e. Most consent forms are written at a level that is too advanced

Delgado and Leskovac (51) provide an overall guiding light regarding the comprehensibility of consent forms. These authors find that the burden of understanding the experimental treatment, and understanding the consent form, shifts to the study subject, in the context of a clinical trial. The reason the burden shifts is that only the potential subject can decide whether or not to enroll.

Paasche-Orlow et al. (52) also find that the burden shifts to the study subject. These authors wrote, "[e]ven though consent forms are never used in isolation, text written at a 4th-grade level would promote the autonomy of most candidates for participation in medical research."

Paasche-Orlow et al. (53) obtained 114 consent forms that had been used in clinical studies, and analyzed them using a standard reading level test, the Flesch-Kincaid score. The authors found the average readability to be at the 10th to 11th grade level. In view of evidence that half of American adults read at the 8th grade level (or lower), these authors recommended that the reading level of consent forms be at the 4th grade level. Table 29.2, which is from Paasche-Orlow et al. (54) provides concrete examples of 4th grade language versus college-level language.

Table 29.3, which is from Jefford and Moore (55) also provides a list of language to avoid, along with reasonable alternatives.

Davis et al. (56) conducted a study with a complex consent form, written at the 16th grade level (college level) and a simple consent form, written at the 7th grade level. The study was conducted on 153 adults. The simple consent form was distinguished in that it contained a drawing showing a woman receiving an injection (Treatment A) and a woman receiving an injection and a bottle of pills (Treatment B).

The subjects preferred the simpler consent form, and felt that the complex consent form might discourage them from enrolling in a clinical trial for cancer. However, this survey also determined that there was little or no difference in the comprehension of the two forms.

[51] Delgado R, Leskovac H. Informed consent in human experimentation: bridging the gap between ethical thought and current practice. *UCLA Law Rev*. 1986;34:67.

[52] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *New Engl J Med*. 2003;348:721–726.

[53] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *New Engl J Med*. 2003;348:721–726.

[54] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *New Engl J Med*. 2003;348:721–726.

[55] Jefford M, Moore R. Improvement of informed consent and the quality of consent documents. *Lancet Oncol*. 2008;9:485–493.

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