

Avoiding Critical Flaws in the Consent Process



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INFORMED CONSENT



The illustration shows a white document with a blue border and a blue pencil pointing to it. The document has three horizontal lines of text. The first line is crossed out with a red 'X'. The second line is also crossed out with a red 'X'. The third line is not crossed out. The background is yellow and blue.



Disclosure to Learners

No planner, faculty, or staff of this Educational Program has any relevant financial relationships with ineligible companies.



More Than Just a Signature

- Detailed communication between the physician and patient that provides the patient with enough information to make an informed decision.
- Common Law and Patient Rights.
- Establishes realistic expectations. Good consent is Expectation Management.
- Patient signature is not enough; it must also be documented in the medical record .
- Risks of failure to obtain or incomplete consent.

Required Elements of Informed Consent

- Explanation of the nature and purpose of the proposed treatment.
- The risks, complications and expected benefits of the recommended treatment, including the likelihood of success or failure.
- Any alternatives to the recommended treatment and their risks and benefits.
- The risks and benefits of declining the proposed treatment.



Risk Reductions Strategies



PATIENT SAFETY

For planned procedures, don't wait to obtain consent on the day of the procedure.

Stick to simple easy-to-understand language when having the consent discussion.

Thoroughly document the informed consent discussion being sure to include all required elements.

Documentation of the informed consent conversation and the potential risks should be specific to the procedure being performed.

Ensure that a copy of the signed consent form is placed in the patient's medical record and a copy in the hospital record as well

Stay within the scope of the procedure noted on the signed consent form.

Health Literacy and Cultural Considerations

Individual differences and cultural diversity in the patient populations can impact both perception and expectations on both side.

- Family and Cultural Expectations
- Literacy and Health Literacy
- Appropriate use of Interpreters
- Legal Documents and Signatures



California Civil Jury Instruction 534. Informed Refusal



- [A/An] [insert type of medical practitioner] must explain the risks of refusing a procedure in language that the patient can understand and give the patient as much information as [he/she/nonbinary pronoun] needs to make an informed decision, including any risk that a reasonable person would consider important in deciding not to have [a/an] [insert medical procedure].
- The patient must be told about any risk of death or serious injury or significant potential complications that may occur if the procedure is refused. [A/An] [insert type of medical practitioner] is not required to explain minor risks that are not likely to occur.

Teach Back Method

Employ the “Teach Back” method by asking open ended questions to learn what the patient understands rather than just asking if they understand.

- It’s not what you say, it is what they hear.
- It’s not what you show, it is what they see.
- It’s not what you mean, it is what they understand
- Perception is Reality



Key Points to Remember



Provide enough information so the patient can make an educated decision



Provide the information in the language the patient understands



Evaluate the patient's understanding through teach-back methods



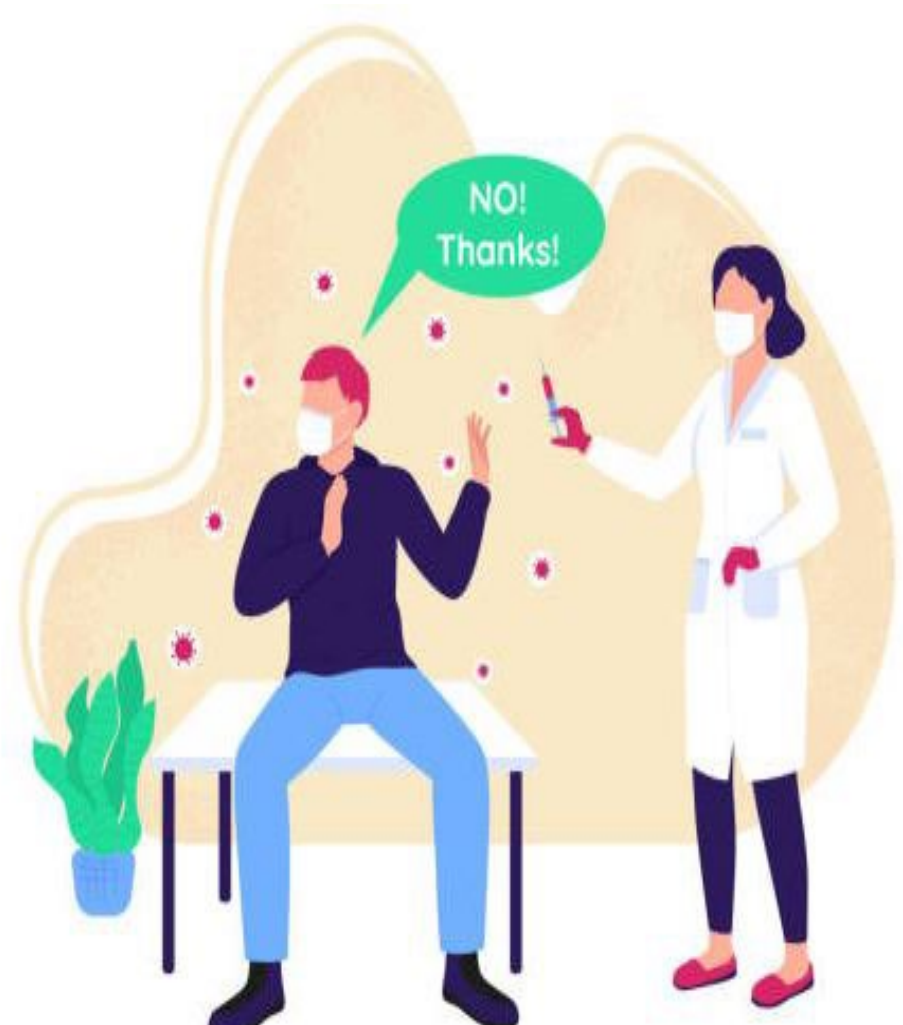
Identify an alternative treatment plan



Obtain the patient's signature, if possible



Document your discussion



Sources & For More Information

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