

ATTACHMENT H - Interview and Site Visit Guide

Interview Guide

Hospital: _____ Interviewer: _____

Unit: _____ Respondent: _____

Date: _____

Obtained signed consent form: Y/N Interviewer Initials: _____

Permission to record: Y/N Interviewer initials: _____

Interviewer Instructions

The following interview guide is for all individuals being interviewed at the hospital, including: health care professionals, unit leads, hospital liaisons, hospital leaders (e.g., quality or safety officer), and other relevant individuals (e.g., patient and family advisory council member involved in improving informed consent). The reference point for the question changes for each of the respondent types as appropriate (e.g., *your/ your unit/your hospital's approach* to be asked for individual clinicians, unit leads, and hospital leaders, respectively). In general, questions of health care professionals will be either at the individual or unit level, questions of unit leads will be regarding unit-level changes, and questions of the hospital liaison and other leaders (e.g., quality or safety officers) will be regarding hospital-level changes.

Role in Informed Consent [Interviewer: Do not ask staff who were interviewed as part of the Baseline Assessment.]

1. What has been your role and responsibilities in the informed consent process?

PROBES:

- If not directly involved, were you aware when, how, or whether informed consent was obtained?
- Did you conduct informed consent discussions with patients?
- Did you provide information? Show decision aids?
- Did you oversee an aspect of the informed consent process? What?
- Did you work on informed consent as part of your safety or quality role?

Public reporting burden for this collection of information is estimated to average 30 minutes per response, the estimated time required to complete the interview. 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.

Post-Implementation Climate

2. In general, do you think your hospital/unit staff and leadership perceived there was a need to improve your informed consent practices?
3. How well do you think improving informed consent practices aligned with your hospital/unit's norms or values?
4. Has improving informed consent practices been a priority for your hospital/unit? Why or why not?
5. What incentives were there for champions/unit leads to lead changes in your hospital/unit?
6. What incentives, if any, were there for you/staff members to make these changes?
7. What level of engagement from leadership was there regarding improving informed consent? Please describe.
8. What resources were dedicated to improving informed consent (e.g., staff time, financial, incentives)?

Role in Implementation

9. What was your role in improving informed consent in your hospital/unit?

PROBES:

- To complete the training and self-initiate changes
- To complete the training and implement changes selected by unit lead/team
- Championed changes in hospital/unit
- Held others accountable for making changes in hospital/unit

Training

10. Which training courses did you complete, or at least start?

PROBES

- Completed Leaders course
- Completed Health Care Professionals course
- Started but didn't finish Leaders course
- Started but didn't finish Health Care Professionals course
- None

11. What in the [insert module] training did you find MOST useful?
12. What in the [insert module] training did you find LEAST useful?
13. What do you think should be added to the module(s), if anything?
14. What do you think should be removed or further clarified in the module(s), if anything?
15. Did you receive/provide staff any additional training regarding improving informed consent?
Please describe.

Implementation Plans

16. Did you/your unit/your hospital attempt to use any of the strategies or resources from the Health Care Professionals course?

PROBES:

- Strategies for Clear Communication
 - Strategy 1: Prepare for the Informed Consent Discussion
 - Strategy 2: Use Health Literacy Universal Precautions (e.g., plain language, speaking slowly, using graphics)
 - Strategy 3: Remove Language Barriers (e.g., using qualified interpreters)
 - Strategy 4: Use Teach-Back
- Strategies for Presenting Choices
 - Strategy 5: Offer Choices
 - Strategy 6: Engage the Patient and Their Family and Friends
 - Strategy 7: Elicit Goals and Values
 - Strategy 8: Encourage Questions
 - Strategy 9: Show High Quality Decision Aids
 - Strategy 10: Explain Benefits, Harms, and Risks of All Options

17. Did you/your hospital attempt to use any of the strategies or resources from the Leaders' course?

PROBES:

- Crafting and disseminating a clear and comprehensive informed consent policy?
- Building Systems to Improve the Informed Consent Process
 - Support #1: Compile a library of clear and simple informed consent forms
 - Support #2: Maintain a library of high-quality decision aids and patient education materials
 - Support #3: Provide language assistance (e.g., qualified interpreters)
 - Support #4: Stock assistive communication devices
 - Support #5: Establish efficient workflows

- Support #6: Train staff at all levels
- Developing and Implementing an Action Plan
 - Championing Change (i.e., Kotter's 8-steps for organizational change)?

18. Did you/your unit/your hospital use strategies or tools from other sources? If so, please describe.

Implementation Experiences

19. Which strategies were you able to implement? How?

20. Which strategies were you not able to implement? Why?

21. Which strategies were easiest to sustain? Why?

22. What motivated you/your unit/your hospital make these changes?

PROBES:

- Apparent need for improvement
- Pressure from outside constituencies (e.g., patient and family council, threat of lawsuits)
- Patients responded well
- Recognized changes were an improvement
- Hospital/unit leaders indicated changes were a priority and set expectations that changes were to be made.
- Improving informed consent practices was a priority for me
- Colleagues were going through changes too
- Anything else?

23. What helped you/your unit/your hospital make these changes?

PROBES:

- Support from hospital leadership (e.g., policies were clarified)
- Support from unit leadership (e.g., workflow changes, team responsibilities clarified)
- Sufficient time to improve my informed consent practices
- Changes were simple enough to make/integrate
- Additional training or other reinforcement of material
- Incentives
- Recognition
- Held accountable for changes
- Anything else?

24. What were some of the barriers or challenges to making these changes?

PROBES:

- Electronic health record issues
- Staff turnover, shortages or limited availability
- Competing priorities
- Lack of accountability
- Lack of resources
- Lack of time for informed consent discussions
- Issues related to teamwork and communication among team members
- Resistance from certain team members on the unit for improving the process
- Lack of leadership support/Not viewed as a priority of leadership
- Time required to make changes
- Lack of champion/lead

Results

25. What has been the effect of the training courses on your/staff's skills and behaviors in informed consent? Please describe.

26. What has been the effect of the [interviewer: insert specific improvements hospital/unit implemented] on your unit/hospital's informed consent practices, if any? Please describe.

Informed Consent Policies and Practices

27. Are you aware of what your hospital's informed consent **policy** was before this initiative?

If, yes:

- a. How, if at all, has your **unit's** informed consent **policy** changed since this initiative began?
- b. How were these changes communicated to you? (e.g., unit meeting, supervisor, email)

28. How, if at all, have informed consent **processes** changed in your hospital/unit?

PROBE:

- Have any staff members taken on different responsibilities?
- Has the workflow (sequence of activities) changed?
- Is there different oversight of the informed consent process?
- Has the documentation process changed?

29. Which aspects, if any, of your informed consent processes do you think improved since this initiative began.

PROBES:

- Assessing patients' decision-making capacity
- Allocating ample time and private space for the informed consent discussion
- Using health literacy universal precautions
- Calling for qualified interpreters when conducting a consent discussion with a patient with limited-English proficiency
- Using teach-back techniques to check patient understanding
- Engaging patients, family, and friends
- Eliciting patients' goals and values and help them make a choice
- Encouraging questions
- Using structured patient decision aids (e.g., tool to help a patient understand the benefits, harms, and risks of a procedure and make a decision)
- Neutrally presenting benefits, harms, and risk of the proposed treatment/procedure and of alternatives, including the option of "no treatment"
- Asking patients to confirm consent when consent is obtained in advance
- Clarifying team roles
- Documenting informed consent

Informed Consent Effectiveness

30. Do you think most clinicians obtaining consent in your hospital/unit treat the informed consent process as merely getting a signature on a form, or do they tend to really make sure patients understand that they have choices and what those choices are?

a. Has this changed since this initiative began?

31. On a scale from 1 to 10, where 1 is the worst and 10 is the best, how well does your hospital/unit ensure patients are making an informed choice?

a. Has this changed since this initiative began?

Teach-back Self Efficacy [Interviewer: ask this of clinicians only]

Teach-back is a way to check that you have explained to patients what they need to know in a manner that they understand. Patient understanding is confirmed when they are able to explain it back to you in their own words.

32. Had you used teach-back before this initiative?

33. Have you used teach-back since this initiative began?

34. On a scale from 1 to 10, how confident are you in your ability to use teach-back in an informed consent discussion? (1 = “not at all confident”, 10 = “very confident”)

a. Has this changed since this initiative began?

Attitudes

35. What changes, if any, have there been in your/ your unit's/ your hospital's attitudes about informed consent since completing the training and implementing changes?

PROBES: How have attitudes changed about:

- The value of engaging patients, families, and friends as active participants in decisions about tests, treatments, and procedures
- Whether patients should be given a choice among **all** treatment options, including the option of no treatment
- Whether clinicians have the responsibility to ensure that patients understand all relevant benefits, harms, and risks before making a decision
- The acceptability of getting by without qualified interpreters
- The importance of following the hospital's informed consent policy
- Whether informed consent is a safety and quality issue or a compliance activity

Effect on Patients

36. What effect do you think the informed consent changes have had on patients?

PROBES:

- Do they appear more engaged in the process (e.g., ask more questions)?
- Do they appear happier with their choices?
- Are they more likely to read the informed consent form?

Other Effects

37. What other effects have resulted from the changes you/your unit/your hospital implemented to improve informed consent practices?

PROBES:

- Increase in staff morale?
- Spurred other quality improvement efforts?

Unintended Consequences

38. What, if any, unintended consequences occurred as a result of the implemented changes?

PROBES:

- Detracted from other quality improvement efforts?
- Interrupted workflow?
- Delayed tests, treatments, or procedures?
- Created conflict among staff members?

Conclusion

39. What advice would you give to other hospitals/units who want to use these training modules to improve their informed consent processes?

40. Is there anything else you think would be helpful for us to know about your experience with the training and implementing changes?

Background Information [Interviewer: Do not ask staff who were interviewed as part of the Baseline Assessment.]

41. How long have you worked in this hospital?

42. How long have you worked in your current hospital work area/unit?

43. What is your staff position in this hospital?

PROBES: RN, PA, NP, LVN/LPN, Aide, Attending MD, hospitalist, resident, fellow.

44. How long have you worked in your current specialty or profession?

Site Visit Guide

The following observations and data should be collected, to the extent possible, from hospitals at the time of the site visit:

- Observe, to the extent possible, any signage related to informed consent policies or practices, EHR functionalities, action plans, anything else relevant to improvements in the informed consent processes. Do not observe patient-clinician interactions.
- Collect copies of relevant documents, including: informed consent forms, policies, training materials, communications to staff, implementation materials (e.g., action plan, report to hospital board or patient and family advisory council, data collection tools)
- Examine informed consent forms embedded in EHRs, if applicable
- Obtain secondary data, for example:
 - Training completion rates and numbers by hospital and unit (from LMS)
 - Implementation tracking data (e.g., action plan tracking)
 - Patient reported feedback form results or completed forms
 - Surgical cancellation and delay rates related to the informed consent process
 - Other data relevant to improving informed consent