Quick Safety
An advisory on safety & quality issues

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Informed consent: More than getting a signature

Issue:

There are numerous challenges to implementing an effective informed consent process – that is, one in which the patient fully understands the health care treatment or surgical procedure they are agreeing to undergo. Even after signing a consent form, patients frequently do not understand the risks, benefits and alternatives involved in their course of treatment or surgical procedure – all of which are imperative for a patient to provide valid authorization.[1]

Stated simply, informed consent in medical care is a *process of communication* between a clinician and a patient that results in the patient's authorization or agreement to undergo a specific medical intervention (see sidebar box for The Joint Commission's glossary definition). In addition to the process of communicating to their patients, clinicians are concerned with obtaining the evidence of consent that serves to document their legal and ethical responsibility.

Unfortunately, the emphasis on obtaining a patient's signature as documentation of informed consent results in varying effectiveness of the communication between a clinician and a patient.[1,2] The process of obtaining informed consent is an essential aspect of patient-centered care and remains central to patient safety. The Joint Commission's Sentinel Event database includes 49 reports of informed consent-related sentinel events over the 2010-2021 timeframe; 36 of the reports were specifically related to wrong site surgery, and six were related to operative or post-operative complication. Other reports were related to elopement, falls, medication errors, unintended retentions, and suicide.

Informed consent: *Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.*

Source: The Joint Commission. 2022. Comprehensive Accreditation Manual glossary.

Barriers to understanding

There are many barriers that contribute to a lack of understanding on the part of the patient, including:

- A lack of basic information on the consent form. One research study found that four basic elements of informed consent – nature of the procedure, risks, benefits and alternatives – were included on the consent forms only 26.4% of the time.[3]
- Ineffective provider-patient communication and lack of shared decision-making between patient and provider. Effective provider communication and shared decision making have been shown to improve the adequacy of the informed consent process.[1,2,4,5,6,7] Improved communication of information to patients and families enhances their trust – even in situations where caregivers have unwillingly harmed patients through system failures and predictable human error.[8,9]
- Lack of consideration of the health literacy of patients when developing informed consent communication forms and other materials.[10,11] One study highlights how adoption of a new health literacy-based consent form and process stimulated patient provider communication, enhanced patient comfort in asking questions and influenced the use of teach back (a health literacy-based technique) in the perioperative setting.[12]
- Lack of consideration of cultural issues of patients when developing informed consent communication forms and other materials.[12,13] Cultural sensitivity is paramount to obtaining informed consent. In some cultures, the decision-maker is designated by the group; a signature on a piece of paper as opposed to verbal consent may convey a lack of trust; illegal immigrants may be reluctant to sign for fear of

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deportation; and for some Asian immigrants, the patriarch or a male designated by the family must be consulted.[13,14,15,16]

Safety Actions to Consider:

Health care organizations can improve the process of informed consent and enhance the safety of their patients by doing the following:

- Promote the notion of informed consent as a **process** of effective communication between a provider and patient and **not a signature on a form.**[17,18]
- Have clear written policy on informed consent for care, including:
    - Procedures requiring written consent
    - Professional roles in the informed consent process
    - Use of qualified medical interpreters
    - The role of patients' substitute decision makers
    - Timing of informed consent
    - Nature of a complete informed consent process
    - Documentation and verification process
    - Related tools and resources available for provider use to enhance the informed consent process
- Provide a formal training program to physicians on effective provider-patient communication and shared decision-making and the impact on informed consent and patient safety.
- Simplify the content, length and language of informed consent documents and patient education materials.
- Implement policy and interventions for patients with limited health literacy, limited English proficiency, or visual or hearing impairments, and emphasize the use of qualified medical interpreters.
- Make available appropriate communication tools and materials based on patient's cultural and language preferences.
- Provide tools to improve shared decision-making between patients and providers.
- Provide communication models for physicians to evaluate patient understanding and make follow-up conversations to address miscommunications.

Providers can improve the process of informed consent and enhance the safety of their patients by doing the following:

- Ensure that informed consent is truly informed by making sure that the patient understands what they are consenting to undergo.
- Do not assume that patients understand the medical terms in the consent form. A consent form alone is not sufficient for informed consent. Make use of decision aids, interactive media, graphical tools and other aids to enhance shared decision making and effectively asses and present risks during shared decision making.
- Make use of everyday language instead of medical jargon in communicating with patients or substitute decision makers.
- Make use of appropriate communication materials based on the patient's cultural or language preferences and allow patients time to consider the information provided.
- Overcome language barriers by making use of health literacy screening tools and medical interpreter services for patients with limited health literacy and/or limited English proficiency.
- To enhance active patient participation, employ patient engagement techniques and use more open-ended questions to elicit information regarding patients' needs and preferences, and encourage patients to ask questions.
- Use tools such as the teach-back method to determine whether patients understand the risks, benefits, and alternatives to treatment. Teach-back can help to focus patients and clinicians on what's important.

Resources:

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Note: This is not an all-inclusive list.