Abstracts of Note: The Bioethics Literature

This section is meant to be a mutual effort. If you find an article you think should be abstracted in this section, do not be bashful—submit it for consideration to feature editor Kenneth V. Iserson care of *CQ*. If you do not like the editorial comments, this will give you an opportunity to respond in the letters section. Your input is desired and anticipated.

Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine* 2003;348(8):721–6.

Institutional review boards (IRBs) supposedly safeguard research subjects, including those with limited literacy. These authors from Johns Hopkins conclude that IRBs actually may be subverting this goal by promulgating unreadable consent forms. Believing that IRB-provided informed-consent forms fail their own readability standards, they examined informed-consent-form templates that 114 U.S. medical school IRBs provided to researchers on their Web sites. They ran each template against the Flesch-Kincaid scale, which assigns a score based on the minimal grade level required to read and understand English text (range 0–12, corresponding to the reading level at that grade in school). Additionally, using publicly available information, they tested whether the IRB text's readability was related to the institution's level of research activity, local literacy rates, or federal oversight of the IRB.

They found that the average readability score for IRB-provided informed-consent forms was 10.6 on the Flesch-Kincaid scale. On the 61 Web sites where IRBs specified a required readability standard (54% of the studied sites) for informed-consent forms, it ranged from a fifth-grade to a tenth-grade reading level. The mean Flesch-Kincaid scores for the readability of the IRB-provided sample text exceeded their stated standards by 2.8 grade levels. Although the text readability was not associated with either the level of research funding or local rates of literacy, the 52 schools that had been made subject to oversight by the Office for Human Research Protections (46%) had slightly lower Flesch-Kincaid scores than the other schools (10.2 vs. 10.9). This suggests that IRBs need to (1) review their sample forms for readability, (2) review their readability standards—given that an eleventh-grade reading level may be too high for many research subjects, and (3) be subjected to enhanced federal oversight.

Reynolds TM. Down's syndrome screening is unethical: views of today's research ethics committees. *Journal of Clinical Pathology* 2003;56(4):268–70.

As the ability to screen for genetic abnormalities increases, ethics committees and IRBs may find themselves increasingly involved in determining what type and level of screening is ethical. This study surveyed members from 40 randomly chosen British IRBs to investigate their attitudes toward prenatal screening under several conditions varying in clinical severity and prognosis, including Down's syndrome. They each received questionnaires describing 19 clinical scenarios based around four "clinical" conditions: ones that were potentially embarrassing, that affected life span but not mental ability, that caused premature death, and that impaired intellect with a risk of neonatal cardiac defects (Down's syndrome). Screening tests with different degrees of effectiveness were described, and the diagnostic test descriptions ranged from those having no risk to those causing the spontaneous abortion of two normal fetuses for each affected fetus identified.

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Although the responding IRB members supported prenatal screening for treatment of a life-threatening condition (95% in favor), they felt that it was unethical to screen for conditions with only a slight increase in premature death (14%) or for conditions that would only alter a person's appearance (10%). They were ambiguous (49%) about screening for conditions that would significantly shorten an individual's lifespan. Screening for Down's syndrome was considered more ethical (56%) when described as a "serious condition" than when the clinical features were detailed (44%). When respondents were told of the risks associated with screening, most (79% for "serious conditions" and 86% for "clinical features") decided that screening was unethical.

Screening for Down's syndrome is just the tip of the ethical iceberg. The future will bring us more subtle and difficult genetic cases involving both prenatal and postnatal screening.

Williams BF, French JK, White HD. Informed consent during the clinical emergency of acute myocardial infarction (HERO-2 consent substudy): a prospective observational study. *Lancet* 2003;15;361 (9361):918–22.

Questions about informed consent have stymied much of the needed acute medical care research. Even when informed consent is part of the acute care research process, questions have been raised about its validity. It is believed that the anxiety, fear, and pain that patients often experience during medical crises or their treatment with potentially mind-altering analgesics often compromise patients' ability to comprehend information about, and give informed consent for, participation in clinical trials. These authors sought to assess whether patients with acute myocardial infarction could understand written and verbal information and whether they were competent to give autonomous informed consent to participate in a clinical trial.

They prospectively studied 399 patients with acute myocardial infarction in 16 hospitals in New Zealand and Australia who were eligible to participate in two large multicenter clinical trials. They also assessed the readability of patient information sheets, the patients' educational status, their views of the consent process, their comprehension of verbal and written information, and their ability to give consent.

They found that the patients would need to have a college freshman's reading level (Year 13 in their system) to comprehend the patient information sheets, although only 22% had been educated beyond secondary school. In any event, only 18% actually read the patient information sheet before giving or refusing consent to participate. Patients who gave consent were more likely to report good or partial comprehension of the information provided than were those who refused consent (89% vs. 70%, respectively; $p = 0.009$). Fifty-two percent of the patients were thought to be at the lowest level of decisionmaking capacity to consent, and 18% were not competent to consent.

The authors concluded that, although the consent process for these studies met regulatory requirements for clinical trials, it was inappropriate for most patients. The patients' comprehension of the information provided and their competence to autonomously give consent were less than optimal.

Korenbrot CC, Ehlers S, Crouch JA. Disparities in hospitalizations of rural American Indians. *Medical Care* 2003;41(5):626–36.

Are American Indians (AI) and Alaska Natives (AN) receiving poorer healthcare relative to other Americans? These authors from the University of California, San Francisco, used disparities in hospitalization rates, particularly rates for avoidable hospitalizations, to indicate potentially unmet health needs and inefficient use of health resources. The authors claim that the Indian Health Service (IHS) cannot track all hospitalizations of AI/AN in their population, so the hospitalization rates reported by the IHS underestimate disparities for AI and AN relative to other Americans.

Therefore, these authors compared the hospitalization and avoidable-hospitalization rates for a rural AI/AN population with those of non-Indians living in the same counties where both groups use the same hospital system, regardless of the expected source of payment. Specifically, they analyzed (for hospitalizations and avoidable hospitalization rates and risk ratios [RR]) California hospital discharge data for 1996 linked to rural IHS user data for 1995 and 1996 (3,920 hospitalizations) compared with a random sample of discharge data for the non-Indian population in the 37 counties of the IHS Contract Health Service delivery area (7,840 hospitalizations).

They found that hospitalization and avoidable-hospitalization rates were both higher for the AI/AN population than for the non-Indian general population. The age-adjusted hospitalization ratios were 72% higher for AI/AN men (RR = 1.72) and 52% higher for AI/AN women (RR = 1.52). The comparable ratios for avoidable hospitalizations were 136% higher for AI/AN men (RR = 2.36) and 106% higher for AI/AN women (RR 2.06). They concluded that disparities in healthcare access exist for the AI/AN population, and that current methods of assessing them are inadequate.