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 editors Kenneth V. Iserson and Barry Morenz at bmorenz@email.arizona.edu.

Ogbuanu CA, Probst J, Laditka SB, Liu J, Baek J, Glover S. Reasons why women do not initiate breastfeeding: A southeastern state study. *Women's Health Issues* 2009; 19:268–78.

Breastfeeding offers important benefits to infants and mothers. In *Healthy People 2010*, the Centers for Disease Control and Prevention (CDC) aimed to increase breastfeeding rates and set a target of 75% of U.S. mothers initiating breastfeeding. Despite efforts to promote breastfeeding, as of 2007, only 21 states had achieved the CDC's goal, and several Southern states, including Arkansas, maintained low breastfeeding initiation rates, ranging from 48% to 59%. The study aimed to identify reasons women give for not initiating breastfeeding and to determine whether such reasons vary by race/ethnicity or other demographic/explanatory variables. The authors conducted a cross-sectional analysis of women in Arkansas for 2000 to 2003. Data were obtained from the Arkansas Pregnancy Risk Assessment Monitoring System (PRAMS), a surveillance instrument that collects information on the attitudes and experiences of mothers during the preconception, gestation, and postpartum periods. The sample was limited to mothers who were Arkansas residents who gave birth to live singletons in-state (n = 7,127). Approximately 38% of women did not initiate breastfeeding. Compared to women who breastfed, a greater proportion of women who did not initiate breastfeeding were Black, unmarried, had one or more children, earned less than $18,001 per year, did not receive a phone number for breastfeeding help, received a gift pack with formula, were not taught how to breastfeed, did not receive information about breastfeeding, and did not room-in with their babies. The majority of women who did not initiate breastfeeding (63%) cited individual reasons such as not liking breastfeeding, not wanting to be tied down, feeling embarrassed, and wanting one's body back to oneself. About 34% cited household reasons, and about 33% cited circumstances such as going back to work or school and having a partner who did not want the baby breastfed. There was only a modest relation between the reasons women gave for not breastfeeding and race/ethnicity. Hispanics were more likely than Whites to cite circumstances as a reason for not breastfeeding. Hospital support for breastfeeding and maternal age were significantly associated with reasons given for not breastfeeding. Women who were not taught to breastfeed by hospital staff were more likely to cite individual reasons or household reasons for not breastfeeding compared to mothers who were instructed. Teenage mothers were much more likely than older mothers to list circumstances such as returning to work or school as the reason for not initiating breastfeeding. *Tailoring breastfeeding interventions to specific subgroups of women and hospital support for breastfeeding may improve breastfeeding initiation rates.*

Okike K, Kocher MS, Wei EX, Mehlman CT, Bhandari M. Accuracy of conflict-of-interest disclosures reported by physicians. *New England Journal of Medicine* 2009; 361(15):1466–74.

Physicians' conflict-of-interest disclosures are generally done on a voluntary basis, even though financial conflict of interest in biomedical research has been associated with a number of potential pitfalls, including an increased likelihood of positive (pro-industry) conclusions, the suppression of negative results, restrictions on the behavior of the investigators, and the use of biased study designs.

Because organizers of and speakers at national meetings can have great influence over their colleagues' practice patterns, it is important for listeners to know about professional biases. The recent public reporting

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of payments made to physicians by orthopedic device manufacturers provided an opportunity to assess the accuracy of physicians' conflict-of-interest disclosures.

The authors analyzed the reports of payments made to physicians by five manufacturers of total hip and knee prostheses in 2007. For each payment recipient who was an author of a presentation or served as a committee member or board member at the 2008 annual meeting of the American Academy of Orthopaedic Surgeons, the disclosure statement was reviewed to determine whether the payment had been disclosed. To ascertain the reasons for nondisclosure, they administered a survey to physicians who had received payments that were not disclosed.

The overall rate of disclosure was 71.2% (245 of 344 payments). For payments that were directly related to the topic of the presentation at the meeting, the rate was 79.3% (165 of 208), for payments that were indirectly related, the rate was 50.0% (16 of 32), and for payments that were unrelated, the rate was 49.2% (29 of 59; $p = .008$). In the multivariate analysis, payments were also more likely to have been disclosed if they exceeded $10,000 ($p < .001$), were directed toward an individual physician rather than a company or organization ($p = .04$), or included an in-kind component ($p = .002$). Among the 36 physicians who responded to the survey regarding reasons for nondisclosure (response rate, 39.6%), the reasons most commonly given for nondisclosure were that the payment was unrelated to the topic of presentation at the annual meeting (38.9% of respondents) and that the physician had misunderstood the disclosure requirements (13.9%); 11.1% reported that the payment had been disclosed but was mistakenly omitted from the program. The amount of the 43 undisclosed payments that were directly related to talks totaled $4,320,563. The 16 payments related indirectly to talks totaled $7,772,105.

In this study of self-reported conflict-of-interest disclosure by physicians at a large annual meeting, the rate of disclosure was 79.3% for directly related payments and 50.0% for indirectly related payments. *This level of nondisclosure and its effect on medical practices and patient care will, undoubtedly, lead to more stringent regulations. Unfortunately, it also illustrates a lack of ethical behavior on the part of our colleagues.*

Morrison CA, Horwitz IB, Carrick MM. Ethical and legal issues in emergency research: Barriers to conducting prospective randomized trials in an emergency setting. *Journal of Surgical Research* 2009;157(1):115–22.

One of the most important advances in medicine over the past several decades has been the establishment of randomized controlled clinical trials as the gold standard for evidence-based practice. Clinical trials are the foundation of current management strategies for nearly all major diseases and conditions except, as these authors point out, for trauma resuscitation. Many trauma and critical emergency medical patients are either unconscious or have limited mental capacity at the time treatment is required. Because of this, clinicians cannot obtain informed consent as in other areas of medicine. Trauma, a leading cause of mortality in the United States, is incurred disproportionately by minorities and those in low socioeconomic groups; minorities also have worse treatment outcomes than nonminority individuals. This article implicitly asks: Have bioethicists' concerns contributed to putting an extremely vulnerable population—severely injured patients—at risk?

In 1995, the Food and Drug Administration (FDA) issued the ''Common Rule'' (21 CFR 50.24), allowing a waiver of informed consent that was supposed to alleviate ethical concerns about ''non-consent'' research and make it easier to advance medical treatment for acute, critically ill, and injured patients. After a literature review, the authors found that in the 10 years following the passage of the FDA's Common Rule, only 21 published emergency medicine research studies were conducted under the waiver of informed consent.

They also found multiple sources citing both misconceptions regarding federal regulations and the cumbersome process of obtaining internal review board approval as significant barriers to conducting prospective randomized trials in the emergency setting. Ironically, whereas the Common Rule was enacted to protect vulnerable populations from exploitation, the authors found that the Rule seems to have been a barrier to clinical trials in trauma and emergency care research. This has deprived some of the most vulnerable groups from the benefits of evidence-based treatments.

The authors' review also revealed that the ambiguity of the Common Rule's wording about the informed consent exception has deterred many trauma and emergency medicine investigators from pursuing potentially life-saving research that could improve care. In particular, the language that requires "community consultation" and the demonstration that existing treatments are "unproven or unsatisfactory" has been identified as the most problematic. *These authors conclude that it is imperative that the current exemptions to the Common Rule be clearer and more functional, so that emergency medicine and trauma research can better serve this vulnerable population (i.e., severely injured patients) with evidence-based treatments.*

Smith-Doerr L. Discourses of dislike: Responses to ethics education policies by life scientists in the U.K., Italy, and the U.S. *Journal of Empirical Research on Human Research Ethics* 2009;4(2):49–57.

Since 2000 there has been greater effort and focus placed on research ethics education, which has included greater ethics mandates for researchers. And a variety of government and institutional policies have evolved regarding human research. These policies are often difficult to translate into specific practice. In response, education courses have evolved such as Web-based ethics training in the United States, presumably to assist researchers in complying with these ethics mandates. Through interviews with researchers in the United Kingdom, Italy, and the United States, the author explored scientists' reactions to the policies and the ethics training requirements that have evolved with the policies.

To prepare this paper, the author conducted 30 semistructured conversational interviews with scientists in the United States, Italy, and the United Kingdom, with 10 interviews in each country. Scientists who participated in the interviews were selected through the author's own social networks, cold calls to scientists, and referrals from scientists who had already been interviewed. Twelve interviews were conducted by phone, 17 were face to face, and, at the scientist's request, one was conducted by e-mail. The semistructured questions included discussion of ethics policies relevant to the scientists' work, the scientists' responses to the policies, and how the scientists learned about the policies and how to abide by the policies. Other topics addressed were typical attitudes of the respondent's colleagues toward ethical issues, significant changes in the life sciences related to society, and views on policies regarding ethics education requirements attached to research funding.

The results of the interviews indicated that in the United Kingdom, science policies, including ethics policies, changed substantially with turnover in leadership of the Medical Research Council. Thus scientists in the United Kingdom tended to ignore new rules so as not to squander their time when the policies might shift quickly. For example, a mandate for graduate students to complete courses in "transferable skills," which addressed the ethical, social, and commercial roles scientists play, became routinized when faculty were not invested in them because the requirement for them might disappear with the next leader of the Medical Research Council. In Italy, research funding from the government is through a patronage system where the well connected do better than those who are not so well connected. However, Italian scientists can also obtain research funding from the European Commission (EC). However, the application procedure is so complex that, for those scientists in Italy willing to submit an application, portions of the application not having to do with science, such as ethics education or reviews by ethics committees, are completed by companies who specialize in writing the nonscience portion of the EC's research applications. A cottage industry of firms in Europe has developed to assist with writing these complex applications. Although the Italian scientists indicated they routinely discussed ethics issues with their graduate students, they were dismissive about the bureaucratically complex ethics portions of the European Commission research applications. The Italian scientists simply said that those parts were completed by "somebody else, a specialist." In the United States, requirements for Web-based ethics training developed in a top-down manner after an unfortunate death in a gene therapy trial during the Clinton administration. One U.S. scientist stated in the interview that "most of them see it as a joke, frankly," referring to graduate students' perspectives on required ethics education, and he added that, "yeah, the faculty are no better." Seven out of the 10 U.S. scientists interviewed tended to "ridicule" the

routine modular ethics education that they saw as irrational. The only type of positive statements were ones such as "at least it was over quickly."

Unfortunately, as the author states, "It appears that an imposed ethics requirement is interpreted as an inane obstacle to funding that caricatures important issues rather than raising them for substantive consideration." The author states that the implications of his qualitative research are mostly about what is undesirable, specifically, "Avoid unreflective routinized ethics training." One promising experiment the author noted was being undertaken at Arizona State University through integrating research ethics into a required science course for graduate students. Integrated into the course are exercises requiring critical thinking about the social responsibilities of the science community. *The author concludes that "[e]thics education is meant to help research and clinical academics deal with complexities but if it is standardized, then the innovation needed in ethical thinking and behavior will be diminished."*

These Abstracts of Note were written by Aimee Kaempf, Ken Iserson, and Barry Morenz.