Form Approved
OMB No. 0935-XXXX
Exp. Date XX/XX/20XX

ATTACHMENT D -Pre and Post Quizzes for Training for Health Care Professionals Module

Questions for Pre- and Post-Training Quizzes

1. True or false: A signed consent form protects the medical care team against lawsuits alleging lack of informed consent.

€ True

Incorrect. Some lawsuits over lack of informed consent have succeeded despite the presence of a signed form. If the patient signs the form without understanding the treatment and its risks, the medical care team can still be held liable. What protects the medical care team is the informed consent PROCESS, not the form. During the informed consent process, the proposed treatment is explained to a patient including its benefits, harms, and risks. When the patient understands the nature of the treatment and its possible benefits and harms, and accepts the risks, he or she is less likely to file a lawsuit alleging lack of informed consent and such lawsuits are less likely to be successful.

€ False

Correct. Some lawsuits over lack of informed consent have succeeded despite the presence of a signed form. If the patient signs the form without understanding the treatment and its risks, the medical care team can still be held liable. What protects the medical care team is the informed consent PROCESS, not the form. During the informed consent process, the proposed treatment is explained to a patient including its benefits, harms, and risks. When the patient understands the nature of the treatment and its possible benefits and harms, and accepts the risks, he or she is less likely to file a lawsuit alleging lack of informed consent and such lawsuits are less likely to be successful.

Public reporting burden for this collection of information is estimated to average 20 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850.

2. A 25-year old white woman presented alone to the ER, vomiting and fainting. When the ER doctor saw her, she was unconscious and the ER doctor thought she might have life-threatening meningitis. Was the doctor right to immediately perform a lumbar puncture on her without her consent or the consent of a surrogate decision maker in order to provide a potentially life-saving treatment?

€ Yes

Correct. Since the patient had lost consciousness and there was no time to find a surrogate decision-maker, the doctor was justified to perform the lumbar puncture. If the patient had been conscious or if a surrogate decision maker had been available, the doctor would have had to obtain informed consent.

€ No

Incorrect. Since the patient had lost consciousness and there was no time to find a surrogate decision-maker, the doctor was justified to perform the lumbar puncture. If the patient had been conscious or if a surrogate decision maker had been available, the doctor would have had to obtain informed consent.

- 3. When a doctor reviews the treatment options for his kidney disease, a 50-year-old African American man repeats his emphatic refusal to discuss the option of a kidney transplant. The doctor's best response is:
 - "Some patients don't want transplants, and you can make that choice. I respect that. So let me go over the other options with you (...)" Incorrect. The doctor does not know what the patient's goals and values are and whether in fact a kidney transplant could be the patient's preferred option. The doctor should help the patient clarify his goals and values. The patient may not be solely focused on the best clinical outcome. For example, in the African American community patients have been known to reject transplants because they do not want to make family members vulnerable by sacrificing a kidney. By asking the patient what he worries about most, the doctor can determine whether there's any misinformation that needs correcting, explore alternatives the patient didn't consider, and to help the patient match his values with the treatment options.
 - "Some patients don't want transplants, and you can make that choice. Let's just check whether it's the best choice for you. When you hear about a kidney transplant, what worries you most?"
 Correct. The doctor should help her patient clarify his goals and values. The patient may not be solely focused on the best clinical outcome. For example, in the African American community patients have been known to reject transplants because they do not want to

make family members vulnerable by sacrificing a kidney. By asking the patient what he worries about most, the doctor can determine whether there's any misinformation that needs correcting, explore alternatives the patient didn't consider, and help the patient match his values with the treatment options.

- "Some patients don't want transplants, and you can make that choice. But it's my job to explain the benefits, harms, and risks of all the options so you can make a good choice. So here's what you need to know about kidney transplants...."
 Incorrect. If the doctor proceeds to describe the benefits, harms, and risks of a kidney transplant, the patient is unlikely to take in the information. The doctor should help her patient clarify his goals and values. The patient may not be solely focused on the best clinical outcome. For example, For example, in the African American community patients have been known to reject transplants because they do not want to make family members vulnerable by sacrificing a kidney. By asking the patient what he worries about most, the doctor can determine whether there's any misinformation that needs correcting, explore alternatives the patient didn't consider, and help the patient match his values with the treatment options.
- 4. A 65-year old Filipino man requires amputation of one of his legs due to complications of diabetes. In the hospitalist's assessment, failure to amputate the leg within the next 48 hours could be fatal. The hospitalist explains that an amputation may be needed, and introduces the surgeon. As the surgeon begins to discuss the benefits, harms, and risks of amputating and not amputating the leg, the patient covers his ears and refuses to talk to the surgeon. What is the surgeon's best course of action?

€ Obtain consent from a duly authorized surrogate decision-maker

Incorrect. If the hospitalist feels the procedure should be done in the next 48 hours, there is some time to let the patient absorb the information given so far and try again later to discuss the options. The patient could not handle the information at that particular moment – probably because of anxiety, stress and shock. Sometimes the consent discussion needs to happen over several sessions, so the patient can better process stressful information. Note that there **is** a choice to be made. There is a legal precedent to allow patients to refuse amputation even when the amputation is deemed necessary to save the patient's life. In the meanwhile, the surgeon could, with the patient's permission, speak to friends or family of the patient who might be able to help the patient through this difficult time. Finally, if it appears the patient might not have capacity to refuse surgery, the surgeon could also start to line up a surrogate decision-maker in case trying again later doesn't help.

€ Try again a little later

Correct. If the hospitalist feels the procedure should be done in the next 48 hours, there is some time to let the patient absorb the information given so far and try again later to discuss the options. The patient could not handle the information at that particular

moment – probably because of anxiety, stress and shock. Sometimes the consent discussion needs to happen over several sessions, so the patient can better process stressful information. Note that there **is** a choice to be made. There is a legal precedent to allow patients to refuse amputation even when the amputation is deemed necessary to save the patient's life. In the meanwhile, the surgeon could, with the patient's permission, speak to friends or family of the patient who might be able to help the patient through this difficult time. Finally, if it appears the patient might not have capacity to refuse surgery, the surgeon could also start to line up a surrogate decision-maker in case trying again later doesn't help.

€ Sit down next to him and make it clear that this is a life-threatening situation Incorrect. If the hospitalist feels the procedure should be done in the next 48 hours, there is some time to let the patient absorb the information given so far and try again later to discuss the options. The patient could not handle the information at that particular moment – probably because of anxiety, stress and shock. Sometimes the consent discussion needs to happen over several sessions, so the patient can better process stressful information. Note that there is a choice to be made. There is a legal precedent to allow patients to refuse amputation even when the amputation is deemed necessary to save the patient's life. In the meanwhile, the surgeon could, with the

patient's permission, speak to friends or family of the patient who might be able to help the patient through this difficult time. Finally, if it appears the patient might not have capacity to refuse surgery, the surgeon could also start to line up a surrogate decision-

5. True or false: Informed consent is legally binding while informed choice is not?

maker in case trying again later doesn't help.

€ True

Incorrect. Informed choice fully meets all the legal obligations of informed consent. The term "informed choice" may even be preferable to "informed consent," since it makes it clear that patients get information about the benefits, harms, and risks of **all** of their options, including what happens if they have no treatment. The clinician's task in "informed choice" is to help the patient make decisions based on their goals and values.

€ False

Correct. Informed choice fully meets all the legal obligations of informed consent. The term "informed choice" may even be preferable to "informed consent," since it makes it clear that patients get information about the benefits, harms, and risks of **all** of their options, including what happens if they have no treatment. The clinician's task in "informed choice" is to help the patient make decisions based on their goals and values.

6. True or false: When a clinician speaks only English and the patient does not speak English, having a bilingual staff member provide in-person interpretation is a safer way to obtain informed consent than using a medical interpreter via telephone.

€ True

Incorrect. Anyone – including a bilingual staff member – who has not been trained as an interpreter is more likely to make clinically significant errors than a trained interpreter. Ideally translated informed consent forms would be used in conjunction with qualified interpreters. When translating forms in advance is impractical, trained interpreters can provide a sight translation of the English form.

€ False

Correct. Anyone – including a bilingual staff member – who has not been trained as an interpreter is more likely to make clinically significant errors than a trained interpreter. Ideally translated informed consent forms would be used in conjunction with qualified interpreters. When translating forms in advance is impractical, trained interpreters can provide a sight translation of the English form.

- 7. You're an attending physician, and you're always short of time. What's the best way to make sure that patients don't misunderstand what they are consenting to?
 - Determine which patients have limited health literacy so you can prioritize spending time with them explaining the benefits, harms, and risks of the proposed tests, treatments or procedures and their alternatives.

 Incorrect. You can't tell which patients have limited health literacy by looking. Any patient may experience instances of limited health literacy, especially when they're sick, tired, or frightened. While you might need to spend more with patients experiencing limited health literacy, using high quality structured decision aids can help you save time in explaining things to patients. The only way to be sure that patients are not misunderstanding, however, is to ask patients to describe the benefits, harms and risks of the alternatives in their own words.
 - € Use structured decision aids and then ask patients to explain their understanding of the benefits, harms, and risks of the proposed tests, treatments or procedures and their alternatives.

Correct. Using structured decision aids can help you save time in explaining things to patients, but isn't a substitute for the informed consent discussion. And the only way to be sure that patients are not misunderstanding is to ask them to describe the benefits, harms, and risks of all the alternatives. Other members of the team may help educate patients, for example by showing them a structured decision aid, but it is the responsibility of the clinician performing a procedure or ordering a test or treatment to have the informed consent discussion with the patient.

Ask residents or other clinical staff who have more time to explain the benefits, harms, and risks of the proposed treatments or procedures and their alternatives.

Incorrect. While others may help educate patients, for example by showing them a structured decision aid, it is the responsibility of the clinician performing a procedure or ordering a test or treatment to have the informed consent discussion with the patient. Since any patient may experience instances of limited health literacy, especially when they're sick, tired, or frightened, you need to confirm all patients' understanding by asking them to describe the benefits and risks of all the alternatives.

8. Which practices improve safety of informed consent? (Check all that apply)

- Show technical pictures of anatomy
- Do not permit persons other than the patient to be present during the informed consent discussion
- Use plain language
- Speak slowly
- Encourage questions
- Have the patient repeat back exactly what they were told
- Listen without interrupting
- Use terms like "very likely" instead of giving numeric probabilities

You got X out of 9 correct.

Correct answer: Use plain language, speak slowly, encourage questions, listen without interrupting. Only score as correct if they have all the right answers and none of the wrong answers.

While using graphics and models can help get your point across, overly detailed pictures can be cluttered and confusing.

While you should assure patients can have confidential discussions, they should be the ones to determine who is present at the informed consent discussion. Make sure you have space for any persons patients want present during the discussion.

Health care professions tend to used specialized medical terms. Instead, use plain language – the kind of language you speak in your living room.

When you've got a lot of information to cover in a short period of time, the instinct is to talk fast. Speaking slowly, however, is important to help patients assimilate all the new information you are giving them.

Patients often have unanswered questions about their choices. Be sure that your body language as well as your words make it clear that you expect them to have questions.

When patients repeat exactly what they're told – word for word – you can't tell whether they actually understood or are just automatically parroting what they heard.

One of the tasks in informed consent is to elicit patients' values and preferences. Try to listen without interrupting and let patients know you are listening by asking follow up questions.

Subjective terms like, "very likely," may mean something quite different to patients than it does to you. It's important to also use numbers when conveying risk information, even though it's hard to make numbers easy to understand.

- 9. You've just explained to a patient the benefits, harms and risks of angioplasty. Which of these questions can best help you to check that the patient understands?
 - € Do you understand how the procedure I just described could help your heart, and also what might possibly go wrong?

 Incorrect. This question can be answered with a yes or no, and many patients will say yes even if they do not understand. The best way of eliciting whether your patients understand, without making it sound like you're testing them, is to say, "Just to make sure I explained it well, can you tell me in your own words the pros and cons of general anesthesia?" This allows the clinician to make an objective assessment as to whether the patient actually understood.
 - € So tell me, what didn't you understand about how the procedure I just described could help your heart, and also what might possibly go wrong?

 Incorrect. This is better than asking "Do you understand?", but is still problematic. While this question can't be answered with a yes or a no, patients may be reluctant to admit that they didn't understand something. The only way of knowing whether your patients understand is to ask them to explain it **in their own words**. Saying, "Just to make sure I explained it well..." has the advantage of avoiding the impression that you're testing them.
 - € Just to make sure I explained it well, can you tell me in your own words how the procedure I just described could help your heart, and also what might possibly go wrong? Correct. This question is open-ended, meaning it can't be answered with yes or no. It is also phrased as a test of the clinician's ability to explain, and doesn't require the patient to confess to not understanding something. Finally, it allows the clinician to make an objective assessment as to whether the patient actually understood.
- 10. You are in charge of a hospital unit that receives patients who are having elective knee surgeries. You always obtain signed consent forms for these surgeries before the surgery is

scheduled. A staff member suggests that nurses in the pre-op room confirm patients' understanding of what they've consented to. Which is the best response?

- Explain that the surgeon has already confirmed patients' understanding when they got the form signed and when the surgeon had lots of time for the discussion. Incorrect: Many patients sign consent forms without fully understanding the information they contain. When the patient does not understand the information presented, the signed informed consent form neither shields the clinician from liability, nor protects the patient from unwanted treatments. While the surgeon should have confirmed that the patient understood before getting the patient's signature, you can't be sure that this has happened. Confirming patients' understanding the day of surgery improves safety, but the patient is likely to be reluctant to call off the surgery if you wait until the patient is in the pre-op room. The best answer is therefore to explore instituting a confirmation process when the patient first reports to the hospital on the day of the surgery.
- € Reply that verifying consent in the pre-op room is too late, and explore instituting a verification process when the patient first reports to the hospital on the day of the surgery.
 - Correct. Many patients sign consent forms without fully understanding the information they contain. When the patient does not understand the information presented, the signed informed consent form neither shields the clinician from liability, nor protects the patient from unwanted treatments. While the surgeon should have confirmed that the patient understood before getting the patient's signature, you can't be sure that this has happened. Confirming patients' understanding the day of surgery improves safety, but the patient is likely to be reluctant call off the surgery if you wait until the patient is in the pre-op room. The best answer is therefore to explore instituting a confirmation process when the patient first reports to the hospital on the day of the surgery.
- € Commend the staff member for the good idea and tell her you'll bring the suggestion to the next patient safety team meeting.
 - Incorrect. Many patients sign consent forms without fully understanding the information they contain. When the patient does not understand the information presented, the signed informed consent form neither shields the clinician from liability, nor protects the patient from unwanted treatments. While the surgeon should have confirmed that the patient understood before getting the patient's signature, you can't be sure that this has happened. Confirming patients' understanding the day of surgery improves safety, but the patient is likely to be reluctant call off the surgery if you wait until the patient is in the pre-op room. The best answer is to explore instituting a confirmation process when the patient first reports to the hospital on the day of the surgery.