Difficult words and complex text in clinical consent forms can make it hard for patients to give truly informed consent. This is particularly relevant in cancer treatment, given its technical and abstract nature. A recent national study of radiotherapy consent forms found that less than 10% met the National Cancer Institute’s (NCI) recommended readability level. A supplement to the study notes the most difficult words to avoid.

The AMA Code of Medical Ethics provides additional guidance on shared decision-making, such as opinion 2.1.1, “Informed Consent,” to help physicians support patients in making well-considered choices about their care.

The study, published in JAMA Oncology, analyzed more than 100 forms from over 50 academic radiation oncology departments. Using seven validated readability indices, researchers found just 8% met NCI’s recommended eighth-grade readability level for research consent forms, and not one met this recommendation based on an index designed for non-narrative texts.

Average form readability ranged in grade level from 10.6 to 14.2. The only other study known to the authors to look at the readability of radiotherapy forms found readability grade levels ranging from 12.8 to 16.1.

In addition, the study found the forms used an average of 7.2 difficult words, assessed using “The Living Word Vocabulary,” which assigns readability grade levels from six to 12 to about 44,000 common words.

What to avoid (or replace)

A supplement to the study identifies more than 100 commonly used difficult words, some of which have a 16th-grade readability level. Following are the ones that appeared most often, along with their
recommended replacements.

**Alternative or alternate.** More than half of the surveyed consent forms included this word. Consider “other” or “possible” instead.

**Oncologist or oncology.** “Cancer doctor” is a recommended replacement for these words, used in 31% of the forms evaluated.

**Simulation.** These words, used in 21% of forms, should be substituted with something like “practice setup used to plan your treatment.”

**Attending (physician).** “Senior doctor” is an alternative to this term, used 19% of the time.

**Contraindicated or contraindications.** Consider replacing these words, employed in 16% of the consent forms, with “reasons to do something” or “reasons not to do something.”

**Interventions or interventional.** “Treatment” is easier to understand than these terms, used in 15% of the forms analyzed.

**Recurrences or recurrent.** The authors recommend “comes back” instead of these words, which also appeared in 15% of the consent forms.

**Why readability is important**

“Effective and ethical informed consent practices are crucial to protection of patient autonomy and shared decision making,” wrote the authors, who include researchers from Columbia University, University of Chicago, University of Illinois at Chicago and the University of Michigan. In addition, they noted, “Recent research suggests that nearly half of patients initiating radiotherapy have heard frightening stories, heightening the need for optimal communication during the consent process.”

And while NCI’s recommendation reflects the readability level that the average U.S. citizen comprehends, the average Medicaid enrollee reads at a fifth-grade level.

“These data suggest a need for reevaluation and modification of many current cancer radiotherapy consent documents using simple strategies, as well as the need for further research to evaluate consent processes in other settings—ideally with guidance from and templates designed by national professional organizations,” the authors wrote.

They noted several limitations to the study, including a lack of correlation of the forms with patient preferences or understanding, as well as the possibility that results were affected by response bias.
More on this

A recent issue of AMA Journal of Ethics® (@JournalofEthics) explores language and hierarchy in medicine and includes “The Role of Universal Health Literacy Precautions in Minimizing ‘Medspeak’ and Promoting Shared Decision Making,” which discusses legal, practical and ethical means physicians can use to enhance shared decision making and improve outcomes.

The CME module “Informed Consent and Decision Making” is enduring material and designated by the AMA for a maximum of 1 AMA PRA Category 1 Credit™ (CME information and disclosures). It incorporates animation, infographics and scenario-based learning to help physicians identify the standard process of informed consent, how to handle situations when patients cannot give informed consent, and issues related to informed consent in special situations.