Measure Background

Self-determination in healthcare is fundamentally predicated on whether a patient freely consents to a procedure, without duress, and with a complete understanding of the implications of their choice. Although existing legal and procedural mandates ensure that generally patients are provided at least some information prior to signing a consent form, research suggests the current standard for informed consent is well below demonstrated patient preferences.

Patients Drive the Informed Consent Process

In 2019, a research team based at Yale University convened a series of roundtables with stakeholders including physicians, patients and their advocates, and measure development experts to identify a set of key elements of high-quality consent forms. These include descriptions of the procedure, a clinical rationale, and assessment of risks, alternatives, and providing the form to the patient at least one day in advance.[2]

Another team of researchers surveyed patients and found that many items typically omitted from the informed consent process, such as the clinician's level of experience with a procedure, whether any trainees would be involved, the alternatives and the risks and benefits of each, as well as expected difficulties and recovery times, were all highly important to patients.[3]

Just over half of U.S. adults have a reading level that permits them to understand and synthesize information from a complex text. According to a Gallup analysis, 54% of Americans between the ages of 16 and 74 read below the equivalent of a sixth-grade level.[4]

To address this problem in the context of consent forms for COVID-19 vaccine trials, a group of researchers showed it was possible to adapt standard consent forms that were complex and at a grade 9 reading level to a shorter and more readable form.[5]

Leapfrog's Informed Consent Standard

Leapfrog scores and publicly reports surgery centers on their policies and procedures for obtaining informed consent from patients.

Surgery centers achieving Leapfrog's Informed Consent standard meet all the following:

1. Training on informed consent that tailors different training topics to different staff roles and has made the training required for newly hired staff and existing staff who were not trained.
2. Ensures that as part of the process for obtaining informed consent, clinicians explain expected difficulties, recovery time, pain management, and restrictions after a procedure, and give the patient an opportunity to ask questions.
3. Ensures every consent form used by the facility documents the name of the clinician performing the procedure, whether the clinician is expected to be absent (if applicable), and whether any assistants or trainees will be involved (if applicable).
4. Ensures every consent form is written at a 6th grade reading level or lower.
5. Prior to conducting the informed consent discussion, identifies the patient/legal guardian's preferred language and where needed, provides a medical interpreter (not a family member or caregiver), and has a place in the consent form that indicates whether an interpreter was used.
6. Requires clinicians at the facility to use the "teach back method" with patients/legal guardians.

Download the complete Leapfrog ASC Survey scoring algorithms document at ASC Scoring and Results webpage.

Why Purchasers Need to Get Involved

Using their leverage as purchasers, employers can recognize and reward surgery centers that have implemented The Leapfrog Group's standards on informed consent. Purchasers and payors can promote dialogue about informed consent by educating patients and calling attention to the importance of choosing surgery centers that take steps to ensure patients are completely informed about the procedure they

undergo, and have an opportunity to ask questions and receive answers in a language they prefer for medical decision-making. Importantly, purchasers can continue to apply pressure on surgery centers to be transparent about their informed consent policies and procedures.

References

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5. Emanuel EJ, Boyle CW. Assessment of Length and Readability of Informed Consent Documents for COVID-19 Vaccine Trials. JAMA Netw Open. 2021;4(4):e2110843.

For a comprehensive list of references please review the Informed Consent Bibliography, available at https://ratings.leapfroggroup.org/measure/asc/2025/informed-consent