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# Making Informed Consent an Informed Choice:

## Training for Health Care Leaders



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

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*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



## 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:

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



# Course Contents

## 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: Crafting and disseminating your informed consent policy

**Purpose:** Assess current policies, and develop and disseminate improved policies on informed consent

## Section 3: Building systems to improve the informed consent process

**Purpose:** Describe systems and resources that need to be put into place to support the effort to improve the informed consent process

### Important

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.



## 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 1: Principles of Informed Consent

When "informed" consent is NOT informed



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

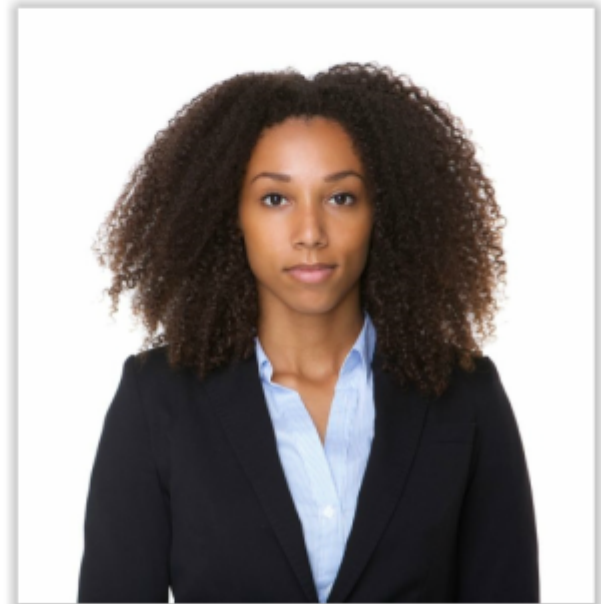
*Video (from the health literacy kit) - Copyright 2007 American Medical Association Foundation and American Medical Association*

## 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:

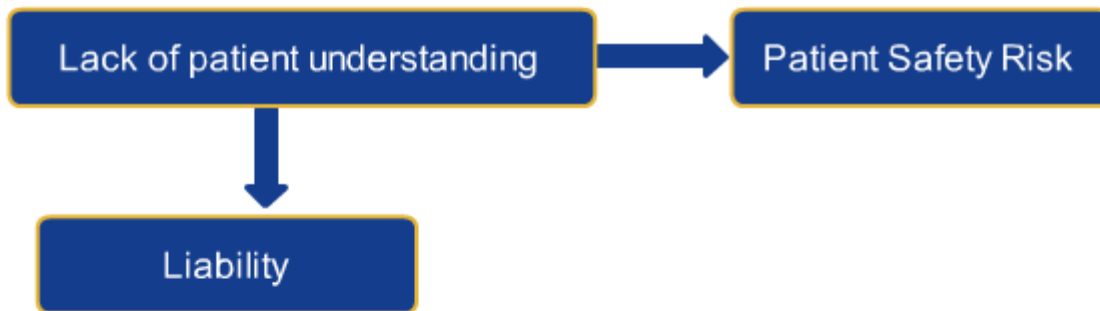
- Make care decisions
- Receive adequate disclosure
- Choose treatment options
- Refuse medical intervention
- Withdraw consent



## 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



Re

### What is a lack of capacity?

incapacity  $\neq$  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  $\neq$  having conditions that make it harder to communicate or make decisions

**Lack of Capacity**

**Authorized Representative**

**Adequate Disclosure**

*Select each principle for additional information.*



## 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:

- A 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

*Select each principle for additional information.*

## 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 (Continued)

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



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

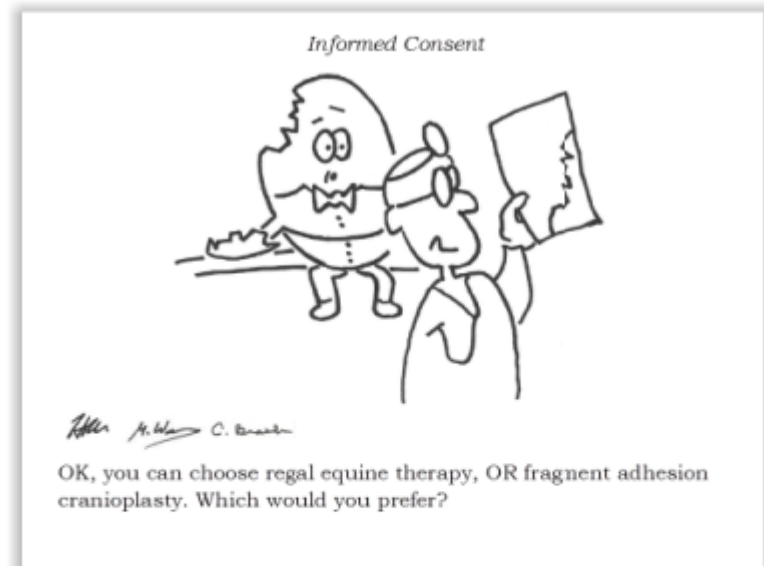


Informed Choice

**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.



*Click on the image to enlarge it*

## *Informed Consent*



*Miller M. Wang C. Brach*

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

## Section 2: Crafting and Disseminating Your Informed Consent Policy

Why focus on a hospital's informed consent **policy**?

Hospitals with no policy on informed consent or a poor policy can:

- Be found to be out of compliance with accreditation standards
- Fail to obtain informed consent in accordance with hospital policy
- Provide insufficient detail for clinicians to implement hospital policy

## Section 2: Crafting and Disseminating Your Informed Consent Policy

Frequently asked questions about hospitals' policies on informed consent:

- What are the appropriate processes to follow in obtaining informed consent and documenting signatures of physicians, patients, and witnesses?
- How far in advance can we obtain informed consent?
- What are the language requirements on consent forms? For example, is the use of nontechnical terms required? Can English-language forms be used for persons with limited English proficiency (LEP)?
- How should we engage representatives authorized to make decisions on behalf of patients?
- How can we obtain informed consent for children?
- What are the appropriate practices for explaining and documenting the benefits, harms, and risks of treatment alternatives?
- To what extent do patients have the right to refuse care?

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent Policy Audit Exercise

To conduct a review of your informed consent policy, you will need:

- Your hospital's informed consent policy
- The Informed Consent Policy Worksheet

[No policy?](#)

- Double-check
- Create one

Informed Consent Policy Improvement Task Force should include:

- Legal
- Risk management
- Medical
- Patients

[Informed Consent  
Policy Worksheet](#)



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

# Informed Consent Policy Worksheet

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

# Informed Consent Policy Worksheet

Policy Component	Does your policy:	What improvements are needed, if any?
<p>6. Content of an informed consent discussion</p>	<p>Include information regarding the content of an informed consent discussion?</p> <p>Specify that the discussion should include:</p> <ul style="list-style-type: none"> <li>• Patient’s condition and need for tests/ treatments/ procedures?</li> <li>• Description of all feasible options (i.e., possible tests/treatments/ procedures)?</li> <li>• Who will perform and their experience?</li> <li>• Probable benefits and harms               <ul style="list-style-type: none"> <li>○ Anticipated results</li> <li>○ Temporary discomfort, disability or disfigurement</li> <li>○ Probable complications</li> <li>○ Any permanent results</li> </ul> </li> <li>• Risks, including remote but severe risks?</li> <li>• Option of getting no treatment, and its benefits, harms, and risks?</li> <li>• Any plans the care team has to film, photograph, or record?</li> <li>• Encourages questions?</li> <li>• Teach-Back to check understanding?</li> </ul>	
<p>7. Documentation of consent</p>	<p>Clearly state:</p> <ul style="list-style-type: none"> <li>• Which procedures are covered by blanket consent?</li> <li>• When a signature is required?</li> <li>• What documentation is needed for verbal consent and by whom?</li> </ul>	



# Informed Consent Policy Worksheet

Policy Component	Does your policy:	What improvements are needed, if any?
8. Verification of consent	Specify who is accountable for verifying consent discussions that have taken place outside the hospital?	
9. Exceptions to informed consent	<p>Clearly enumerate exceptions, such as treatment that is legally-mandated/ court-ordered or a patient asks not to be informed?</p> <p>Does it define what constitutes an emergency?</p> <p>Does it specify when a patient is considered incapacitated?</p>	
10. Informed consent for minors	<p>Clearly define:</p> <ul style="list-style-type: none"> <li>• Who is a mature minor?</li> <li>• What services minors can consent to?</li> <li>• When clinicians should seek assent by minors?</li> </ul>	
11. Clear communication	<p>Include information regarding clear communication to ensure understanding?</p> <p>Foster a culture of clear communication by highlighting the importance of:</p> <ul style="list-style-type: none"> <li>• Using plain language, clear and simple forms, high-quality decision aids, and graphics and other educational materials?</li> <li>• Always using teach-back to verify comprehension?</li> <li>• Accommodating patients' communication needs with professionally translated forms, language assistance, visual aids, or reading assistance?</li> </ul>	

# Informed Consent Policy Worksheet

Policy Component	Does your policy:	What improvements are needed, if any?
12. Compliance	Comply with: <ul style="list-style-type: none"> <li>• Federal, State and local laws?</li> <li>• Regulations (e.g. CMS rules)?</li> <li>• Accreditation standards?</li> </ul>	
13. Enforcement	Include information regarding enforcement?  Clearly state who to call if someone observes a violation of the policy?	
14. Periodic Policy Review	Specify: <ul style="list-style-type: none"> <li>• A review schedule?</li> <li>• Who should review the policy?</li> <li>• How often it should be reviewed?</li> </ul>	
15. Dissemination	How does your hospital inform patients and clinicians about its informed consent policy?  What other channels could be used to better disseminate this information? (e.g.: online, brochures, information sheets, posters, trainings, patient/family-centered networks?)	

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Statement of Purpose and Summary of Principles

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

Wellness Hospital  
Informed Consent Policy

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

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


Wellness Hospital  
Informed Consent Policy

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

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Statement of Purpose and Summary of Principles

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

Wellness Hospital

Select the button to see an example policy from a fictional hospital 

### Wellness Hospital Informed Consent Policy

Pur  
me  
for

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

Patients have the right to:

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

Im

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Who Can Obtain Informed Consent

All policies should indicate who can obtain informed consent.

- The physician, independent nurse practitioner or independent physician assistant in charge who orders a test, prescribes a treatment, or performs a procedure is responsible for the informed consent process.
- Other staff members can play a supporting role.
- In many facilities: staff members are confused about who can play what role.

Wellness Hospital  
Informed Consent Policy

*Select the button to see the example policy*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Who Can Obtain Informed Consent

All policies should indicate who can obtain informed consent



e

- **Wellness Hospital Informed Consent Policy**

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

- 1. The physician, independent nurse practitioner or independent physician assistant who orders a test, prescribes a treatment, or performs a procedure is responsible for holding an informed consent discussion with the patient and for ensuring that the patient understands the potential benefits, harms, and risks and chooses the test, treatment, or procedure over alternatives.
- 2. Anesthesiologists are responsible for holding a separate consent discussion with the patient that is focused on anesthesia.
- 3. Nurses and residents may prepare a patient for informed consent discussions by holding education sessions with the patient about their condition and what tests, treatments, or procedures they can consider.
- 4. While more than one team member may provide information to the patient about a treatment or procedure, the physician, independent nurse practitioner or independent physician assistant in charge is responsible for ensuring the coordination and consistency of information given to the patient.

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Procedures that Require Explicit Consent

Certain procedures require explicit consent. A policy should list what those procedures are.

Wellness Hospital  
Informed Consent Policy

*Select the button to see an example policy.*

All surgeries, invasive procedures or treatments involving risk, such as cardiac catheterizations, lumbar punctures, biopsies, blood transfusion, PICC and central line placement, anesthesia, and administration of medicines, require explicit consent.



### Did You Know?

Explicit consent does not always require a patient's signature.

### Important



Review your institution's policy to ensure it addresses other situations that require informed consent such as group practice consents that cover multiple partners in a practice (e.g. group OB practice) and multiple surgeries or procedures scheduled (e.g. tumor biopsy and possible tumor removal or de-bulking).

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Timing of Informed Consent Discussion

A policy should explain that the informed consent discussion should occur:

- Before the test, treatments, or procedure, and
- With enough advance time for the patient to process the information.

Wellness Hospital  
Informed Consent Policy

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

### Timing of Informed Consent Discussions

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



## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.

Need

Options

Who Performs?

Probable Benefits,  
Harms, and Risks

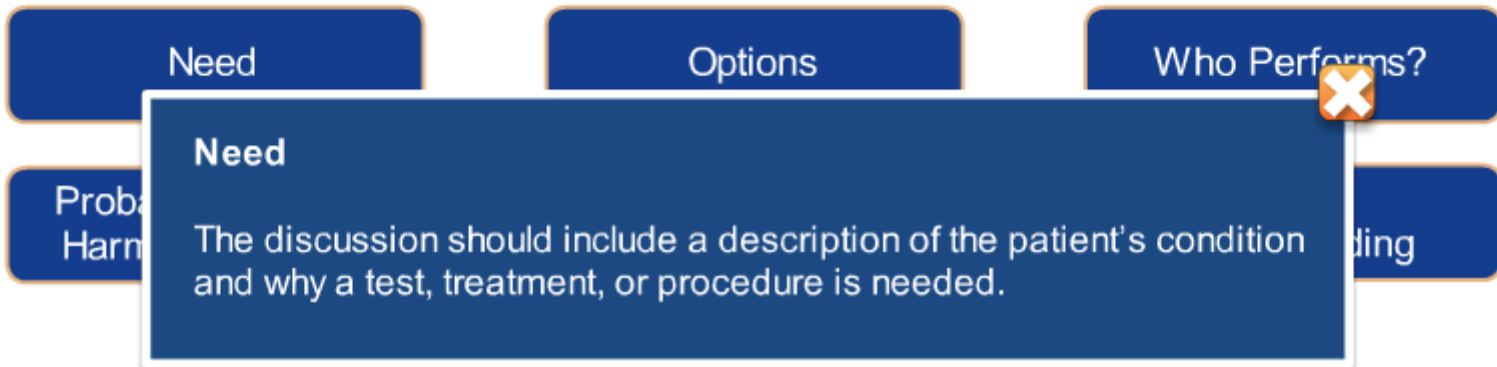
Questions

Check  
Understanding

*Select each item for additional information.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.



*Select each item for additional information.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.

### Options

The discussion should include a description of all feasible options (i.e., possible tests/treatments/procedures)

The policy should direct physicians, independent nurse practitioners or independent physician assistants to let patients know that they can choose to have no treatment, and discuss the benefits, harms, and risks related to no treatment.

Select

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.

### Who Performs?

The policy should address informing the patient about:

- Who will perform the test, treatment, or procedure, including members of the team who will be performing major tasks; and
- In the case of surgery, how many times the surgeon has performed a given procedure in the past year and in their lifetime.

Select each item for additional information.

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.

### Probable Benefits, Harms, and Risks

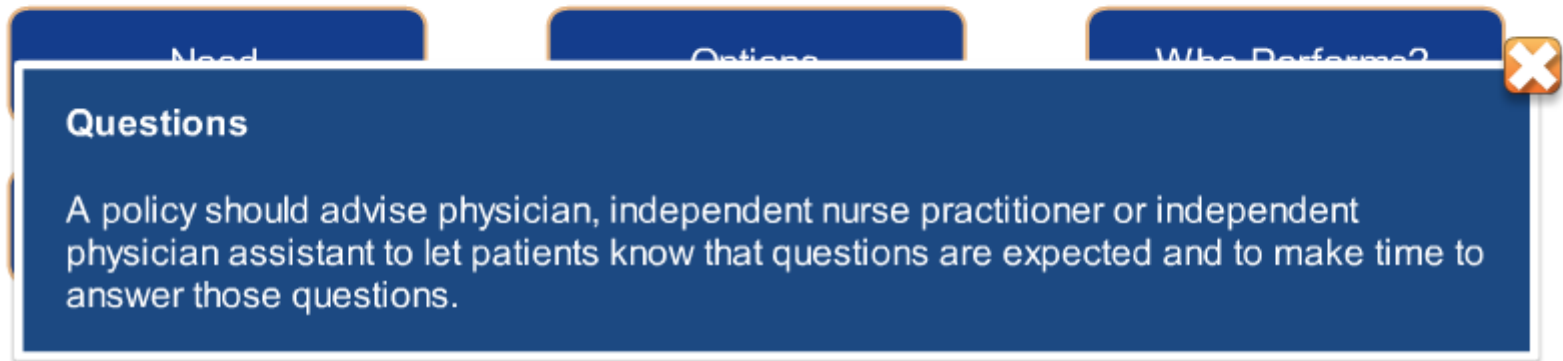
The policy should address discussing probable benefits and harms, including:

- Anticipated results
- Temporary discomfort, disability or disfigurement
- Probable complications
- Any permanent results
- Explain all foreseeable risks, including remote but severe risks

Select e

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.



Need Options Who Performs?

### Questions

A policy should advise physician, independent nurse practitioner or independent physician assistant to let patients know that questions are expected and to make time to answer those questions.

*Select each item for additional information.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Content of an Informed Consent Discussion

Informed consent policies will vary depending on state laws, but should contain at least the following information regarding the content of an informed consent discussion.

Need

Options

Who Performs?

### Check Understanding

Policies should include a requirement to check patient understanding, by using a method such as teach-back.

*Select each item for additional information.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Documentation and Verification of Consent

A policy should contain documentation of consent information such as:

- Which procedures:
  - Are covered by blanket consent
  - Require verbal consent
  - Require written consent
- How to document:
  - Notes in medical records
  - Signatures, including interpreters
- Special considerations:
  - Standard forms for recurring care such as radiation therapy or chemotherapy
  - How to verify and document consent that occurred outside your hospital

Wellness Hospital  
Informed Consent Policy

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





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## Wellness Hospital Informed Consent Policy

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

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

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

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

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

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## Section 2: Crafting and Disseminating Your Informed Consent Policy: Exceptions to Informed Consent

A hospital's policy should list exceptions to informed consent. These situations may include:

- Certain emergencies
- Incapacitated patient (a surrogate can consent)
- Minors
- Treatment that is legally-mandated or court-ordered
- Patient asks not to be informed



The resources section cites a legal reference book by Fay Rozovsky that provides extensive information on this and other informed consent topics.

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Exceptions to Informed Consent (Continued)

The policy should also include instructions on what to do for an exception, such as:

- If time allows and treatment is not mandated, by law or by a court, identify a surrogate decision maker.
  - Give priority to persons named in health proxies or hold power-of-attorney.
  - Specify rules/hierarchy of potential decision makers; and
- Keep communicating with the patient about his or her treatment even if the patient cannot communicate or consent to care, unless the patient has asked not to be informed.



Spouse                      Patient



Adult children



Sibling



Medical team

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent for Minors

A hospital's general policy on informed consent regarding minors should:

- Define when parental consent is required.
- Seek assent from minor when possible. Consider:
  - Giving teens (about age 14+) information similar to that given to their parents or guardian, and
  - Explaining to younger children (about age 7+) what the experience will be, how it may help, how long it will take, and whether it may be painful or uncomfortable.




*Select the image for a real-life example.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent for Minors

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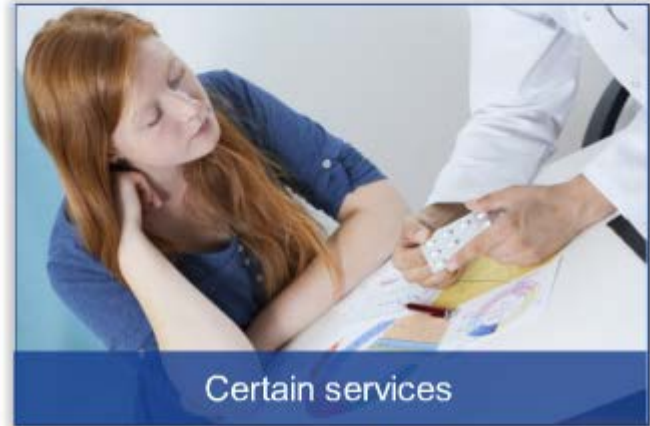
 A 14-year-old was distressed upon learning a PICC line went to her heart, so she pulled it out on her own.

*Select the image for a real-life example.*



## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent for Minors (Continued)

A policy should note exceptions to the rule that minors cannot consent. These may include:



*Select each image for additional information.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent for Minors (Continued)

A policy should note exceptions to the rule that minors cannot consent. These may include:



### Mature minors

- Some states allow mature minors to consent to treatment without their parents' involvement.
- Definitions of "mature minors" vary between states.
- Your policy should define who should be considered a mature minor on the basis of:
  - Age,
  - Marital or parental status,
  - Cognitive capacity, and
  - Social maturity.

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent for Minors (Continued)

A policy should note exceptions to the rule that minors cannot consent. These may include:



*Select each image for additional information.*

### Minor parents

Minors who are parents generally have the right to consent to care on behalf of their children.





## Section 2: Crafting and Disseminating Your Informed Consent Policy: Informed Consent for Minors (Continued)

A policy should note exceptions to the rule that minors cannot consent. These may include:



### Certain services

Some states allow minors to consent to certain services without involvement by their parents, such as:

- Reproductive health care, and
- Substance abuse treatment.



## Section 2: Crafting and Disseminating Your Informed Consent Policy: Clear Communication Policies

A hospital's informed consent policy should foster a culture of clear communication to ensure that patient consent is informed. Highlight the importance of:

- Using plain language, clear and simple forms, high-quality decision aids, and graphics and other educational materials.
- Always using teach-back to verify comprehension.
- Accommodating patients' communication needs with professionally translated forms, language assistance, visual aids, or reading assistance.

Wellness Hospital  
Informed Consent Policy

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



*Select the image of Magda to hear how she avoided accidental sterilization.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Clear Communication Policies

A hospital's informed consent policy should foster a culture of clear communication to ensure that patient consent is informed. Highlight the importance of:



### Wellness Hospital Informed Consent Policy

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

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

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

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## Section 2: Crafting and Disseminating Your Informed Consent Policy: Clear Communication Policies

A hospital's informed consent policy should foster a culture of clear communication to ensure that patient consent is informed. Highlight the importance of:

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- Always using teach-back to verify comprehension.
- Accommodating patients' communication needs with professionally translated forms, language assistance, visual aids, or reading assistance.

Wellness Hospital  
Informed Consent Policy

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



*Select the image of Magda to hear how she avoided accidental sterilization.*

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Compliance and Enforcement

A hospital's policy must

- Comply with:
  - Federal, state, and local laws
  - Regulations (e.g., Medicare rules)
  - Accreditation standards
- Include a point of contact for enforcement with a clear process for
  - Referring complaints
  - Quality improvement
  - Disciplinary action

Wellness Hospital  
Informed Consent Policy

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

### Questions, Concerns or Complaints:

- Everyone at Wellness Hospital is responsible for following this informed consent policy. If you have questions or concerns, or to report that this policy is not being followed, please call 1.800.xxx.xxx or visit [informedconsent.wellnesshospital.net](http://informedconsent.wellnesshospital.net).



## Section 2: Crafting and Disseminating Your Informed Consent Policy: Periodic Review of Informed Consent Policy

Plan for periodic review of the hospital's informed consent policy. To do this, you should:

- Indicate the time frame
- Designate people who are responsible for review
- Date-stamp the policy

Wellness Hospital  
Informed Consent Policy



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

## Section 2: Crafting and Disseminating Your Informed Consent Policy: Periodic Review of Informed Consent Policy

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### Wellness Hospital Informed Consent Policy

#### Policy Review Schedule:

This policy shall be reviewed and updated at least every two years by the Patient Safety Officer, the Director of Risk Management, and others appointed by the Directors of Quality and Patient Experience.

Review policy in light of:

- New legal or ethical doctrines
- New evidence (e.g., which procedures are risky)
- Hospital experience



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## Section 2: Crafting and Disseminating Your Informed Consent Policy: Disseminating the Hospital's Policy on Informed Consent

Use multiple methods to disseminate your hospital's policy to both patients and clinicians, such as the following:

- Hospital's website
- Posters
- Trainings and orientation for clinicians
- Plain-language brochures in multiple languages distributed upon admission
- Hospital's patient- and family-centered care networks
- Hospital's online patient social networks



**Resources**

*Select the Resources button to learn more.*



## Section 2: Crafting and Disseminating Your Informed Consent Policy: Disseminating the Hospital's Policy on Informed Consent

Use multiple methods to disseminate your hospital's policy to both patients and clinicians, such as the following:

- Hospital's website
  - In the Resources section of this course, you will find:
    - General and legal references to help you craft your informed consent policy, and
    - Examples of brochures informing patients of their rights.
- Hospital's patient- and family-centered care networks
- Hospital's online patient social networks

[Resources](#)

*Select the Resources button to learn more.*



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

To make informed consent an informed choice, clinicians need supportive systems that include:

- Maintaining a library of clear and simple informed consent forms
- Maintaining a library of high-quality decision aids and other patient education materials
- Removing communication barriers by:
  - Providing language assistance (e.g., qualified medical interpreters)
  - Stocking assistive communication devices
- Establishing efficient workflows
- Training staff at all levels



[Systems Worksheet](#)

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

# Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
<b>Supportive System #1. Library of plain-language informed consent forms</b>	<p>A single centralized library of standardized informed consent forms?</p> <p>Does it include forms for <b>all</b> tests, procedures, and treatments that require a written informed consent?</p> <p>Is each form listing the appropriate benefits, harms, and risks with no unnecessary information?</p> <p>Has each form been checked for:</p> <ul style="list-style-type: none"> <li>• Comprehensiveness?</li> <li>• Accuracy?</li> <li>• Incorporation of latest evidence?</li> <li>• Adherence to health literacy principles?</li> <li>• Understandability?</li> </ul> <p>Have forms been professionally translated into languages commonly spoken by your patients?</p> <p>Have forms been tested with a sample of diverse patients including patients who have a vision impairment?</p> <p>Is someone charged with maintaining the library?</p> <p>How are the forms distributed or accessed by clinicians?</p> <p>Is there a process for approving new forms and periodically reviewing and updating approved forms?</p> <p>How are staff notified when a form is changed?</p>	
<b>Supportive System #2. Library of high-quality decision aids and patient education materials</b>	<p>A single centralized library of high-quality decision aids and patient education materials?</p>	

# Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
	<p>Is the library comprehensive (i.e., include materials for all common tests, treatments, and procedures)?</p> <p>Has each material in the library been assessed for quality, verifying that it:</p> <ul style="list-style-type: none"> <li>• Comes from a reliable source</li> <li>• Is complete                             <ul style="list-style-type: none"> <li>○ All feasible options</li> <li>○ Benefits, harms, and risks</li> <li>○ Option of no treatment</li> </ul> </li> <li>• Is based on up-to-date scientific evidence</li> <li>• Is unbiased</li> <li>• Is understandable                             <ul style="list-style-type: none"> <li>○ Health literacy strategies</li> <li>○ Multiple languages</li> <li>○ Moderately paced and distinct audio</li> </ul> </li> <li>• Clarifies patient’s goals and values</li> </ul> <p>Have forms been tested with a sample of diverse patients including patients who have a vision impairment?</p> <p>Is someone charged with identifying materials and maintaining the library?</p> <p>How are the forms distributed or accessed by clinicians?</p> <p>Is there a process for approving new materials and periodically reviewing and updating them?</p> <p>How are staff encouraged to use the materials?</p>	
<b>Supportive System #3. Removing Communication Barriers</b>	<p>Have a:</p> <ul style="list-style-type: none"> <li>• Systematic and accurate way to identify patients’ preferred language?</li> </ul>	

# Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
	<ul style="list-style-type: none"> <li>System to verify language skills of bilingual staff?</li> <li>System to access qualified medical interpreters 24/7, including sign languages interpreters?</li> </ul> <p>Is someone charged with planning for and implementing language assistance?</p> <p>Is the necessary communication equipment acquired and maintained (e.g., dual handset phones, video interpreting equipment, devices for sound amplification and magnifying readers)?</p> <p>Are staff trained on when and how to access interpreters and other communication supports?</p>	
<b>Supportive System #4. Clear, efficient workflows for informed consent</b>	<p>Have clear, efficient workflows for informed consent?</p> <p>A process that meets the letter <b>and</b> the spirit of your hospital's informed consent policy?</p> <p>Is your process easy for patients?</p> <p>Does it take into account the diversity of patients?</p> <p>Is your process efficient?</p> <p>Have roles of each staff member been unambiguously assigned?</p>	

# Informed Consent Systems Worksheet

Systems Component	Does your hospital have:	What improvements are needed, if any?
<p><b>Supportive System</b> <b>#5. Staff Training</b></p>	<p>Training for all staff on informed consent principles and hospital policy?</p> <p>Do you provide training on strategies for clear communication, such as:</p> <ul style="list-style-type: none"> <li>• Preparation for the informed consent discussion</li> <li>• Health literacy universal precautions</li> <li>• Language preference identification and when to use interpreters</li> <li>• Teach back</li> </ul> <p>Is there training that addresses strategies for presenting choices, including:</p> <ul style="list-style-type: none"> <li>• Informed consent principles and hospital policy?</li> <li>• Strategies for clear communication?</li> <li>• How to offer choices and explain benefits, harms and risks of all options?</li> <li>• Engaging patients and family members?</li> <li>• Eliciting goals and values?</li> <li>• Using decision aids and patient education materials?</li> </ul> <p>Are all responsible staff members training on how to properly document informed consent?</p>	

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms

A hospital should have clear and simple forms for informed consent that:

- Cover tests, treatments, and procedures requiring a signed form
- Create a roadmap for the informed consent discussion
- Are professionally translated into common languages
- Follow health literacy principles of
  - Plain language
  - Logical flow of information
  - Informative headings
  - Clear layout



### Important !

A signature on a form that the patient has NOT understood does **NOT**:

- Document informed consent, or
- Protect you or your hospital from liability.

What does an informed consent that follows health literacy principles look like?

Before

After

*Select both the Before and After buttons.*



# Where We Started

## AUTHORIZATION FOR THE PERFORMANCE OF SURGICAL AND OTHER PROCEDURES

1. I, (Name of Patient), \_\_\_\_\_ and/or such other doctors he/she may designate, to perform or assist in the performance of the following operations or procedures: \_\_\_\_\_
  
- I also authorize the performance of any other operations/procedures which my doctor(s) and/or whomever he/she designates, considers necessary or advisable for my welfare because of conditions presently unforeseen.
2. \_\_\_\_\_ has explained to my satisfaction:
  - a. Name of Physician \_\_\_\_\_
  - b. The procedure(s) or operation(s) to be performed.
  - c. The risks and benefits reasonably anticipated by undergoing this procedure or operation, including the possible consequences and complications.
  - d. The risks reasonably anticipated by not undergoing this procedure or operation, including the possible consequences and complications.
  - e. Any reasonable alternatives to this method of treatment and that the choice to undergo or not undergo the procedure or operation is mine alone.
  - f. I have also been informed that there are other risks such as loss of life, loss of blood, infection, cardiac arrest, damage to teeth, etc., that are attendant to the performance of any surgical or anesthetic procedure.
3. I have received all the explanation that I wish to receive and I have been given the opportunity to ask questions of the physician regarding the procedure and I have no further questions. I do hereby assume all risks involved. No guarantee or assurance of success of the procedure has been given to me by anyone.
4. I consent to the administration of anesthesia to be applied by the physician responsible for this service, who is not an employee or agent of the hospital, and to the use of such anesthetic as may be deemed advisable, with the exception of \_\_\_\_\_
5. I consent to one or more transfusions of blood/blood components, if my doctor(s) determines this to be necessary.
6. I authorize the scientific preservation, use and disposal of any tissue or organs, amputated parts, or foreign objects that may be removed during the operation. Disposal will be at the discretion of the hospital pathologist or my doctor(s).
7. For the purposes of advancing scientific knowledge or medical education or providing product/equipment technical assistance, and at the discretion of my doctor(s), I consent to the following:
  - a. The photographing or televising of the procedure or operation being performed upon me as long as my identity is not revealed in any way.
  - b. The admittance of observers, including product/equipment manufacturer representatives, to the operating room to view the procedure being done on me. The representatives will at no time participate in the operative procedure.

Upon signing this form, I acknowledge that I have read and understand the foregoing authorization. Any parts in this authorization to which I do not consent have been crossed off and initialed by me. Any exceptions to the above authorization have been entered and initialed by me.

Signature of Patient or Authorized Person \_\_\_\_\_ Relationship/interpreter to Patient (if appl) \_\_\_\_\_  
 A.N.  
 Witnessed by: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ P.M.  
 Patient is unable to sign consent because \_\_\_\_\_

**Original:  
 Readability  
 score of 16+  
 (grade level)**

*Iowa Health System example,  
 IOM Roundtable on Health Literacy,  
 April 2013*



Best Outcome for Every Patient Every Time







# Where We Are

## 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

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

After: Readability Score of 7 - 8 (Grade level)

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)

### Where to obtain clear and simple forms

To build a library of informed consent forms, you can:

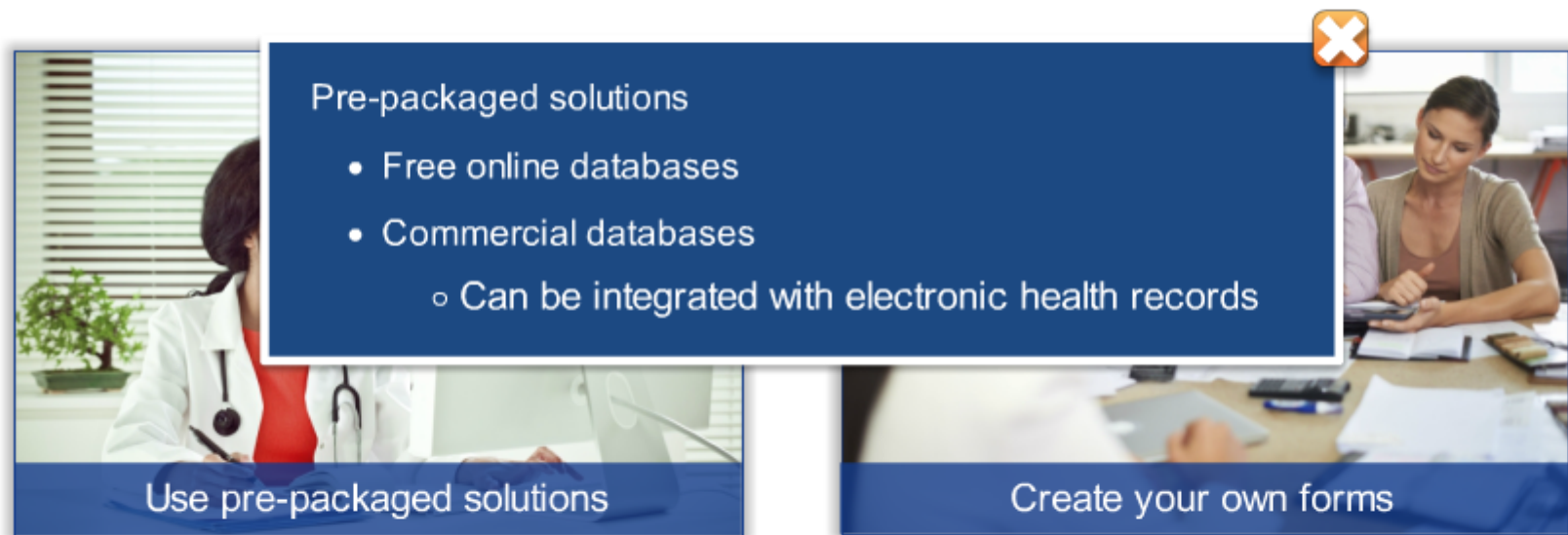


*Select both images for additional information.*

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)

### Where to obtain clear and simple forms

To build a library of informed consent forms, you can:



Pre-packaged solutions

- Free online databases
- Commercial databases
  - Can be integrated with electronic health records

Use pre-packaged solutions

Create your own forms

*Select both images for additional information.*

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)

### Where to obtain clear and simple forms

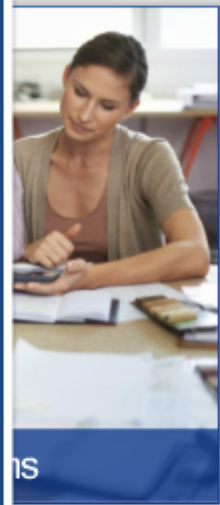
To build a library



Use pre

Create your own forms by:

- Consulting writing guides
- Using health literacy experts
- Educating and collaborating with lawyers or risk managers
- Involving clinicians
- Getting patient and family input
- Pilot testing before roll-out
- Updating forms on a regular basis



ns

*Select both images for additional information.*

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)

### Where to obtain clear and simple forms

To build a library of informed consent forms, you can:



Use pre-packaged solutions

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

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



Create your own forms

*Select both images for additional information.*

**Resources**

*Select the Resources button to learn more.*



## **Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms (Continued)**

*Select the image of Mary Ann Abrams (not a model) to learn how the Iowa Health System developed reader-friendly informed consent forms.*



Mary Ann Abrams

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #1: Create a Library of Clear and Simple Informed Consent Forms

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Iowa Health System leaders noticed that their surgical informed consent forms were complex and hard to read, so the leaders decided to:

- Work with clinicians, health literacy experts, and new readers [adult education students] to make their consent forms more reader-friendly, and
- Use simpler language, encourage discussion, and promote teach-back

As a result:

- More patients read the forms
- A higher proportion of patients were able to describe the procedure in their own words
- Patients felt more comfortable asking questions
- Patients, families, and nurses reported higher levels of satisfaction

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



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials

### Decision aids:

- Provide unbiased information on options, and their expected outcomes, benefits, harms, and risks;
- Come in a variety of formats: paper-based, audio-visual, multimedia, web-based, or interactive; and
- Can be used by patients alone or with clinicians.



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials

### Benefits of using decision aids include:

- Helping clinicians structure conversations about treatment choices
- Improving patients' knowledge of their options
- Giving patients more accurate expectations of possible benefits, risks, and harm
- Helping patients feel more informed and clear about what matters most to them
- Increasing patient participation and communication
- Helping patients weigh the options and reach decisions based on their own goals and values
- Preparing patients to cope with treatment outcomes or adverse events
- Serving as evidence that consent was informed

### Important

Decision aids are NOT a substitute for the informed consent discussion.

**Resources**

*Select the Resources button to learn more.*

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials

### Benefits of using decision aids include:

- Helping clinicians
- Improving
- Giving patients
- Helping patients
- Increasing
- Helping patients understand their options and values
- Preparing patients to cope with treatment outcomes or adverse events
- Serving as evidence that consent was informed

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

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

### Important

Decision aids are NOT a substitute for the informed consent discussion.

[Resources](#)

*Select the Resources button to learn more.*

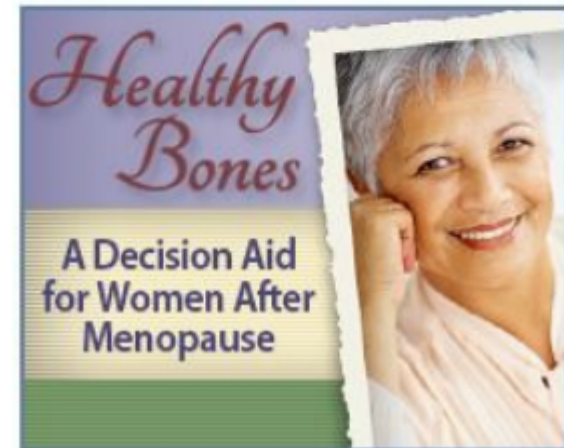
## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)

### Other patient education materials:

- Help patients to understand and remember information about:
  - Their conditions, and
  - The options for tests, treatments, or procedures.
- Do not compare options.

### Find high-quality decision aids and educational materials by:

- Using free online databases
- Buying commercial databases
  - Can be integrated with electronic health records
- Creating your own
  - Test with a diverse range of patients



*Click the image for more details*

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)

**How do you know whether you have a high-quality decision aid?**

Check whether the decision aid:

- Comes from a reliable source
  - With experience
  - With testing history
  - With no vested interest
- Is complete
  - Shows all feasible options
  - Shows benefits, harms, and risks
  - Shows option of no treatment
- Is based on up-to-date scientific evidence
- Is unbiased
- Is understandable
  - Uses health literacy strategies
  - Uses moderately paced and distinct audio
  - Uses multiple languages
- Helps patients to clarify their goals and values

### Important

Test high-quality decision aids with clinicians and a diverse range of patients to make sure they are useful and practical in your hospital.

## **Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #2 - Maintain a Library of High-Quality Decision Aids and Patient Education Materials (Continued)**

### **Administer your library by:**

- Assigning responsibility for maintenance
- Reviewing materials for clinical currency
- Pruning the library accordingly
- Establishing a process for adding new materials
- Notifying staff members
- Encouraging use of the library

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers

**Addressing communication barriers** is an important element in the informed consent process, for these reasons:

- Patients with limited English proficiency are at greater risk of not understanding informed consent.
- Hospitals participating in Medicare or Medicaid are required to take reasonable steps to ensure equal access.
- Failure to provide language assistance is risky for patients and can serve as the basis for lawsuits.



*Select each image for an example of a language barrier.*





## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers

**Addressing communication barriers** is an important element in the informed consent process, for these reasons:

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- Failure to provide language assistance is risky for patients and can serve as the basis for lawsuits.



### The Tran Case.

A 9-year-old girl died from a reaction to the drug Reglan:

- 1) Parents primarily spoke Vietnamese, but no qualified interpreter was used.
- 2) 9-year old patient and 16-year old brother served as interpreters.
- 3) Physician couldn't adequately inform parents about:
  - the side effects and warnings of Reglan use, or
  - the instructions to return to the emergency room for serious side-effects.
- 4) A \$200,000 settlement was awarded to the parents and the insurer paid \$140,000 in legal fees.



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers

**Addressing communication barriers** is an important element in the informed consent process, for these reasons:

- Patients with limited English proficiency are at greater risk of not understanding informed consent.
- Hospitals participating in Medicare or Medicaid are required to take reasonable steps to ensure equal access.
- Failure to provide language assistance is risky for patients and can serve as the basis for lawsuits



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

*Each image for an  
of a language barrier.*



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers

**Addressing communication barriers** is an important element in the informed consent process, for these reasons:

- Patients with limited English proficiency are at greater risk of not understanding informed consent.
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- Failure to provide language assistance is risky for patients and can serve as the basis for lawsuits.



*Select each image for an example of a language barrier.*



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

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers (Continued)

**Strategies to identify patient language include:**

- Informing patients of their right to a free interpreter
- Asking which language they prefer
- Using “I speak” cards, touch-screen menus, or over-the-phone patient language identification

**Important** 

Never let friends, family members, or children serve as the interpreter!



**Options for high quality language assistance:**

**Bilingual staff**

**Bilingual staff as interpreters**

**Qualified medical interpreters**

*Select each button to learn more.*

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers (Continued)

Strategies to identify patient language include:

- Informing patients of their right to a free interpreter
- Asking which language they prefer
- Using “I speak” cards, touch-screen menus, or over-the-phone



**Important** !

Never let friends

**Bilingual staff**

- Verify language skills
- No "getting by" with basic or intermediate language skills

Options for high quality language assistance:

**Bilingual staff**

**Bilingual staff as interpreters**

**Qualified medical interpreters**

*Select each button to learn more.*



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers (Continued)

Strategies to identify patient language include:

- Informing patients of their right to a free interpreter
- Asking which language they prefer
- Using “I speak” cards, touch screen menus, or over-the-phone patient language lines

### Important !

Never let friends, family members, or

### Bilingual staff as interpreters

- Unsafe without training
- Certification
- Consider release time

Options for high quality language assistance:

Bilingual staff

Bilingual staff as interpreters

Qualified medical interpreters

Select each button to learn more.



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers (Continued)

Strategies to identify patient language include:

- Informing patients of their right to a free interpreter
- Asking which language they prefer
- Using “I speak” cards, telephone over-the-phone patient language lines

### Important !

Never let friends, family members

### Qualified medical interpreters

- Staff interpreters
- Language banks
- Telephone medical interpreters
- Video medical interpreters

Options for high quality language services

Bilingual staff

Bilingual staff as interpreters

Qualified medical interpreters

Select each button to learn more.





## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #3: Remove Communication Barriers (Continued)

### Planning language assistance

- Interpreter Services Coordinator
- Provide resources to mobilize qualified interpreters
- Train staff members to call for and work with interpreters
- Procure equipment
  - Dual-handset or speaker telephones
  - Video equipment and connections
  - Assistive devices (sound amplification devices, magnifying readers)
  - Maintain, store, and notify clinicians about equipment

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

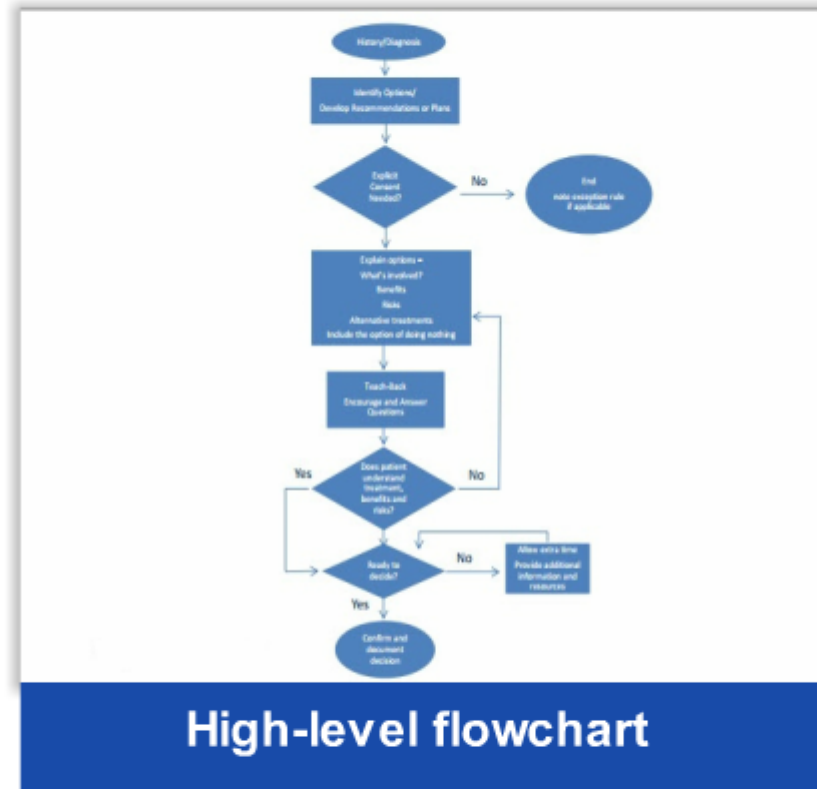
## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #4: Improving Workflows

A workflow map or flowchart can help clarify and improve the informed consent process.

- High-level flowcharts: outline major steps
- Detailed flowcharts: clarify how process steps fit together and who performs them.

When developing a flowchart, you should:

- Make it a group exercise
- Map the process as it is, not as it should be
- Validate through observation
- Work with the clinical team to improve the workflow



Select the flowchart for a larger view.

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

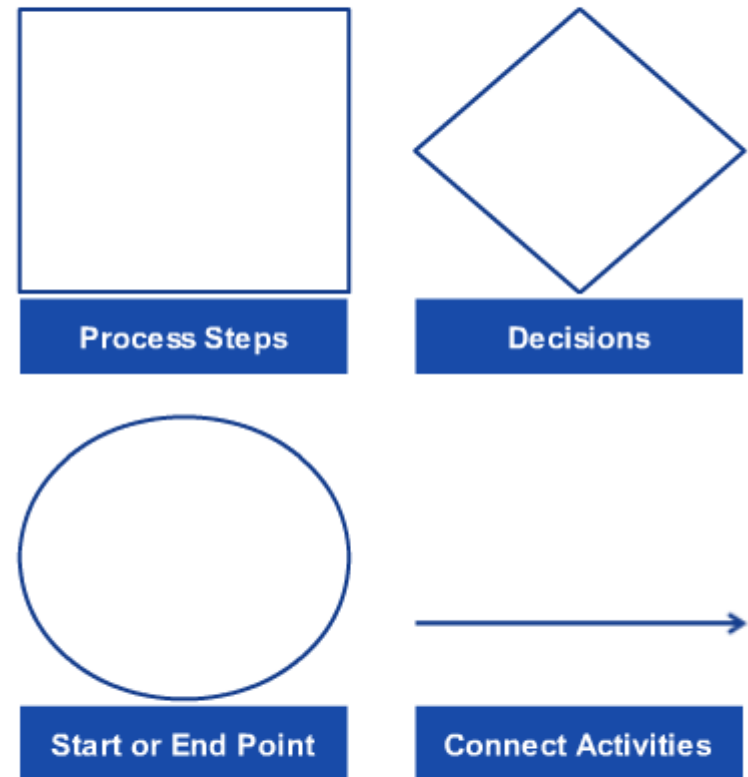
## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #4: Improving Workflows (Continued)

### Flowcharts can clarify:

- the steps in the process, and
- how every team member fits into the process.

### Process map exercise should:

- Include
  - All people involved in the process
  - One person not involved in the process
  - A neutral facilitator
  - A patient advocate
- Map the process as it is
- Validate through observation
- Design a better workflow



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #4: Improving Workflows (Continued)

Addressing the following questions can help you improve your workflow.

*Select each of the images for additional information.*





## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #4: Improving Workflows (Continued)

Addressing the following questions can help you improve your workflow.

*Select each of the images for additional information.*



The Big Picture



Efficiency



Workforce

### The Big Picture

- Is the process in line with the hospital's informed consent policy?
- Does the process guard against errors?
- Can we improve the patient experience with this process?
- Are all the critical steps included?

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #4: Improving Workflows (Continued)

Addressing the following questions can help you improve your workflow.

*Select each of the images for additional information.*



### Efficiency

- Are all steps necessary? Are some duplicative?
- Is there a more logical way to sequence the steps?
- Can some steps be performed simultaneously?
- Is there any technology that would make this process more efficient or easier to perform?
- Can we learn from other units that have a great informed consent workflow?



## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #4: Improving Workflows (Continued)

Addressing the following questions can help you improve your workflow.

*Select each of the images for additional information.*



### Workforce

- What skills are necessary to perform each step?
- Are there any places where it is unclear who is responsible for a particular step?
- Is each step performed by someone with the right skills?
- Can any of the steps be performed by someone with fewer skills? What training would they need?





## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #5: Address Staff Training Needs

**The fifth supportive strategy is addressing staff training needs.**

Building systems should include training all levels of hospital staff about their roles in the informed consent process.

- Hospital leaders should take all the training offered
- Clinicians should take specific training on offering choices and explaining benefits, harms, and risks
- All staff members should take training regarding strategies for clear communication and presenting options
- Train staff on your hospital's policies and resources



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

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

## Addressing Staff Informed Consent Training Needs

Training Topics	Hospital Leader	MD/Independent Nurse Practitioner/ Independent Physician Assistant*	Nurse or Other Clinical Staff	Administrative Staff	Interpreter
Principles of informed consent	√	√	√	√	√
Hospital informed consent policy	√	√	√	√	√
How to support adherence to informed consent policy	√				
Strategies for clear communication					
<ul style="list-style-type: none"> <li>• Preparation for the informed consent discussion</li> </ul>		√	√	√	√
<ul style="list-style-type: none"> <li>• Health literacy universal precautions</li> </ul>		√	√	√	√
<ul style="list-style-type: none"> <li>• Language preference identification, and when to use and how to work with interpreters</li> </ul>		√	√	√	
<ul style="list-style-type: none"> <li>• Teach back</li> </ul>		√	√	√	√
Strategies for presenting choices					
<ul style="list-style-type: none"> <li>• Offering choices</li> <li>• Explaining benefits, harms, and risks of all options</li> <li>• Helping patients decide</li> </ul>		√			
<ul style="list-style-type: none"> <li>• Engaging patients and family members</li> <li>• Eliciting goals and values</li> </ul>		√	√		
<ul style="list-style-type: none"> <li>• Using decision aids and patient education materials</li> </ul>		√	√		
Documentation					
<ul style="list-style-type: none"> <li>• Document informed consent</li> </ul>		√			
<ul style="list-style-type: none"> <li>• Document verification of informed consent</li> </ul>		√	√	√	√

### Key

MD = Physician

Other clinical staff = allied health professionals (e.g. medical assistants, technicians, therapists, educators)

Administrative staff = registration and billing

Hospital leader = C-suite, risk managers, patient safety and quality officers, heads of departments/units

\*Independent Nurse Practitioner/ Independent Physician Assistant is an individual that is permitted by law and by the organization to provide care and services, without direction or supervision

## Section 3: Building Systems to Improve the Informed Consent Process: Supportive System #5: Address Staff Training Needs (Continued)

When offering training, use multiple avenues to train staff, such as the following:

- In-service training for current staff
  - Stand-alone training on informed choice
  - Grand Rounds
  - As part of patient safety or patient-centered care training
  - As part of diversity or anti-discrimination training
- Informal “Lunch and Learn” sessions
- Department or unit meetings
- As part of orientation for new staff
- Incorporated into residency training
- Follow-up with coaching activities



## Course Summary

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

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

The Resources section includes:

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

### Systems Worksheet



What will be your next steps to make informed consent an informed choice in your hospital?

## Conclusion

**Congratulations!**

You have completed

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

If you have any questions about what you have learned in this course, please  
email us at  
[HealthLiteracy@AHRQ.HHS.GOV](mailto:HealthLiteracy@AHRQ.HHS.GOV)

**Listing of All Resources for Informed Consent Leaders Module** (rev 7/21/16)

Topic	Resource	Notes
<b>Principles of Informed Consent/ Crafting and Disseminating your Informed Consent Policy</b>		
<b>General reference on informed consent to treatment</b>	Fleisher L, Miller M, et al. A Practical Guide to Informed Consent. Available at: <a href="http://www.rwjf.org/en/library/research/2009/04/a-practical-guide-to-informed-consent.html">http://www.rwjf.org/en/library/research/2009/04/a-practical-guide-to-informed-consent.html</a>	PDF is available in course Resources section for download.  This resource is also listed in the <b>Free online libraries of informed consent forms</b> section.
	Informed Consent and Health Literacy. Workshop summary. Alper J, Rapporteur. Institute of Medicine. The National Academies Press. Available at: <a href="http://www.nap.edu/catalog/19019/informed-consent-and-health-literacy-workshop-summary">http://www.nap.edu/catalog/19019/informed-consent-and-health-literacy-workshop-summary</a> .	
	The Joint Commission. Informed consent: More than getting a signature. Available at: <a href="https://www.jointcommission.org/issues/article.aspx?Article=5kmqmwV14ugGGireNakQqaCw1iqenpbl1ljAYdRsubU%3d">https://www.jointcommission.org/issues/article.aspx?Article=5kmqmwV14ugGGireNakQqaCw1iqenpbl1ljAYdRsubU%3d</a>	
<b>Informed consent to research</b>	Educational and quality improvement resources on consent to research. Available at: <a href="http://www.hhs.gov/ohrp/education-and-outreach/index.html">http://www.hhs.gov/ohrp/education-and-outreach/index.html</a>	
	AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. Available at: <a href="http://www.ahrq.gov/funding/policies/informedconsent/index.html">http://www.ahrq.gov/funding/policies/informedconsent/index.html</a>	PDF is available in course Resources section for download.
	Guidelines from the Office of Human Subjects Protection. Department of Health and Human Services. Available at: <a href="http://www.hhs.gov/ohrp/humansubjects/commonrule/">http://www.hhs.gov/ohrp/humansubjects/commonrule/</a>	
	Code of Federal Regulations (Title 45 CFR Part 46). Department of Health and Human Services. Available at: <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</a>	

**Listing of All Resources for Informed Consent Leaders Module** (rev 7/21/16)

Topic	Resource	Notes
<b>Informed consent for end-of-life care</b>	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.	
	Washington State Hospital Association. End of Life Care Manual. Section 4: Establishing Policies and Procedures on Advance Directives. Available at: <a href="http://www.wsha.org/our-members/projects/end-of-life-care-manual/section-4-establishing-policies-and-procedures-on-advance-directives/">http://www.wsha.org/our-members/projects/end-of-life-care-manual/section-4-establishing-policies-and-procedures-on-advance-directives/</a>	
<b>Being part of a team</b>	Blank Informed Consent Team Roles and Responsibilities Table	Document is available in course Resources section for download.
	TeamSTEPPS 2.0: Core Curriculum. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/index.html">http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/index.html</a>	
<b>It's not about a form</b>	Macy v. Blatchford Case Law	PDF is available in course Resources section for download.
<b>Informed consent for persons with a lack of capacity</b>	The Macarthur Treatment Competence Study. MacArthur Research Network on Mental Health and the Law. Available at: <a href="http://www.macarthur.virginia.edu/treatment.html">http://www.macarthur.virginia.edu/treatment.html</a>	PDF is available in course Resources section for download.



**Listing of All Resources for Informed Consent Leaders Module** (rev 7/21/16)

Topic	Resource	Notes
	<p>Appelbaum, P. S. (2007). Assessment of patients' competence to consent to treatment. <i>New England Journal of Medicine</i>, 357(18), 1834-1840. Available at: <a href="http://www.nejm.org/doi/full/10.1056/NEJMcp074045">http://www.nejm.org/doi/full/10.1056/NEJMcp074045</a></p>	
	<p>Karlawish, J. (2007). Measuring decision-making capacity in cognitively impaired individuals. <i>Neurosignals</i>, 16(1), 91-98. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/18097164">https://www.ncbi.nlm.nih.gov/pubmed/18097164</a></p>	
	<p>Rozovsky F. Chapter 1: How to obtain consent: The art of consent communication. In: <i>Consent to Treatment: A Practical Guide</i>. 5th ed. New York, NY: Aspen Publishers: Wolters-Kluwer Law &amp; Business.</p>	
<p><b>Informed consent for minors</b></p>	<p>State Policies in Brief. An Overview of Minors' Consent Law. Guttmacher Institute. Available at: <a href="https://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf">https://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf</a></p>	<p>PDF is available in course Resources section for download.</p>
<p><b>Informed consent during emergency situations</b></p>	<p>Copyrighted and published by Project HOPE/Health Affairs as:</p> <p>Cindy Brach "Even In An Emergency, Doctors Must Make Informed Consent An Informed Choice" <i>Health Affairs (Millwood)</i> 2016, Vol. 35, No. 4, 739-743. The published article is archived and available online at <a href="http://www.healthaffairs.org">www.healthaffairs.org</a>.</p> <p>Article available at: <a href="http://content.healthaffairs.org/cgi/content/full/35/4/739">http://content.healthaffairs.org/cgi/content/full/35/4/739</a></p>	

**Listing of All Resources for Informed Consent Leaders Module** (rev 7/21/16)

Topic	Resource	Notes
<b>NQF Safe Practices</b>	National Quality Forum Safe Practices for Better Healthcare – 2010 Update. Safe Practice 4: Informed Consent. Available at: <a href="https://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_2010_Update.aspx">https://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_2010_Update.aspx</a>	PDF is available in course Resources section for download.
<b>Legal reference book on informed consent</b>	Rozovsky F. <i>Consent to Treatment: A Practical Guide</i> . 5th ed. New York, NY: Aspen Publishers: Wolters-Kluwer Law & Business.	
<b>Disseminating your informed consent policy - Examples of brochures/posters informing patients of their rights</b>	The Patient Care Partnership - Plain language brochures available in multiple languages. Available at: <a href="http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml">http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml</a>	The AHA sells hard copies of the brochures as well as CDs containing the artwork for hospitals that want to customize the brochure.
<b>Building Systems to Improve the Informed Consent Process</b>		
<b>Free online libraries of informed consent forms</b>	Queensland Health's online database of plain language informed consent forms. Available at: <a href="http://www.health.qld.gov.au/consent/html/for_clinicians.asp">http://www.health.qld.gov.au/consent/html/for_clinicians.asp</a>	
	Fleisher L, Miller M, et al. A Practical Guide to Informed Consent. See Appendix C: Sample Informed Consent Forms. Available at: <a href="http://www.rwjf.org/en/library/research/2009/04/a-practical-guide-to-informed-consent.html">http://www.rwjf.org/en/library/research/2009/04/a-practical-guide-to-informed-consent.html</a>	PDF is available in course Resources section for download.  This resource is also listed in the <b>General reference on informed consent to treatment</b> section.

**Listing of All Resources for Informed Consent Leaders Module** (rev 7/21/16)

Topic	Resource	Notes
Improving written materials	Federal plain language guidelines, tips and tools. Available at: <a href="http://www.plainlanguage.gov">www.plainlanguage.gov</a>	
	CMS Toolkit for Making Written Material Clear and Effective. Available at: <a href="http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index.html?redirect=WrittenMaterialsToolkit">http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index.html?redirect=WrittenMaterialsToolkit</a>	Downloading the entire toolkit may be cumbersome. The files are large (5 zipped files, ranging in size from 3MB to 19MB) and according to the CMS website, the toolkits contain copyrighted materials which require obtaining permission from the publisher.
	AHRQ Tool 11: Assess, Select, and Create Easy-to-Understand Materials (AHRQ Health Literacy Universal Precautions Toolkit, 2 <sup>nd</sup> Edition). Available at: <a href="http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool11.html">http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool11.html</a>	PDF is available in course Resources section for download.  Toolkit is also listed in the <b>Organizational Change</b> section.
	CDC's "Every Day Words for Public Health Communication," A list of medical terms and their everyday substitutes. Available at: <a href="https://www.cdc.gov/other/pdf/everydaywordsforpublichealthcommunication_final_11-5-15.pdf">https://www.cdc.gov/other/pdf/everydaywordsforpublichealthcommunication_final_11-5-15.pdf</a>	
Health Literacy and Informed Consent	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: <a href="https://www.ncbi.nlm.nih.gov/pubmed/12523921">https://www.ncbi.nlm.nih.gov/pubmed/12523921</a>	
	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: <a href="https://www.ncbi.nlm.nih.gov/pubmed/20510800">https://www.ncbi.nlm.nih.gov/pubmed/20510800</a>	

**Listing of All Resources for Informed Consent Leaders Module** (rev 7/21/16)

Topic	Resource	Notes
	<p>Miller M, Abrams MA, Earles B, Phillips K, McCleary E. (2011). Improving Patient-Provider Communication for Patients Having Surgery: Patient Perceptions of a Revised Health Literacy-Based Consent Process. <i>Journal of Patient Safety</i>, 7(1): 30-38. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/21921865">https://www.ncbi.nlm.nih.gov/pubmed/21921865</a></p>	<p>Also listed in <b>Leading Change</b> section.</p>
	<p>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. <i>JAMA Intern Med</i>. 2014 Oct;174(10):1614-21. Available at: <a href="http://www.ncbi.nlm.nih.gov/pubmed/25156523">http://www.ncbi.nlm.nih.gov/pubmed/25156523</a></p>	
	<p>Paasche-Orlow MK. (2005). The Challenges of Informed Consent for Low-Literate Populations. In <i>Understanding Health Literacy</i>. Schwartzberg JG, VanGeest JB, Wang CC, Editors. AMA Press, 119-140.</p>	<p>PDF is available in course Resources section for download.</p>
<p><b>Example of health literacy strategies being used to improve informed consent</b></p>	<p>Abrams, MA (2013). A Health Literacy-Based Consent Process &amp; Attributes of a Health Literate Health Care Organization. Roundtable on Health Literacy Workshop: Implementation of Attributes of Health Literacy Washington, DC. Available at: <a href="https://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/PublicHealth/HealthLiteracy/2013-APR-11/Abrams.pdf">https://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/PublicHealth/HealthLiteracy/2013-APR-11/Abrams.pdf</a></p>	<p>PDF is available in course Resources section for download.</p> <p>Also listed in the <b>Leading Change</b> section.</p>
<p><b>Evidence on the benefits of decision aids</b></p>	<p>Kinnersley P, Phillips K, Savage K, Kelly MJ, Farrell E, Morgan B, Whistance R, Lewis V, Mann MK, Stephens BL, Blazeby J, Elwyn G, Edwards AG. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. <i>Cochrane Database Syst Rev</i>. 2013 Jul 6;7:CD009445. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/23832767">https://www.ncbi.nlm.nih.gov/pubmed/23832767</a></p>	

## Listing of All Resources for Informed Consent Leaders Module (rev 7/21/16)

Topic	Resource	Notes
	Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L, Wu JH. Decision aids for people facing health treatment or screening decisions. <i>Cochrane Database Syst Rev.</i> 2014 Jan 28;1:CD001431. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/24470076">https://www.ncbi.nlm.nih.gov/pubmed/24470076</a>	
<b>Free online decision aids</b>	Ottawa Health Resources Institute Decision Aid inventory. Available at: <a href="https://decisionaid.ohri.ca/">https://decisionaid.ohri.ca/</a>	
	AHRQ: Effective Health Care Program- Helping You Make Better Treatment Choices. Available at: <a href="http://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/">http://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/</a>	
	Mayo Clinic decisions aids. Available at: <a href="http://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/">http://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/</a>	
<b>Characteristics of high-quality decision aids</b>	Volk RJ, Llewellyn-Thomas H, Stacey D, Elwyn G (2013). Ten years of the International Patient Decision Aid Standards Collaboration: evolution of the core dimensions for assessing the quality of patient decision aids. Available at <a href="http://www.biomedcentral.com/1472-6947/13/S2/S1">http://www.biomedcentral.com/1472-6947/13/S2/S1</a>	
	International Patient Decision Aid Standards Collaboration (IPDAS). Available at: <a href="http://ipdas.ohri.ca/using.html">http://ipdas.ohri.ca/using.html</a>	
<b>Evaluating patient decision aids</b>	International Patient Decision Aids Standards Instrument. Available at: <a href="http://www.ipdasi.org/">http://www.ipdasi.org/</a>	PDF is available in course Resources section for download.
<b>Evaluating patient education materials</b>	The Patient Education Materials Assessment Tool (PEMAT). Available at: <a href="http://www.ahrq.gov/pemat">www.ahrq.gov/pemat</a>	PDF is available in course Resources section for download.
	The CDC Clear Communication Index (CCI). Available at: <a href="http://www.cdc.gov/ccindex/">http://www.cdc.gov/ccindex/</a>	

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Topic	Resource	Notes
<b>Shared decision making</b>	The SHARE Approach. A five-step process for shared decision making developed by AHRQ. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/">http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/</a>	
	Dartmouth-Hitchcock: Center for Shared Decision Making. Available at: <a href="http://med.dartmouth-hitchcock.org/csdm_toolkits.html">http://med.dartmouth-hitchcock.org/csdm_toolkits.html</a>	
	Website of the Informed Medical Decisions Foundation. Available at: <a href="http://www.informedmedicaldecisions.org/">http://www.informedmedicaldecisions.org/</a>	
<b>Making the case for removing communication barriers</b>	Think Cultural Health. The Guide to Providing Effective Communication and Language Assistance Services? Available at: <a href="https://hclsig.thinkculturalhealth.hhs.gov">https://hclsig.thinkculturalhealth.hhs.gov</a>	
	Evidence Sheet on LEP and Patient Safety. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/lep/handouts/lepevidencesum.pdf">http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/lep/handouts/lepevidencesum.pdf</a>	PDF is available in course Resources section for download.
<b>Systems and strategies to provide language assistance</b>	Joint Commission Roadmap on Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care. Available at: <a href="http://www.jointcommission.org/assets/1/6/roadmapforhospitalsfinalversion727.pdf">http://www.jointcommission.org/assets/1/6/roadmapforhospitalsfinalversion727.pdf</a>	PDF is available in course Resources section for download.  Permission to reproduce this guide for noncommercial, educational purposes with display of attribution is granted.  Suggested citation: The Joint Commission: Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals. Oakbrook Terrace, IL: The Joint Commission, 2010
	Robert Wood Johnson Speaking Together National Language Services Network program. Available at: <a href="http://www.rwjf.org/content/dam/farm/reports/program_results_reports/2011/rwjf70778">http://www.rwjf.org/content/dam/farm/reports/program_results_reports/2011/rwjf70778</a>	PDF is available in course Resources section for download.

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Topic	Resource	Notes
	<p>National certification programs for medical interpreters:</p> <p>The National Board of Certification for Medical Interpreters (National Board). Information about National Board is available at: <a href="http://www.certifiedmedicalinterpreters.org/">http://www.certifiedmedicalinterpreters.org/</a></p> <p>The Certification Commission for Healthcare Interpreters (CCHI). Information about CCHI is available here: <a href="http://www.cchicertification.org/">http://www.cchicertification.org/</a></p>	
	<p>“I Speak” cards to identify languages spoken by patients available at Limited English Proficiency (LEP): A federal interagency website. Available at: <a href="http://www.lep.gov/resources/resources.html#MM">http://www.lep.gov/resources/resources.html#MM</a></p>	
	<p>15-minute video introduction to interpretation and translation services from UCLA Health Interpreter/Translation and Deaf Services program. Available at: <a href="https://www.youtube.com/watch?v=9JLytaKjceU">https://www.youtube.com/watch?v=9JLytaKjceU</a></p>	<p>Also listed in <b>Training</b> section</p>
	<p>HRET Disparities Toolkit, A Toolkit for Collecting Race, Ethnicity and Primary Language from Patients. How to ask patients race, ethnicity and language questions. Available at: <a href="http://www.hretdisparities.org/Howt-4176.php">http://www.hretdisparities.org/Howt-4176.php</a></p>	
	<p>Office of Minority Health, Guide to Providing Effective Communication and Language Assistance Services. Department of Health and Human Services. Available at: <a href="https://hclsig.thinkculturalhealth.hhs.gov">https://hclsig.thinkculturalhealth.hhs.gov</a></p>	
	<p>Training on enhancing patient safety for patients with limited English proficiency through the use of interpreters and teamwork. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/teamsteps/lep/">http://www.ahrq.gov/professionals/education/curriculum-tools/teamsteps/lep/</a></p>	



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Topic	Resource	Notes
	Quan K. (2010). The High Costs of Language Barriers in Medical Malpractice: University of California, Berkeley. School of Public Health. National Health Law Program. Available at: <a href="http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf">http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf</a>	PDF is available in course Resources section for download.
<b>Improving Workflows</b>	AHRQ Practice Facilitator's Handbook: Creating workflow maps. Available at: <a href="http://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/index.html">http://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/index.html</a>	PDF is available in course Resources section for download.
	AHRQ Project RED Training Program: Creating swimlane diagrams. Available at: <a href="http://archive.ahrq.gov/professionals/systems/hospital/red/swimlane.html">http://archive.ahrq.gov/professionals/systems/hospital/red/swimlane.html</a>	PDF is available in course Resources section for download.
<b>Training</b>	Always Use Teach-back! Training toolkit. Available at: <a href="http://www.teachbacktraining.org/">http://www.teachbacktraining.org/</a>	
	Frequently Asked Questions About Teach-Back	PDF is available in course Resources section for download.
	Patient safety for patients with limited English proficiency. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/teamsteps/LEP/">http://www.ahrq.gov/professionals/education/curriculum-tools/teamsteps/LEP/</a>	
	15-minute video training on when to use a qualified medical interpreter from UCLA Health Interpreter/Translation and Deaf Services program. Available at: <a href="https://www.youtube.com/watch?v=9JLytaKjceU">https://www.youtube.com/watch?v=9JLytaKjceU</a>	Also listed in <b>Systems and strategies to provide language assistance</b> section.
	Training to improve practitioners' decision support skills: The Ottawa Decision Support Tutorial (ODST) for health professionals. Available at: <a href="https://decisionaid.ohri.ca/ODST/pdfs/ODST.pdf">https://decisionaid.ohri.ca/ODST/pdfs/ODST.pdf</a>	

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Topic	Resource	Notes
	Training on coaching: TeamSTEPPS 2.0: Module 9. Coaching Workshop. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/module9/slcoaching.html">http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/module9/slcoaching.html</a>	
	Practice Facilitation Handbook: Training Modules for New Facilitators and Their Trainers. Available at: <a href="http://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/">http://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/</a>	
	AHRQ Tool 3: Raise Awareness (AHRQ Health Literacy Universal Precautions Toolkit, 2 <sup>nd</sup> Edition). Entire toolkit available at: <a href="http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool3.html">http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool3.html</a>	PDF is available in course Resources section for download.  PDF of entire Toolkit is available in course Resources section.  Toolkit is also listed in the Organizational Change section.
<b>Organizational Change</b>		
<b>Leading change</b>	Championing Change PowerPoint slide presentation with Notes based on content from the module and a Championing Change Worksheet	PDFs of PowerPoint, PowerPoint with Notes and Worksheet are available in course Resources section.
	The AHRQ Health Literacy Universal Precautions Toolkit. 2 <sup>nd</sup> Edition.	PDF is available in course Resources section for download.
	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. Available at: <a href="https://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/PublicHealth/HealthLiteracy/2013-APR-11/Abrams.pdf">https://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/PublicHealth/HealthLiteracy/2013-APR-11/Abrams.pdf</a>	PDF is available in course Resources section for download.

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Topic	Resource	Notes
	Miller M, Abrams MA, Earles B, Phillips K, McCleary E. (2011). Improving Patient-Provider Communication for Patients Having Surgery: Patient Perceptions of a Revised Health Literacy-Based Consent Process. <i>Journal of Patient Safety</i> , 7(1): 30-38. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/21921865">https://www.ncbi.nlm.nih.gov/pubmed/21921865</a>	Also listed in <b>Health Literacy and Informed Consent</b> section.
	Abrams MA, Kurtz-Rossi S, Riffenburgh A, Savage BA. Building Health Literate Organizations: A Guidebook to Achieving Organizational Change. 2014. Available at: <a href="http://www.unitypoint.org/filesimages/Literacy/Health%20Literacy%20Guidebook.pdf">http://www.unitypoint.org/filesimages/Literacy/Health%20Literacy%20Guidebook.pdf</a>	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: <a href="http://www.ahealthyunderstanding.org/Portals/0/Documents1/IOM_Ten_Attributes_HL_Paper.pdf">http://www.ahealthyunderstanding.org/Portals/0/Documents1/IOM_Ten_Attributes_HL_Paper.pdf</a>	
	<b>Coaching Team Members.</b> TeamSTEPPS 2.0: Module 9. Coaching Workshop. Available at: <a href="http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/module9/igcoaching.html#coaching">http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/instructor/fundamentals/module9/igcoaching.html#coaching</a>	
<b>Results of an informed consent change initiative</b>	Matiassek J, Wynia MK. (2008). Reconceptualizing the Informed Consent Process at Eight Innovative Hospitals. <i>Joint Commission Journal on Quality and Safety</i> , 34(3): 127-137. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/18419042">https://www.ncbi.nlm.nih.gov/pubmed/18419042</a>	
<b>General reference on championing change</b>	Kotter, JP. <i>Leading Change: Why Transformation Efforts Fail.</i> Harvard Business Review, March-April 1995, 59-67. Available at: <a href="https://cb.hbsp.harvard.edu/resources/marketing/docs/95204f2.pdf">https://cb.hbsp.harvard.edu/resources/marketing/docs/95204f2.pdf</a>	