

Remember, patients pick up on the cues you send — so be sure to let them know you want them to ask questions!


Roberta

Select the image of Roberta for an example.

Section 3: Strategies for Presenting Choices:
Strategy 7: Elicit Goals and Values

Patients don't all want the same things, so it is important to find out what your patient's goals and values are. You can do this by asking:

- What matters to you most?
    - Minimizing pain?
    - Getting back to work or school quickly?
    - Being able to participate in a favorite activity?
    - Reducing risk of future injury or illness?
    - Living as long as possible?
- What are your main concerns about the possible treatments?
    - Side effects?
    - Dependency?
    - Possible complications?
    - Likelihood of success?

Section 3: Strategies for Presenting Choices:
Strategy 8: Show High-Quality Decision Aids

Decision aids provide unbiased information about options, outcomes, benefits, harms, and risks.

Using decision aids:

- Helps clinicians structure conversations with patients;
- Improves patients' knowledge about what their options are;
- Increases the accuracy of patients' expectations of possible benefits, harms, and risks of different options;
- Clarifies for patients what matters most to them;
- Increases patient participation and communication;
- Helps patients weigh options based on their values;
- Makes it more likely that patients will reach decisions consistent with their goals and values; and
- Equips patients to cope better with treatment outcomes or adverse events.

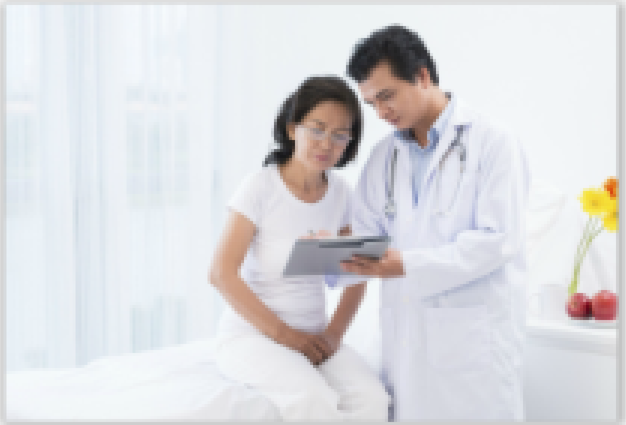
Additional information about interventions to promote informed consent is located in the Resources Section.

Section 3: Strategies for Presenting Choices:
Strategy 8: Show High-Quality Decision Aids (Continued)

When suggesting a decision aid, it is important to consider how your patient best learns.

Types of decision aids include:

- Paper-based,
- Audiovisual,
- Multimedia,
- Web-based,
- Interactive,
- Those for independent patient use, and
- Those for joint use by patient and clinician.



Make sure patients have the right equipment and know-how.

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

Section 3: Strategies for Presenting Choices:
Strategy 8: Show High-Quality Decision Aids (Continued)

Decision aids are designed to complement, rather than replace, the informed consent discussion.

Important !

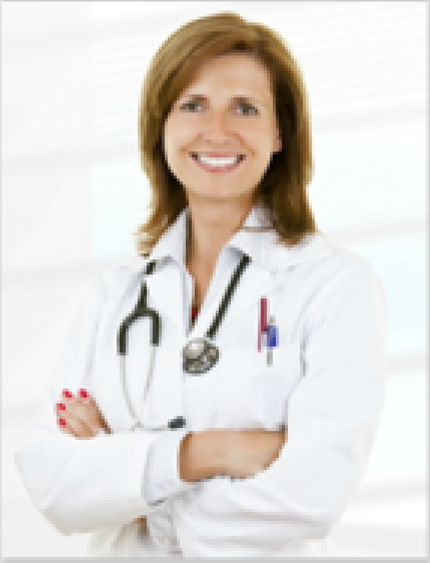
Decision aids are **NOT** a substitute for the informed consent discussion, even if offered as part of a high-quality computerized informed consent system. You still need to:

- Use Teach-Back,
- Personalize information,
- Encourage and answer questions, and
- Put information in the context of a patient's goals and values.

Find high quality decision aids at these locations:

- Your hospital resource center,
- Free from reputable sources on the Internet, and
- In the Resources section of this course.

Section 3: Strategies for Presenting Choices:
Strategy 9: Explain Benefits, Harms and Risks of All Options



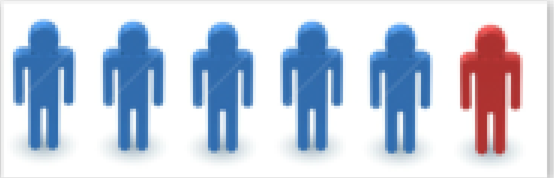
Explain benefits, harms and risks:

- For **all** options – including doing nothing
- Neutrally

Important !

Guard against unconscious tendencies to promote the option you recommend.

- Acknowledge uncertainty
- Specify duration, e.g., "You won't be able to drive for a month."
- Be complete, e.g., "Your skin around the area we cut will be tender."
- Avoid subjective terms, e.g., "Very likely" – 95%? 60%?
- Present balanced information – both positive and negative
  - 16% of patients had this complication, 84% did not.
- Present information in more than 1 way
  - That means 1 in 6 patients got this complication and 5 in 6 did not.



Example of a visual

Section 3: Strategies for Presenting Choices:
Strategy 9: Explain Benefits, Harms and Risks of All Options (Continued)

Select each image for additional information on explaining options.


Personalize


Clinician's Experience


What's Important


Bridge cultural differences


Consult

Section 3: Strategies for Presenting Choices:

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

Select each image for additional information on explaining options.


Personalize


Clinician's Experience


What's Important

Personalize:

- Personalize benefits, harms and risks.
- Don't just give averages.

Section 3: Strategies for Presenting Choices:

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

Select each image for additional information on explaining options.


Personalize


Clinician's Experience


What's Important

Clinician Experience:

Tell your patient about your experience

- National Quality Forum recommends telling patients the number of times a surgeon has performed a procedure
  - In the past year
  - In his or her lifetime
- Inform patients about other team members' experience and qualifications
- Let patients know they have a choice about who provides treatment.

Section 3: Strategies for Presenting Choices:

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

Select each image for additional information on explaining options.


Personalize


Clinician's Experience


What's Important

What's important?

- Let your patient decide what benefits, harms, and risks are important
- Don't minimize harms or risks

Section 3: Strategies for Presenting Choices:

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

Bridge any cultural differences:

- Patients may think differently than you do about benefits, harms, and risks,
- Be sensitive to cultural differences in perception, and
- Use a cultural broker when needed.

References

Carrese JA, Rhodes LA. Bridging cultural differences in medical practice. The case of discussing negative information with Navajo patients. J Gen Intern Med. Feb 2000;15(2):92-96


Bridge cultural differences


Consult

Section 3: Strategies for Presenting Choices:
Strategy 9: Explain Benefits, Harms and Risks of All Options (Continued)

Select each image for additional information on explaining options.

Consult:

Encouraging patients to consult with other clinicians:
- Supplements your expertise
- Shows you're secure
- Gives patients confidence they're making the right choice


Bridge cultural differences


Consult

Section 3: Strategies for Presenting Choices:

Strategy 10: Help Patients Choose

You should:

- Ask patients what they are thinking;
- Answer any additional questions;
- Offer information related to:
    - Patients' goals and values, and
    - Feasibility of each option, e.g., timetables, cost, support needs, time off from work;
- Elicit patients' assessment of the pros and cons of each option; and
- **Help patients choose the options that best fit their goals and values.**

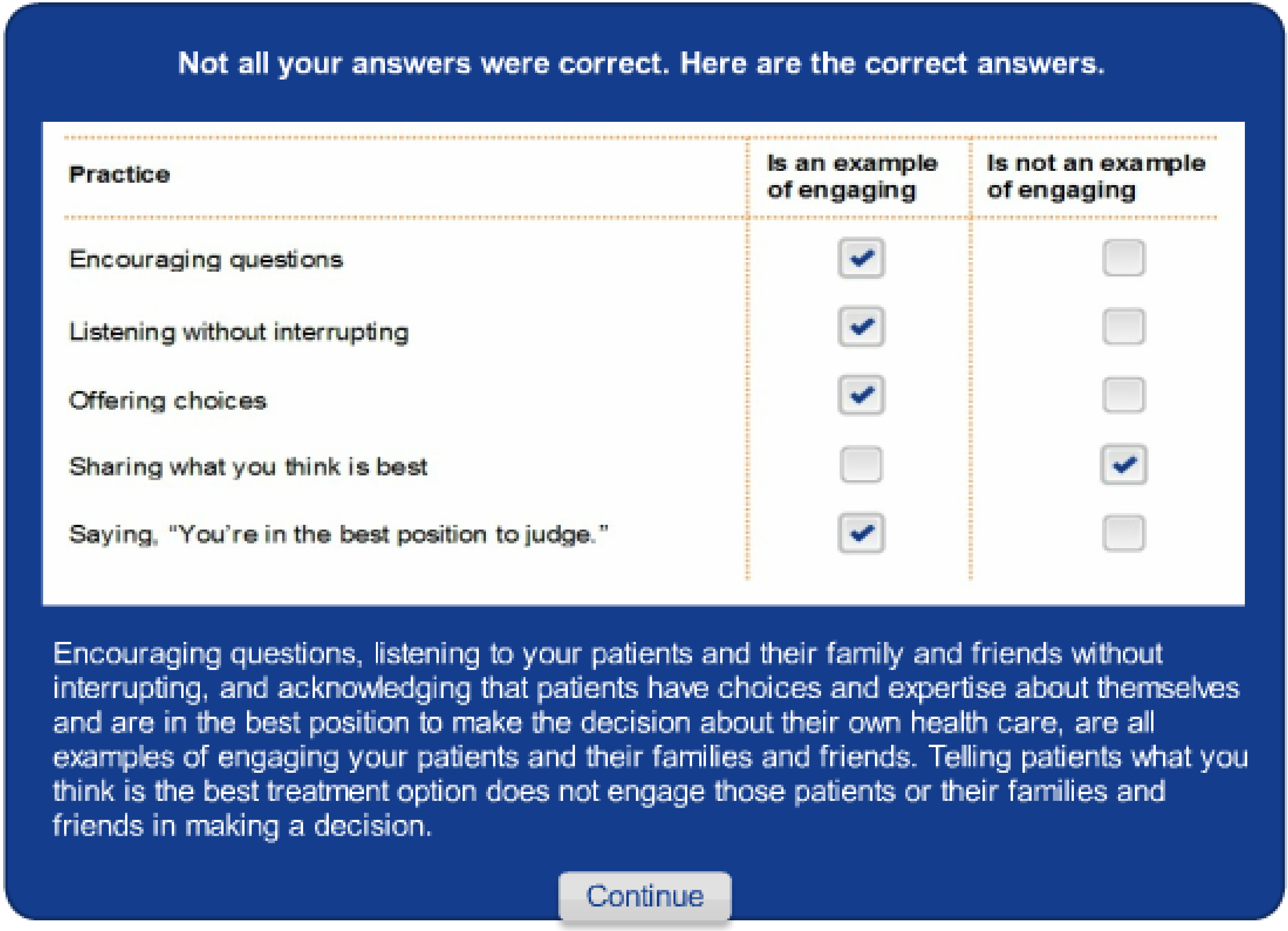
Additional information on shared decision-making is located in the Resources section of this course.

Section 3: Strategies for Presenting Choices

Knowledge Check

Which of the following practices are examples of engaging patients and their families and friends?

Practice	**Is an example of engaging**	**Is not an example of engaging**
Encouraging questions	☐	☐
Listening without interrupting	☐	☐
Offering choices	☐	☐
Sharing what you think is best	☐	☐
Saying, “You’re in the best position to judge.”	☐	☐



Not all your answers were correct. Here are the correct answers.

Practice	Is an example of engaging	Is not an example of engaging
Encouraging questions	☑	☐
Listening without interrupting	☑	☐
Offering choices	☑	☐
Sharing what you think is best	☐	☑
Saying, "You're in the best position to judge."	☑	☐

Encouraging questions, listening to your patients and their family 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 their families and friends in making a decision.

Putting it all together:
A Model Informed Consent Conversation

- 14-day-old boy
- Admitted for hypoxia
- Diagnosed with meningitis
- Unable to perform a lumbar puncture
- Has been receiving IV antibiotics
- Now has vein damage but still needs 2 more days of treatment

Putting it all together:
A Model Informed Consent Conversation (Continued)

Adrian's Mom
Ms. Jenson

Doctor Tabor

Strategy used: Engaging patients, families and friends

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)

Adrian's
Aunt Ana

Adrian's Mom
Ms. Jenson

Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)

Adrian's
Aunt Ana

Adrian's Mom
Ms. Jenson

Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)

Adrian's
Aunt Ana

Adrian's Mom
Ms. Jenson

Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson

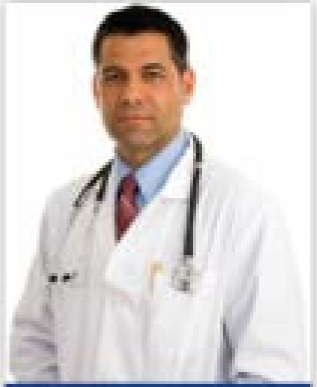

Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

Strategy used: Encourage questions

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)

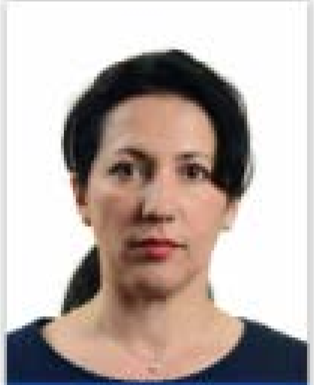
Adrian's
Aunt Ana

Adrian's Mom
Ms. Jenson

Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana


Adrian's Mom
Ms. Jenson


Doctor Tabor

One hour later…

Putting it all together:
A Model Informed Consent Conversation (Continued)

Adrian's
Aunt Ana

Adrian's Mom
Ms. Jenson

Doctor Tabor

Strategy used: Elicit goals and values.

Putting it all together:
A Model Informed Consent Conversation (Continued)

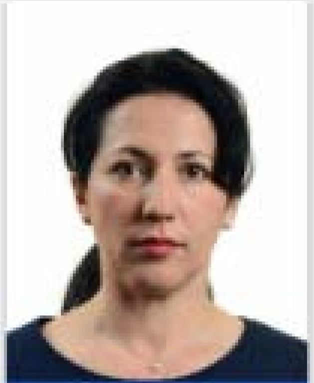
Adrian's
Aunt Ana

Adrian's Mom
Ms. Jenson

Doctor Tabor

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

Putting it all together:
A Model Informed Consent Conversation (Continued)


Adrian's
Aunt Ana

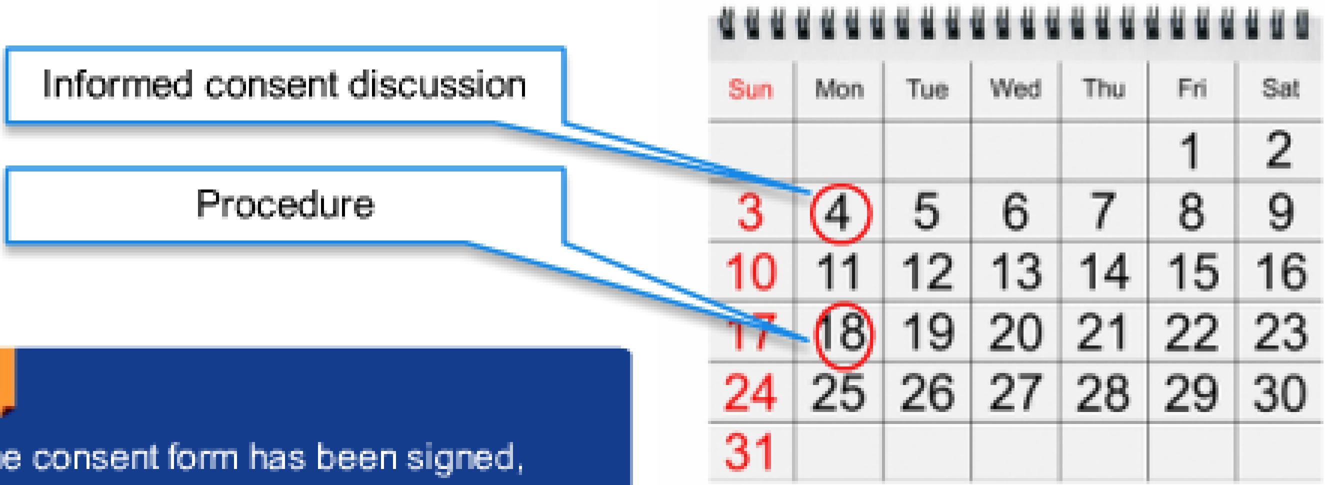

Adrian's Mom
Ms. Jenson


Doctor Tabor

Strategy used: Help patients choose.

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

Confirming Understanding



Informed consent discussion

Procedure

Important !

- Even when the consent form has been signed, check patient's understand and consent.

Why confirm consent?

Patients may have:

- Forgotten
- Misunderstood
- Been given conflicting information
- Gotten misinformation
- Become confused

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

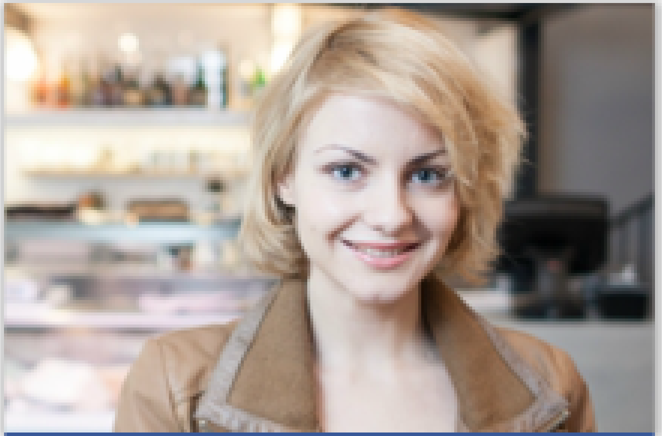
Confirming Understanding (Continued)

Teach-back questions to check understanding right before the test, treatment, or procedure:

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

Safety is Everyone's Job

If you see that a patient doesn't understand, STOP. Do not proceed with the test, treatment, or procedure.



Magda

Select the image to learn more.

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

Documenting Consent

Document both informed consent conversation and the decision.

Different ways to document informed consent:

- Blanket "Consent to treat" form
- Signed written consent: major therapeutic and diagnostic procedures
  - Separate written consent: anesthesia
- Verbal consent
  - Document discussion and consent in medical record.

Important !

Be sure to consult your hospital's policies on documenting informed consent!

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

What to Include

Make sure informed consent documentation is complete by documenting:

- Any use of interpreters,
- All choices presented,
- Decision aids shown to the patient,
- Use of teach-back to verify understanding, and
- Patient's decision, including choice of no treatment.

Important !

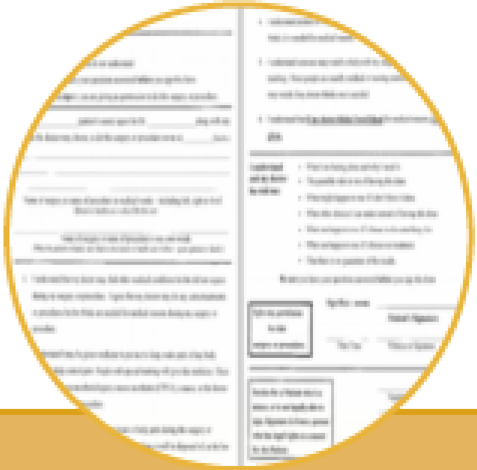
Document **every** informed consent discussion.

- Even if not required,
- In case of lawsuit, and
- Helpful to auditors

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

Appropriate Documentation

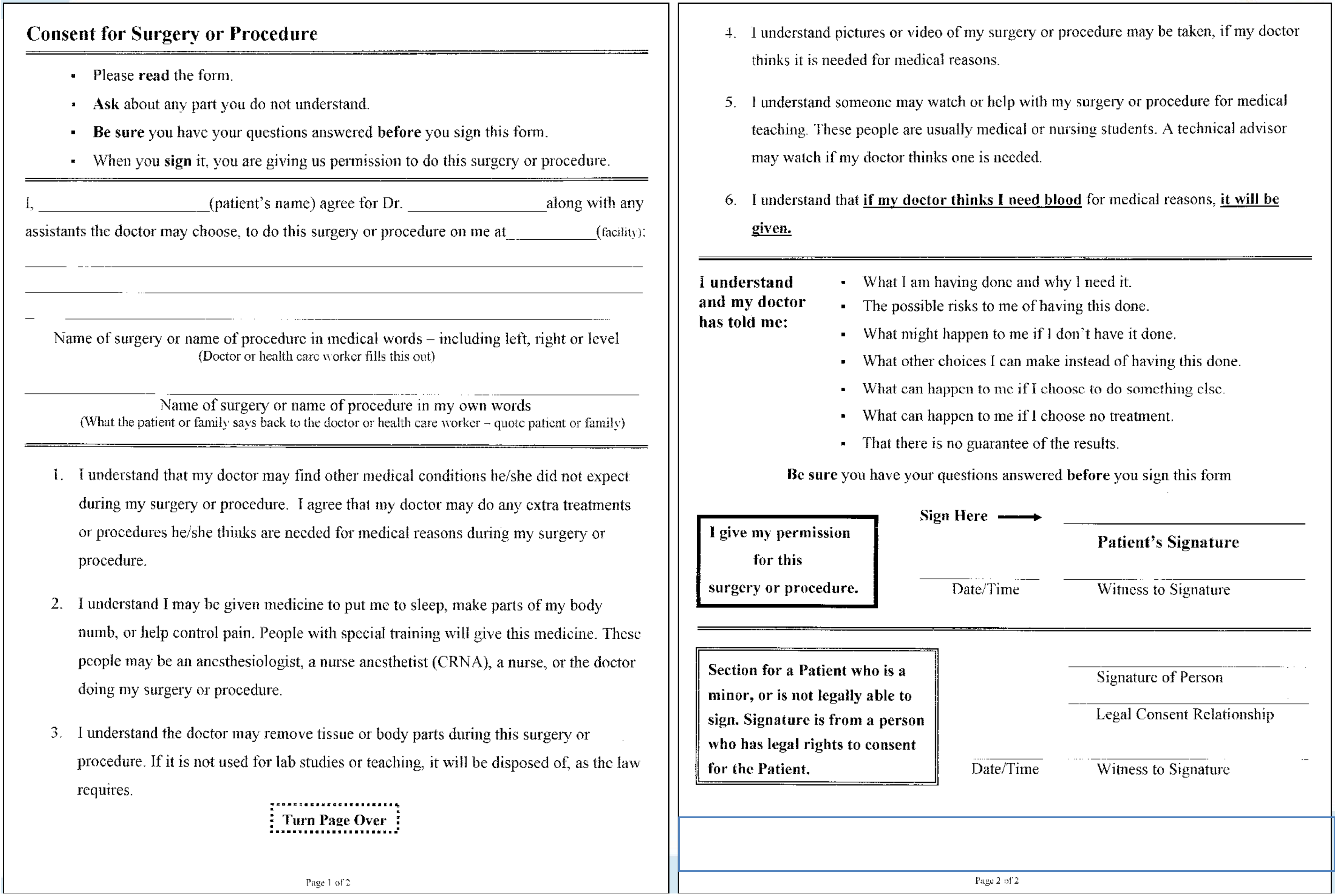
While documentation policies are often hospital-specific and relate to local and state laws, here are some examples of appropriate documentation and verification practices.



Reader-friendly consent form

Patient Chart Note

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



Consent for Surgery or Procedure

- Please **read** the form.
- **Ask** about any part you do not understand.
- **Be sure** you have your questions answered **before** you sign this form.
- When you **sign** it, you are giving us permission to do this surgery or procedure.

I, ____________________(patient's name) agree for Dr. ________________along with any assistants the doctor may choose, to do this surgery or procedure on me at__________(facility):

____

____

____

Name of surgery or name of procedure in medical words – including left, right or level
(Doctor or health care worker fills this out)

____

Name of surgery or name of procedure in my own words
(What the patient or family says back to the doctor or health care worker – quote patient or family)

1. I understand that my doctor may find other medical conditions he/she did not expect during my surgery or procedure. I agree that my doctor may do any extra treatments or procedures he/she thinks are needed for medical reasons during my surgery or procedure.
2. I understand I may be given medicine to put me to sleep, make parts of my body numb, or help control pain. People with special training will give this medicine. These people may be an anesthesiologist, a nurse anesthetist (CRNA), a nurse, or the doctor doing my surgery or procedure.
3. I understand the doctor may remove tissue or body parts during this surgery or procedure. If it is not used for lab studies or teaching, it will be disposed of, as the law requires.

Turn Page Over

Page 1 of 2

4. I understand pictures or video of my surgery or procedure may be taken, if my doctor thinks it is needed for medical reasons.
5. I understand someone may watch or help with my surgery or procedure for medical teaching. These people are usually medical or nursing students. A technical advisor may watch if my doctor thinks one is needed.
6. I understand that **if my doctor thinks I need blood** for medical reasons, **it will be given.**

I understand and my doctor has told me:

- What I am having done and why I need it.
- The possible risks to me of having this done.
- What might happen to me if I don't have it done.
- What other choices I can make instead of having this done.
- What can happen to me if I choose to do something else.
- What can happen to me if I choose no treatment.
- That there is no guarantee of the results.

Be sure you have your questions answered **before** you sign this form

I give my permission for this surgery or procedure.

Sign Here → ____________________

Patient's Signature

____________ Date/Time

____________________ Witness to Signature

Section for a Patient who is a minor, or is not legally able to sign. Signature is from a person who has legal rights to consent for the Patient.

____________________ Signature of Person

____________________ Legal Consent Relationship

____________ Date/Time

____________________ Witness to Signature

Page 2 of 2

Abrams, MA (2013). A Health Literacy-Based Consent Process & Attributes of a Health Literate Health Care Organization. Roundtable on Health Literacy Workshop: Implementation of Attributes of Health Literacy Washington, DC.

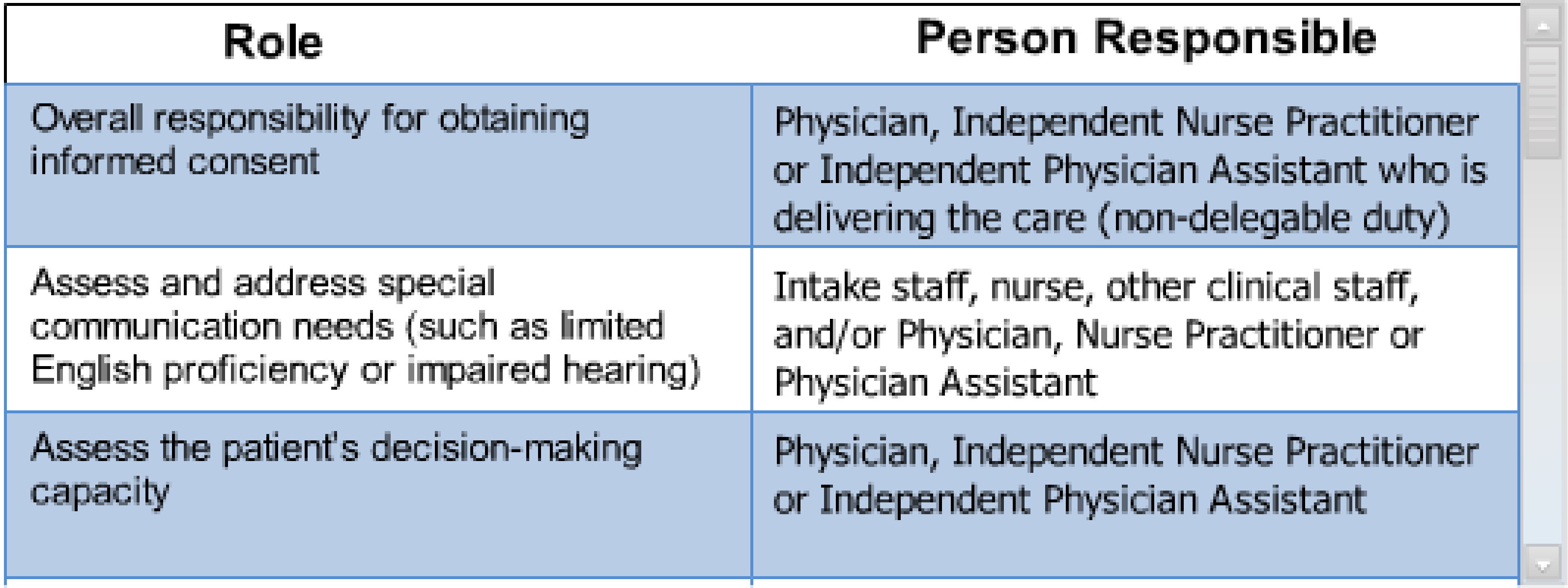
Chart note

Patient's Mom, Dana Miller and Dana's sister, Laurie Otero were present for the informed consent discussion. Dr. Tabor explained the benefits and risks of central line placement [prevent meningitis recurrence but small risk of central-line associated bloodstream infection (CLABSI) versus not completing the course of antibiotics (no CLABSI, but risk of meningitis recurring)]. During teach-back, Mom correctly explained what placing a central line entailed and the benefits and risks of the central line and not completing the antibiotic course. Dr. Tabor answered questions about relative risks of each option. Extra time (1 hour) was given to Mom after initial conversation to reach a decision. Mom opted for central line (Signed Informed Consent form attached).

Adapted from: Abrams, MA (2013). A Health Literacy-Based Consent Process &
Attributes of a Health Literate Health Care Organization. Roundtable on Health Literacy Workshop:
Implementation of Attributes of Health Literacy Washington, DC.

Informed Consent Team Roles and Responsibilities

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



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

Select the image for an enlarged table.

Important !

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

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

- A blank Informed Consent Team Roles and Responsibilities Table
- A training resource on coaching team members on how to be part of a team

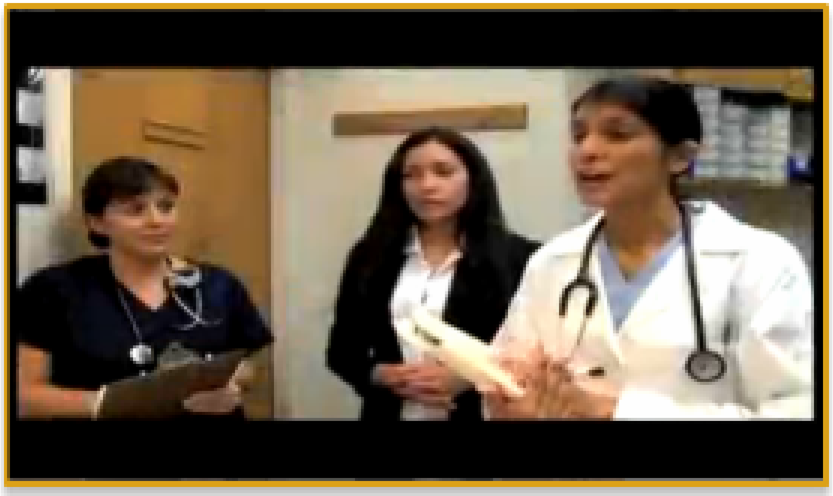
Informed Consent Team Roles and Responsibilities

Role	Person Responsible
Overall responsibility for obtaining informed consent	Physician, Independent Nurse Practitioner or Independent Physician Assistant who is delivering the care (non-delegable duty)
Assess and address special communication needs (such as limited English proficiency or impaired hearing)	Intake staff, nurse, other clinical staff, and/or Physician, Nurse Practitioner or Physician Assistant
Assess the patient's decision-making capacity	Physician, Independent Nurse Practitioner or Independent Physician Assistant
Identify authorized decision makers if a patient lacks decision making capacity	Physician, Independent Nurse Practitioner or Independent Physician Assistant
Schedule times and rooms for discussions, if needed	Receptionist
Explain choices including benefits, harms, and risks; use teach-back to verify patient understanding	Physician, Independent Nurse Practitioner or Independent Physician Assistant
Interpret for patients with limited English proficiency	Qualified medical interpreter
Show decision aids	Physician, Nurse Practitioner, Physician Assistant, Nurse, or other clinical staff
Help the patient to clarify goals and values	Physician, Nurse Practitioner, Physician Assistants, Nurse, or other clinical staff
Stop the line (i.e., halt any activity that could cause harm) if it appears that the patient did not understand	Any team member
Make a decision	Patient or authorized representative
Document the patient's choice (may include signing the form and/or documenting informed consent conversations in the patient's record)	Physician, Independent Nurse Practitioner or Independent Physician Assistant
Confirm that informed consent discussion has been appropriately documented	Nurse or other clinical staff
Confirm that the patient understands benefits, harms, and risks immediately before the test, treatment, or procedure is performed	Physicians, Independent Nurse Practitioners and/or Independent Physician Assistants

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

Understanding Team Roles

- Every team member has a responsibility for safety.
- Use "Concerned, Uncomfortable, Safety" (CUS) words.



Course Summary

Section 1: Principles of Informed Consent

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 challenging. Several strategies can help you to help your patients make informed choices about their medical care.

Section 2: Strategies for Clear Communication

- 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

Section 3: Strategies for Presenting Choices

- 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

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

- Confirm consent and document consent discussion and decision
- Clarify team roles in advance

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Congratulations!

You have completed

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

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

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
Principles of Informed Consent		
General reference on informed consent to treatment	Fleisher L, Miller M, et al. A Practical Guide to Informed Consent. Available at: http://www.rwjf.org/content/dam/web-assets/2009/04/a-practical-guide-to-informed-consent	PDF is available in course Resources section for download.
	Rozovsky, FA (2015). *Consent to Treatment: A Practical Guide.* 5th ed. New York, NY: Aspen Publishers: Wolters-Kluwer Law & Business.	
	Shekelle, P. G., Wachter, R. M., Pronovost, P. J., Schoelles, K., McDonald, K. M., Dy, S. M., ... & Larkin, J. W. (2013). Chapter 39: Obtaining Informed Consent from Patients: Brief Update Review. In: Making health care safer II: an updated critical analysis of the evidence for patient safety practices. Evidence report/technology assessment, (211), 1-945. Available at: http://www.ncbi.nlm.nih.gov/books/NBK133402/	
Informed consent to research	Educational and quality improvement resources on consent to research. Available at: http://www.hhs.gov/ohrp/education/index.html	
	AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. Available at: http://www.ahrq.gov/funding/policies/informedconsent/index.html	PDF is available in course Resources section for download.
	Guidelines from the Office of Human Subjects Protection. Available at: http://www.hhs.gov/ohrp/humansubjects/commonrule/	
	Code of Federal Regulations, Title 45 CFR Part 46. Protection of Human Subjects. Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html	

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
Informed consent for end-of-life care	Rozovsky, FA (2015). Refusing treatment, dying and death, and the elderly. Section 11.6. In: Consent to Treatment: A Practical Guide. 5th ed. New York, NY: Aspen Publishers: Wolters-Kluwer Law & Business.	
It's not about a form	Macy v. Blatchford Case Law	PDF is available in course Resources section for download.
Informed consent for persons with a lack of capacity	The Macarthur Treatment Competence Study. Available at: http://www.macarthur.virginia.edu/treatment.html	PDF is available in course Resources section for download.
	Appelbaum, P. S. (2007). Assessment of patients' competence to consent to treatment. New England Journal of Medicine, 357(18), 1834-1840. Available at: http://www.nejm.org/doi/full/10.1056/NEJMcp074045	
	Karlawish, J. (2007). Measuring decision-making capacity in cognitively impaired individuals. Neurosignals, 16(1), 91-98. Available at: https://www.ncbi.nlm.nih.gov/pubmed/18097164	
	Rozovsky F. Chapter 1: How to obtain consent: The art of consent communication. In: Consent to Treatment: A Practical Guide. 5th ed. New York, NY: Aspen Publishers: Wolters-Kluwer Law & Business.	
Informed consent for minors	State Policies in Brief. An Overview of Minors' Consent Law. Guttmacher Institute. Available at: https://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf	PDF is available in course Resources section for download.

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
Informed consent during emergency situations	Copyrighted and published by Project HOPE/Health Affairs as: Cindy Brach "Even In An Emergency, Doctors Must Make Informed Consent An Informed Choice" Health Affairs (Millwood) 2016, Vol. 35, No. 4, 739-743. The published article is archived and available online at www.healthaffairs.org. Article available at: http://content.healthaffairs.org/cgi/content/full/35/4/739	
Strategies for Clear Communication		
Health literacy and informed consent	Informed Consent and Health Literacy. Workshop summary. Alper J, Rapporteur. Institute of Medicine. The National Academies Press. Available at: http://www.nap.edu/catalog/19019/informed-consent-and-health-literacy-workshop-summary	
	AHRQ Health Literacy Universal Precautions Toolkit, 2nd Edition. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html	PDF is available in course Resources section for download.
	Brach, C., Keller, D., Hernandez, L. M., Baur, C., Parker, R., Dreyer, B., Schillinger, D. (2012). Ten attributes of a health literate health care organization. Washington DC: Institute of Medicine. Available at: https://nam.edu/perspectives-2012-ten-attributes-of-health-literate-health-care-organizations/	
	CDC's "Everyday Words for Public Health Communication," A list of medical terms and their everyday substitutes. Available at: https://www.cdc.gov/other/pdf/everydaywordsforpublichealthcommunication_final_11-5-15.pdf	PDF is available in course Resources section for download

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
	Schillinger, D., Piette, J., Grumbach, K., Wang, F., Wilson, C., Daher, C., Bindman, A. B. (2003). Closing the loop: physician communication with diabetic patients who have low health literacy Arch Intern Med, 163(1), 83-90. Available at: https://www.ncbi.nlm.nih.gov/pubmed/12523921	This resource is also listed in the **Teach-back** section.
	Fink, A. S., A. V. Prochazka, W. G. Henderson, D. Bartenfeld, C. Nyirenda, A. Webb, D. H. Berger, K. Itani, T. Whitehill, J. Edwards, M. Wilson, C. Karsonovich, and P. Parmelee. (2010). Predictors of comprehension during surgical informed consent. Journal of American College of Surgeons 210:919-926. Available at: https://www.ncbi.nlm.nih.gov/pubmed/20510800	This resource is also listed in the **Teach-back** section.
	Miller M, Abrams MA, Earles B, Phillips K, McCleeary E. (2011). Improving Patient-Provider Communication for Patients Having Surgery: Patient Perceptions of a Revised Health Literacy-Based Consent Process. Journal of Patient Safety, 7(1): 30-38. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21921865	
	Goff SL, Mazor KM, Ting HH, Kleppel R, Rothberg MB. How cardiologists present the benefits of percutaneous coronary interventions to patients with stable angina: a qualitative analysis. JAMA Intern Med. 2014 Oct;174(10):1614-21. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25156523	
	Paasche-Orlow MK. (2005). The Challenges of Informed Consent for Low-Literate Populations. In Understanding Health Literacy. Schwartzberg JG, VanGeest JB, Wang CC, Editors. AMA Press, 119-140.	PDF is available in course Resources section for download.
Interpretation and translation	Flores G, Abreu M, Barone CP, Bachur R, Lin H. Errors of medical interpretation and their potential clinical consequences: a comparison of professional versus ad hoc versus no interpreters. *Annals of emergency medicine.* Mar 14 2012. Available at: https://www.ncbi.nlm.nih.gov/pubmed/22424655	
	Patient safety for patients with limited English proficiency. Available at: http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/lep/	

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
	Working with Medical Interpreters. Available at: http://www.health.state.mn.us/divs/idepc/refugee/guide/11interpreters.pdf	
Communicating with patients who are deaf or hard of hearing	ADA Business Brief: Communicating with persons who are Deaf or Hard of Hearing in Hospital Settings. Available at: http://www.ada.gov/hospcombrprt.pdf	PDF is available in course Resources section for download.
	Communicating with People with Hearing Loss. Available at: http://www.ucsfhealth.org/education/communicating_with_people_with_hearing_loss/	
NQF Safe Practices	National Quality Forum Safe Practices for Better Healthcare – 2010 Update. Safe Practice 4: Informed Consent. Available at: https://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_2010_Update.aspx	PDF is available in course Resources section for download.
Teach-back	Always Use Teach-back! Training toolkit. Available at: http://www.teachbacktraining.org/	
	Frequently Asked Questions About Teach-Back	PDF is available in course Resources section for download.
	Schillinger, D., Piette, J., Grumbach, K., Wang, F., Wilson, C., Daher, C., Bindman, A. B. (2003). Closing the loop: physician communication with diabetic patients who have low health literacy *Arch Intern Med, 163*(1), 83-90. Available at: https://www.ncbi.nlm.nih.gov/pubmed/12523921	This resource is also listed in the **Health literacy and informed consent** section.
	Fink, A. S., A. V. Prochazka, W. G. Henderson, D. Bartenfeld, C. Nyirenda, A. Webb, D. H. Berger, K. Itani, T. Whitehill, J. Edwards, M. Wilson, C. Karsonovich, and P. Parmelee. (2010). Predictors of comprehension during surgical informed consent. *Journal of American College of Surgeons* 210:919-926. Available at: https://www.ncbi.nlm.nih.gov/pubmed/20510800	This resource is also listed in the **Health literacy and informed consent** section.

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
	Paasche-Orlow M. Caring for patients with limited health literacy: a 76-year-old man with multiple medical problems. JAMA. 2011 Sep 14; 306(10):1122-9. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21828309	
	Schenker Y, Fernandez A, Sudore R, Schillinger D. (2011). Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. Med Decis Making; 31(1):151-73. Available at: https://www.ncbi.nlm.nih.gov/pubmed/20357225	
Strategies for Presenting Choices		
Engaging patients, families and friends	AHRQ Tool 4: Communicate Clearly (Health Literacy Universal Precautions Toolkit, 2nd Edition). Available at: http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool4.html	PDF is available in course Resources section for download.
	AHRQ Tool: 14: Encourage Questions (Health Literacy Universal Precautions Toolkit, 2nd Edition). Available at: http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool14.html	PDF is available in course Resources section for download.
	AHRQ Guide to Patient and Family Engagement in Hospital Quality and Safety. Available at: http://www.ahrq.gov/professionals/systems/hospital/engagingfamilies/index.html	
	Visualizing Health. Site offering free evidence-based tools for generating graphics to communicate about risks and benefits of medical treatments. Available at: http://www.vizhealth.org	Please refer to the website for specific language when using an image, you wish to use or adapt from the site.

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
	"I Wish I Had Asked That!" worksheet for patients. Available at: http://cdn-www.informedmedicaldecisions.org/imdfdocs/Patient_Visit_Guide.pdf http://www.informedmedicaldecisions.org/thoughtleadership/foundationblog/december-2012/i-wish-i-had-asked-that-a-new-worksheet-for-patie.aspx	
Evaluating patient decision aids	International Patient Decision Aids Standards Instrument. Available at: http://www.ipdasi.org/	
Evaluating patient education materials	The Patient Education Materials Assessment Tool (PEMAT). Available at: www.ahrq.gov/pemat	PDF is available in course Resources section for download.
Decision aids	The Ottawa Personal Decision Guide. Available at: http://decisionaid.ohri.ca/docs/das/OPDG.pdf	PDF is available in course Resources section for download.
	Option Grids: Available at: http://www.optiongrid.org/ Free Registration is required.	
	Kinnersley P, Phillips K, Savage K, Kelly MJ, Farell E, Morgan B, Whistance R, Lewis V, Mann MK, Stephens BL, Blazeby J, Elwyn G, Edwards AGK (2013). Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures (Review) The Cochrane Library, Issue 7. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009445.pub2/abstract;jsessionid=2DDE307A1BAFD543100D5255BB5D8240.f01t01	

Listing of All Resources for Informed Consent Healthcare Professionals Module (by topic) (rev 7/13/16)

Topic	Resource	Notes
Online databases of decision aids	Ottawa Health Resources Institute Decision Aid inventory. Available at: https://decisionaid.ohri.ca/	
	Mayo Clinic decisions aids. Available at: http://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/	
Bridging cultural differences	Carrese JA, Rhodes LA. Bridging cultural differences in medical practice. The case of discussing negative information with Navajo patients. *J Gen Intern Med.* Feb 2000;15(2):92-96. Available at: https://www.ncbi.nlm.nih.gov/pubmed/10672111	
Shared decision making	The SHARE Approach. Available at: http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/	
	Six Steps of Shared Decision Making (for providers): http://cdn-www.informedmedicaldecisions.org/imdfdocs/SixStepsSDM_CARD.pdf	PDF is available in course Resources section for download.
	Informed Medical Decisions Foundation website. Available at: http://www.informedmedicaldecisions.org/	
Being part of a team	Blank Informed Consent Team Roles and Responsibilities Table	Document is available in course Resources section for download.
	TeamSTEPPS 2.0: Core Curriculum. Available at: http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/index.html	