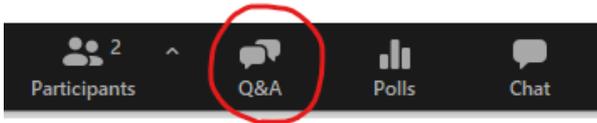


# Town Hall Call Reminders

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Please hold your questions until prompted at the end of today's presentation. Then, please select the Q & A icon at the bottom of your screen to type your questions.



## Use of the Zoom Chat Function

- Please reserve the Zoom Chat Function for reporting technical issues only.

## Accessing the Slides & Recording

- Following the session, a copy of the slides, recording, and a list of resources will be posted and available for download on the Town Hall Calls page:

<https://www.leapfroggroup.org/survey-materials/town-hall-calls>



# Implementing Leapfrog's Informed Consent Standard: Tips and Tools

**Cindy Brach**  
**July 12, 2022**



# Overview

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- My informed consent story
- Making Informed Consent an Informed Choice training modules
- The policy
- The discussion
- Timing
- The form
- Continuous improvement

# Making Informed Consent an Informed Choice

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**Informed Consent**



**Informed Choice**

Informed choice requires:

- Clear, unbiased information about **all** options
- Answer to: What happens if I do nothing?
- Options that align with goals and values

## 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:

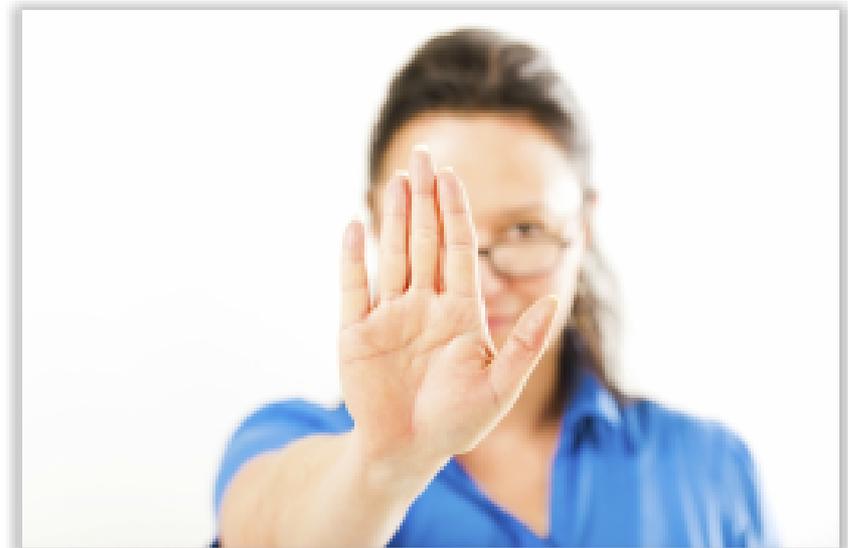
- The benefits, harms, and risks of treatment
- The possibility of poor outcomes
- Their option to say 'no'



### 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.



# My Dad



# Improving Communication

---

- Listen to patient's/family's concerns
- Ask patients/families to share their expertise
- Review all options
  - ▶ Doing nothing
  - ▶ Personalize benefits, risks, & harms
  - ▶ Check understanding

# Building Engagement into Protocols

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- Frenzy to minimize door-to-needle time
- Find time for engagement
  - ▶ During stroke assessment
  - ▶ During CT scan
  - ▶ After CT scan

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



[www.ahrq.gov/informedchoice](http://www.ahrq.gov/informedchoice)

# AHRQ's Two Modules

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- Ingredients for successful quality improvement:
  - ▶ Leadership support
  - ▶ Prepared workforce
- Leaders module – for C-suite and other execs
- Health care professionals module – teaches skills to clinical teams

Both modules are available to Joint Commission-accredited Institutions for free continuing medical education credit or can be run on your own learning management system.

# Interactive Training Modules

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- Video recordings
- Provider illustrations
- Knowledge checks
- Illustrative scenarios
- Patient friendly forms
- Model conversation
- Multiple resources
- Patient stories

# THE POLICY

# Leapfrog Question 1: Policy

---

- Does your hospital have a written policy that describes the informed consent process?
- Has your hospital made the written policy available to all roles and staff levels involved in the informed consent process?

# Policy

---

- Purpose
- Who can obtain IC
- When
- Content
- Documentation
- Exceptions
- Clear communications policy (plain language, using teach-back, accommodating communication needs)
- Compliance
- Enforcement
- Dissemination
- Review

# Informed Consent Policy Worksheet

Policy Component	Does your policy:	What improvements are needed, if any?
<p>1. Statement of purpose</p>	<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>	
<p>2. General policy</p>	<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>	
<p>3. Who is responsible</p>	<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>	

# Pilot Test Results

---

- Lack of clarity
  - ▶ Who can hold the informed consent discussions?  
Residents? Physician Assistants?
  - ▶ Policy and general consent form updated
- Discovery policy wasn't being followed
  - ▶ Large surgical group wasn't transmitting signed forms before surgery
  - ▶ Retraining required on appropriate use of interpreter services

# Leapfrog Question 2: Training

---

- Does your hospital have a training program on informed consent that tailors different training topics to different staff roles
- Has your hospital made the training:
  - ▶ a required component of onboarding for the appropriate newly hired staff, and
  - ▶ required for the appropriate existing staff who were not previously trained?



Since several care team members may be involved in the informed consent process, it is important for each team member to have a clear understanding of his or her role and the roles of other care team members.

You can use the table to clarify roles and responsibilities within your team with respect to informed consent.

To see the entire table, use the scroll bar to the right or select the image for an enlarged table.

There is a blank table in the Resources area of this course that you can download and customize as appropriate for your team. Complete this

Audio Script On

## 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



## 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



# Leapfrog Question 3: Covered Tests, Treatments, & Procedures

---

Does your hospital have a list, or a defined set of guidelines, so the appropriate staff know which tests, treatments, and procedures require patient/legal guardian consent, with any exceptions noted?

# Informed Consent Policy Worksheet



Policy Component	Does your policy:	What improvements are needed, if any?
1. Statement of purpose	Have a statement of purpose?  Is your statement of purpose in sync with your hospital's mission statement?  Will it resonate with your hospital's culture?  Is the language unambiguous?  Is the goal clear without getting bogged down in detail?	
2. General policy	Outline the key principles of informed consent?  Does it give an overview of what the policy covers?  Clearly list patients' rights?	
3. Who is responsible	Clearly specify: <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	Comprehensively list of what tests, treatments, and procedures require explicit consent?  Are the definitions clear?	
5. Timing	Include information regarding the timing of the informed consent discussion?	

# THE DISCUSSION

# Leapfrog Questions 9 and 10

---

Prior to the consent discussion, does your hospital

- Identify the patient/legal guardian's preferred language for medical decision-making, and, where needed, provide the patient/legal guardian a qualified medical interpreter?
- Offer the opportunity for a care partner (i.e., the patient's family, or a chosen friend or advocate) to participate in the discussion?

# Strategy 3: Remove Communication Barriers

## 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!

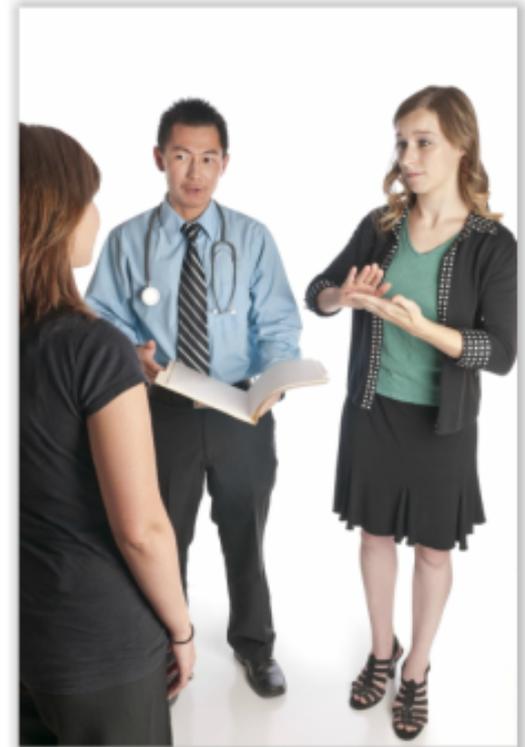
## Options for high quality language assistance:

[Bilingual staff](#)

[Bilingual staff as interpreters](#)

[Qualified medical interpreters](#)

*Select each button to learn more.*



## Section 2: Strategies for Clear Communication:

### Strategy 3: Remove Language Barriers

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

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

*Select each guideline for more information.*

# Leapfrog Questions 4, 5, 6, & 12: Content of Consent Discussion

---

As part of your hospital's process for obtaining informed consent, does the clinician explain:

- **all of the patient's treatment choices**, including the severity and probability of the risks and benefits of each choice, if applicable;
- **expected difficulties, recovery time, pain management, and restrictions** after a test, treatment, or procedure, in the hospital and post-discharge, if applicable;
- **the clinical rationale** (i.e., condition-specific justification) for why the test, treatment, or procedure is being performed
- **their experience** performing the test, treatment, or procedure with the patient/legal guardian?

## Section 3: Strategies for Presenting Choices:

### Strategy 9: Explain Benefits, Harms and Risks of All Options

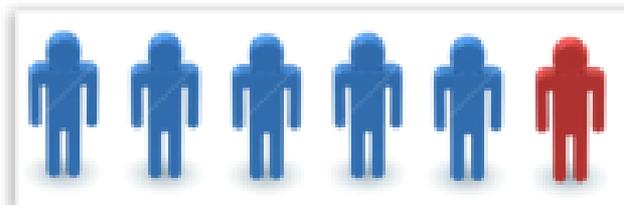
Explain benefits, harms and risks:

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

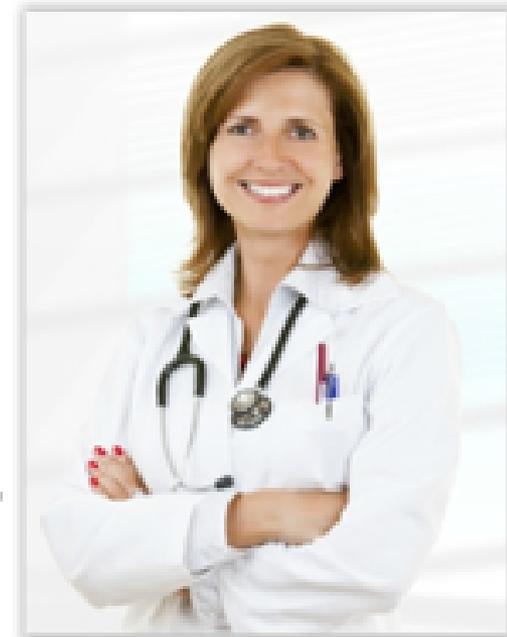
#### Important !

Guard against unconscious tendencies to promote the option you recommend.

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



Example of a visual



# Leapfrog Question 17: Decision Aids

---

For procedures that are scheduled a week (i.e., seven calendar days) or more in advance, does your hospital provide patients/legal guardians with high-quality decision aids (if available for the procedure) and patient education materials to inform their medical care decisions?

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

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

### **Using decision aids:**

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

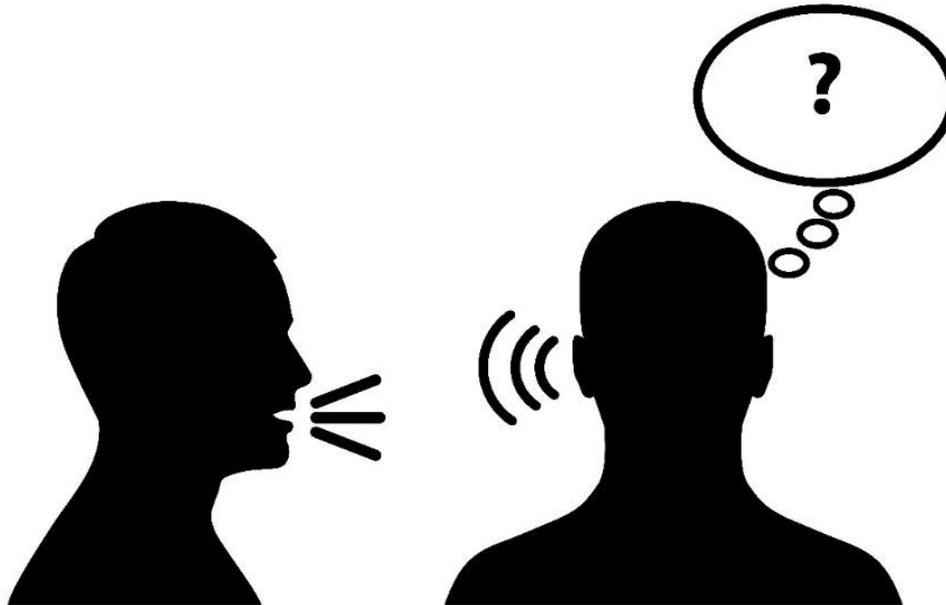


Additional information about interventions to promote informed consent is located in the Resources Section.

# Leapfrog Questions 4, 5, and 6: Questions

---

As part of your hospital's process for obtaining informed consent, does the patient have the opportunity to ask questions



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

### Encourage Questions

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

Patients might not want to ask questions because they:

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

You can encourage patients to ask questions by:

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

### References

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

## Section 3: Strategies for Presenting Choices:

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

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

#### **SAY:**

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

#### **DON'T SAY:**

"Do you have any questions?"

#### **Important !**

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



**Roberta**

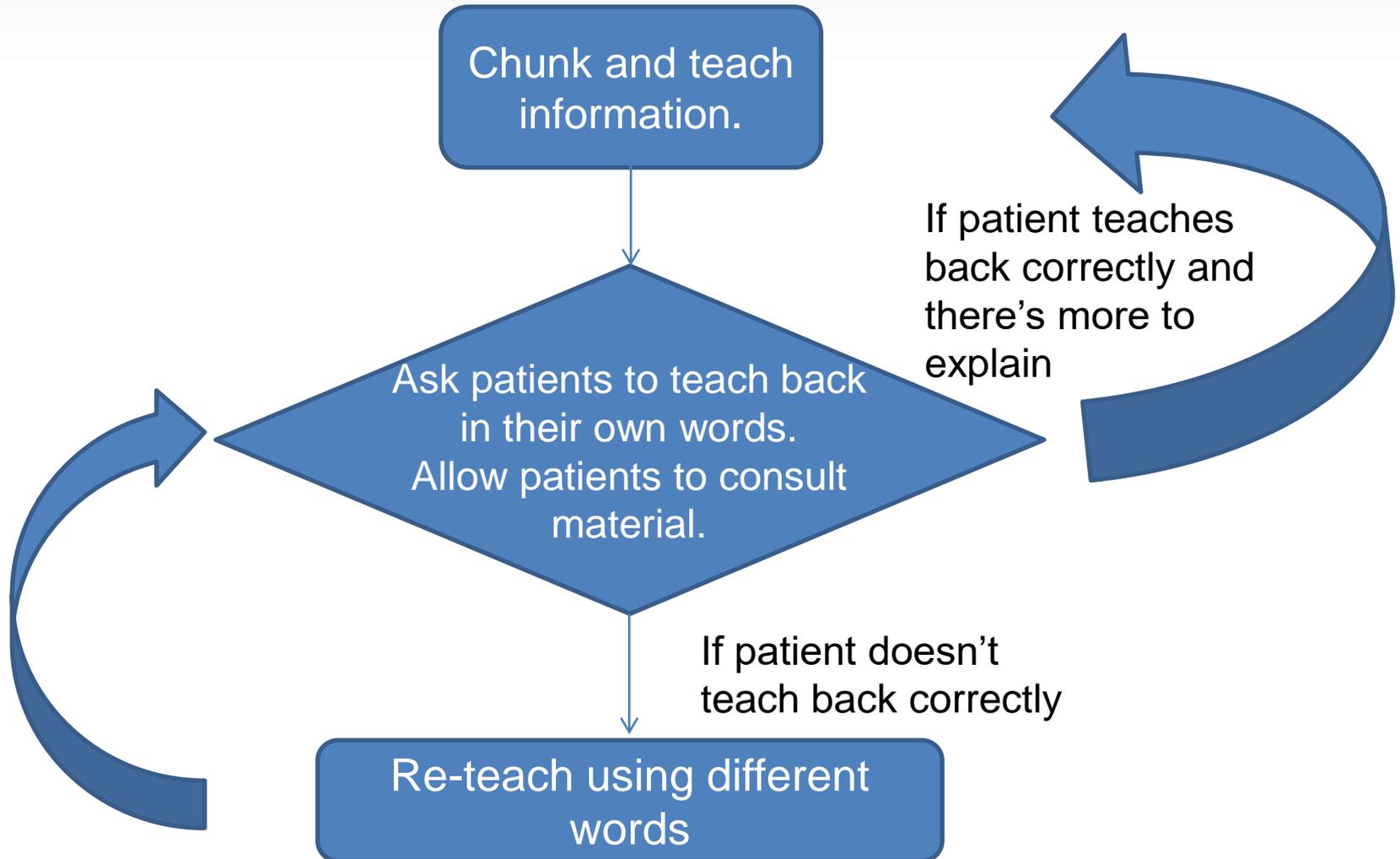
*Select the image of Roberta for an example.*

# Leapfrog Question 11: Teach-back

---

As part of the consent discussion, do clinicians at your hospital use the “teach back method” with patients/legal guardians, where patients/legal guardians are asked to describe, in their own words, what they understand will be done, why it will be done, and what are the primary risks?

# The Teach-Back Method



# TIMING

# Leapfrog Questions 13 and 14

---

For tests, treatments, and procedures that are scheduled a week (i.e., seven calendar days) or more in advance

- Does your hospital share the consent form with the patient at least three calendar days before the patient's test, treatment, or procedure?
- Do clinicians at your hospital discuss the consent form with the patient/legal guardian at least one calendar day before the patient's procedure, and is the patient/legal guardian provided with an opportunity to ask questions?

# THE FORM

# Leapfrog Questions 6 and 7: Contents of the form

---

Does your hospital's consent form include:

- that the elements of the consent discussion have taken place?
- the name(s) of the clinician(s) performing the test, treatment, or procedure;
- whether the clinician is expected to be absent from portions of the test, treatment, or procedure (e.g., opening, closing); and
- if any assistants or trainees will be involved in the test, treatment, or procedure?



# Leapfrog Question 8: Plain language forms

---

Is your hospital's consent form written in plain language and at a 6th grade reading level or lower

# Forms are Documentation of a Discussion

A signature on a form does not provide legal protection. Complex consent forms have been the basis of legal action by patients.

The typical informed consent form is unreadable for any level of reader.

The Joint Commission

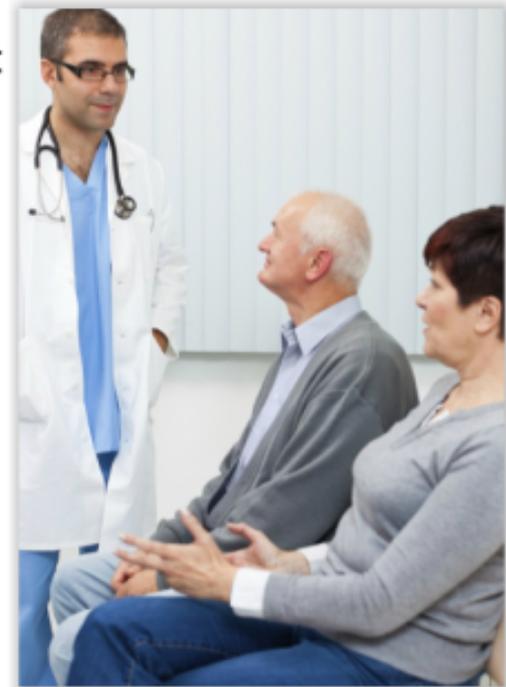
Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

CMS Conditions of  
Participation

## 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.*

# Reading Level Mismatch

---

**Informed consent forms** >  
10th – 12th grade

**U.S. adults average**  
**reading level**  
8-9<sup>th</sup> grade

**20% of U.S. adults read at  
the 5<sup>th</sup> grade level or lower**

# Example of plain language

---

## Before

Your participation in this study is strictly voluntary. You have the right to choose to participate or withdraw your participation at any point in the study without prejudice to your future health care or other services to which you are entitled.

## After

You don't have to be in the study – it is your choice. Your choice will not change your regular care in any way.

# Where We Started

## AUTHORIZATION FOR THE PERFORMANCE OF SURGICAL AND OTHER PROCEDURES

1. I, (Name of Patient), \_\_\_\_\_, authorize Doctor \_\_\_\_\_ 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:
- Name of Physician \_\_\_\_\_
- The procedure(s) or operation(s) to be performed.
  - The risks and benefits reasonably anticipated by undergoing this procedure or operation, including the possible consequences and complications.
  - The risks reasonably anticipated by not undergoing this procedure or operation, including the possible consequences and complications.
  - Any reasonable alternatives to this method of treatment and that the choice to undergo or not undergo the procedure or operation is mine alone.
  - 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 anesthetics 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) determine 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:
- The photographing or televising of the procedure or operation being performed upon me as long as my identity is not revealed in any way.
  - 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 app) \_\_\_\_\_

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



## 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

# Annotated Example

## Labor/Delivery Cesarean Section Delivery Consent

1. I authorize and direct doctor(s) \_\_\_\_\_ or his/her designee and other physicians as deemed qualified by him/her to perform upon \_\_\_\_\_ a Cesarean Section delivery of my child:  
 \_\_\_ with Anesthesia  
 \_\_\_ with other form of sedation: \_\_\_\_\_
2. If any conditions are revealed during the operation/procedure which were not anticipated, I consent to and authorize the performance of such additional operations/procedures and extensions to the operations/procedures as deemed advisable in the exercise of my physicians professional judgment in order to avoid the risks associated with undergoing a second operation/procedure.
3. Possible risks of Cesarean Section Delivery include, but are not limited to, injury to my bowel, urinary tract, nerves, and/or pelvic floor; bleeding; infection; fetal laceration. There are also risks associated with anesthesia, which have been discussed with me by an anesthesiologist. If the Cesarean Section Delivery requires a vertical incision in my uterus, I understand that any future child I bear must be delivered by way of a Cesarean Section. If I have chosen to deliver my child by Cesarean Section based in whole or in part upon the results of my rapid HIV test, which has not been confirmed by a second test, I understand that if my rapid HIV test was a false positive, a Cesarean Section delivery may not have been necessary.
4. The alternatives to proceeding with a Cesarean Section delivery include: \_\_\_\_\_.
5. The nature and purpose of the operation/procedure necessary for my treatment has been explained to me. I am aware that the practice of medicine and surgery is not an exact science and no guarantee about outcome can be made. I have been informed of the medically significant risks and consequences associated with the operation/procedure stated above. I have also been informed of any reasonable alternative courses of treatment and the risks and consequences of these alternative courses of treatment. I have also been informed of the risks and consequences of no treatment is rendered.
6. I understand that there are general risks associated with and surgical or invasive procedure and these risks, which may include infection, bleeding, injury to surrounding structures, stroke, paralysis, and death, have also been explained to me.

## Cesarean Section Delivery Consent

Patient Name: \_\_\_\_\_

Print patient name at top of form

**A Cesarean Section is surgery to deliver your baby. The baby is removed through a cut in your lower abdomen.**

Box in and highlight important information

I approve and direct Dr. \_\_\_\_\_, other doctors or others judged qualified by him or her (including residents or fellows) to perform a Cesarean Section delivery of my child(ren):

\_\_\_ with anesthesia (pain medicine that will keep you from feeling anything)

Define complex terms

\_\_\_ with other sedation (medicines used to make you calm, drowsy, or fall asleep)

My doctor may need to do other procedures during the Cesarean Section. This could happen if he or she finds an unexpected condition. If my doctor feels it's needed, I agree to these added procedures. These would be done to avoid the risks of having a second surgery or procedure.

### Cesarean Section Risks

Create sub-headings and separate

I understand there are risks to a Cesarean Section.

These risks include but are not limited to:

- injury to my bowel, urinary tract, nerves, or pelvic floor
- bleeding
- infection and
- injury to the baby

Bulleted list of risks

If the doctor makes a vertical cut in my uterus during surgery, I understand that I must have any future child by Cesarean Section.

Anesthesia also has risks. The anesthesiologist (doctor who gives pain medicine) explained these risks to me.

Reduced density of text

Increased white space

Source: [A Practical Guide to Informed Consent](#)

# InfoMapping Example

7. I authorize \_\_\_\_\_ to preserve and use, for any purpose it deems appropriate, and to dispose of in accordance with customary medical practice, any tissue, organs or other body parts removed during the operation/procedure, unless otherwise stated. I disclaim any ownership I may have in such tissue, organ, or other body part once removed.
8. I consent to the taking of photographs for the purpose of medical study or research and the initial reproduction or publication of these photographs in any manner, providing my identity is not revealed. For the purpose of advancing medical education, I also consent to the admittance of observers, technical representatives and participants in the operating room, and understand that I may be subject to a physical examination conducted for educational purposes.
9. **Consent for Administration of Blood and Blood Products:** I understand that during the operation/procedure or other treatments and for the immediate post-operative period (generally not to exceed one week), it may be advisable to administer blood or blood products to me. I am aware that there are certain risks involved in the administration of blood and blood products including, but not limited to: blood reaction with fever, chills, and breathing difficulties; contracting of blood-transmitted diseases which are not capable of detection by the testing of blood before it is administered. I acknowledge that the risks of accepting blood and blood products have been fully explained to me. I consent to the administration of blood or blood products as deemed advisable in my physician's professional judgment.

Source: [A Practical Guide to Informed Consent](#)

**IMPORTANT!**

Did we do a good job?

Are you ready to sign this consent form?

You sign here

Your doctor signs here

A witness signs here

Someone who represents the patient may need to sign here

Did you use a translator? They sign here

**Before you sign....let's make sure you understand everything**

To make sure we have explained this well, please answer these questions:

1. The surgery to remove my baby is called a \_\_\_\_\_.
2. Anesthesia is \_\_\_\_\_ used to keep me from feeling anything.
3. There are risks to this surgery. One of the risks is \_\_\_\_\_.
4. Having a Cesarean Section can lower the risk of passing \_\_\_\_\_ infection to a baby.
5. I agreed to allow \_\_\_\_\_ Hospital to keep any \_\_\_\_\_, organs, or body parts taken out during my surgery.

**Signatures**

My signature below means that:

- I have read and understand this consent form.
- I have been given all the information I asked for about the procedure(s), risks, and other options.
- All my questions were answered.
- I agree to everything explained above.

Patient's Signature: \_\_\_\_\_

Date signed: \_\_\_\_\_

Doctor's Signature: \_\_\_\_\_

Date signed: \_\_\_\_\_

Witness: \_\_\_\_\_

Date signed: \_\_\_\_\_

If the patient is not able to consent for herself, complete the following:

Patient \_\_\_\_\_ is not able to consent because:

Legally responsible person: \_\_\_\_\_

Relationship to patient: \_\_\_\_\_

Date signed: \_\_\_\_\_

If an interpreter was used:

Signature of interpreter: \_\_\_\_\_

Date of service: \_\_\_\_\_

# CONTINUOUS IMPROVEMENT

# Leapfrog Question 15 and 16: Continuous Improvement

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At least once a year, does your hospital

- solicit feedback from patients/legal guardians about your hospital's informed consent process to understand how it can be improved over time?
- complete an audit of the informed consent process to evaluate its efficacy and provide feedback to staff on opportunities for improvement?

## *Informed Consent*



*John M. Wan C. Brash*

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

# What questions do you have?

