Assessing quality of informed consent documents: Taxonomy of key elements
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Research Objective:
The informed consent document is an important component of the informed consent process intended to support patient autonomy by promoting information sharing, transparency and trust. Hospitals can tailor consent documents, in accordance with state laws; however, while these customizations meet legal standards, they commonly do not fully support the principles of informed consent or patients’ decisional needs. To drive greater patient-centered care, under contract with the Centers for Medicare and Medicaid Services (CMS), we are developing a hospital-level measure of the quality of informed consent documents for elective hospital-based procedures. As a critical first step, we constructed a taxonomy of key elements to assess informed consent document quality based on published standards, medical literature, and the perspectives of patients and patient advocates. This taxonomy will inform the development of an instrument to assess consent document quality.

Study Design:
We employed a mixed methods approach to develop a taxonomy (classification structure) of informed consent document quality. We conducted a narrative review of peer-reviewed publications and an environmental scan of informed consent standards and guidelines to identify overarching domains and key elements of high-quality informed consent documents. Additionally, we convened a working group of nine patients and advocates with diverse experiences as patients, caregivers, champions of vulnerable populations, and patient safety experts. Over five, 90-minute meetings, the working group offered feedback on the taxonomy and it was refined accordingly.

Population Studied:
The targeted population is patients who are considering elective hospital-based procedures.

Principal Findings:
The taxonomy includes three comprehensive domains of informed consent document quality: Content, Presentation, and Timing. These domains are sub-classified into 20 dimensions which are specified into 53 items. For example, among the dimensions in the Content domain are risks, benefits and alternatives. The Presentation domain includes legibility, use of non-medical terminology, and opt-out clauses (e.g., picture/video-taking; tissue donation). The Timing domain includes receiving the informed consent document prior to the day of the procedure. The working group’s input focused on elements that facilitate patients’ understanding of the procedure (e.g., receiving the document with sufficient time for review; plain language descriptions of procedures); transparency about the frequency and magnitude of benefits/risks; and patient safety (e.g., patient-specific risk information; knowledge of anticipated anesthesia modality).

Conclusion:
Using a rigorous, patient-partnered approach, we developed a taxonomy of informed consent document quality comprehensive of ethically and legally-mandated informed consent standards and relevant to patients’ informational needs. The taxonomy provides a detailed structure of key elements of informed consent documents, along with examples of how to operationalize in a standard consent document. Thus, it can be used as a foundation for assessing quality of informed consent documents.

Implications for Policy or Practice:
The taxonomy will inform the development of an instrument to evaluate informed consent documents, providing the foundation for a measure of hospital-level informed consent document quality. This measure will critically impact patients’ experiences with informed consent processes by incentivizing hospitals to make significant improvements to the content, presentation and timing of documents shared with patients.