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.

Pesik N, Keim ME, Iserson KV. Terrorism and the ethics of emergency medical care. *Annals of Emergency Medicine*. 2001;37(6): 642–6.

Rationing, the infrequently mentioned "R" word of ethics, becomes explicit in the face of dire need and desperate shortages. Nowhere is that more obvious than in a mass casualty situation caused by an unseen enemy—the stuff of bioterrorism. Emergency medical personnel must consider in advance how we will deal with such situations, if we are to avoid chaos and the societal degeneration that can follow.

The threat of domestic and international terrorism involving weapons of mass destruction–terrorism (WMD–T) has become an increasing public health concern for U.S. citizens. WMD-T events may have a major effect on many societal sectors, and particularly on the healthcare delivery system. Anticipated medical problems might include the need for large quantities of medical equipment and supplies and capable and unaffected healthcare providers. In the setting of WMD–T, triage may bear little resemblance to the standard civilian approach. For the maximum benefit to patients, the authors argue that the emergency medical community must first develop collective forethought and a broad-based consensus about decisions that reach of necessity beyond the hospital emergency department.

Because they contend that critical decisions under these circumstances should not be made on a case-by-case basis, these authors suggest an algorithm to use in planning for such disasters. Individual physicians should never be placed in a position of deciding to deny treatment to patients without the guidance of a policy or protocol. Emergency physicians, however, may easily find themselves in a situation in which the demand for resources clearly exceeds supply. It is for this reason that emergency care providers, personnel, hospital administrators, religious leaders, and medical ethics committees need to engage in bioethical decisionmaking before an acute bioterrorist event.

Rivera S, Kim D, Garone S, Morgenstern L, Mohsenifar Z. Motivating factors in futile clinical interventions. *Chest*. 2001; 119(6):1944–7.

With modern medical technology, it is now possible to sustain life for prolonged periods in critically ill patients, even when there is no reasonable hope of improvement or achieving the goals of therapy. Such futile and medically inappropriate interventions may violate both the ethical and medical precepts generally accepted by patients, families, and physicians. In this study, the authors sought to determine who was primarily responsible for such interventions, the nature of their motivation, and the role of a timely bioethical consultation.

Using a retrospective review, they identified 100 patients of 331 bioethical consultations who were determined to have had futile or medically inappropriate therapy. The average age of patients was 73.5 $\pm$ 32 years (mean $\pm$ 2 SD) with 57% being male. Physicians admitted 57% of the patients to the hospital with a degenerative disease, 21% with an inflammatory disease, and 16% with a neoplastic disease. The family was responsible for continuing futile treatment in 62% of cases, the physician in 37% of cases, and a court-appointed surrogate in one case. Unreasonable expectations for improvement was the most common underlying factor. Family dissent was involved in seven of the 62 cases in which the family requested continued treatment, but there was no dissent when the

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physicians were primarily responsible for such treatment. Liability issues motivated physicians in 12 of 37 cases where they were responsible, but in only one of the cases when the family decided on continued treatment. Significantly, when a bioethics consultation resulted in the cessation of therapy, the patients died in a median of 2 days as opposed to 16 days if therapy continued.

Venturini F, Alberti C, Alberti MP, Scroccaro G. Clinical trials in Italy: focus on the protocols submitted to ethics committees. *Journal of Clinical Pharmacy and Therapeutics*. 2001;26(2):103–10.

This study endeavored to describe the main characteristics of clinical research protocols submitted to Italian local ethics committees (LECs). Working with 20 Italian LECs from nine regions in Italy, the authors prospectively surveyed all research protocols evaluated during the period from 1 September 1998 to 31 July 1999. They collected data on the studies' general characteristics, diseases and drugs under investigation, the population under study, methodological characteristics (e.g., sponsorship, multicentered, presence of a control group), LEC decisions, and the monitoring being done.

The authors evaluated data on 449 protocols. The majority of these protocols (83.1%, $n = 373$) were investigational drug studies, sponsored 76.8% ($n = 345$) of the time, with 86.4% ($n = 388$) being multicenter trials. The majority of the drug protocols were on antineoplastic drugs (27.7%, $n = 104$), cardiovascular agents (15.4%, $n = 58$) and systemic anti-infective agents (13.8%, $n = 52$). A few of the drugs investigated were new entities. Only a few of the studies focused on subpopulations, such as elderly and children (10 and 16, respectively). Early development phases (I and II) were less likely to be sponsored or multicenter trials. The most represented drug category in phase I and II trials was the antineoplastic agents.

The authors concluded that only a small portion of the research protocols submitted to Italian LECs relate to innovative research. On a positive note, new Italian legislation that decentralizes approval of clinical trials, allowing it to occur at the local level, will lead to shorter approval times and should stimulate more original research. Unfortunately, experience shows that decentralization has the opposite effect. The researchers suggest further surveys and monitoring of LECs to determine the research areas being reviewed, the methodological quality of approved studies, and whether the results are being published.

Soderstrom M. Darfor uteslot forskarna kvinnor ur sina studiepopulationer. [Why researchers excluded women from their trial populations]. *Lakartidningen*. [Swedish] 2001;98(13):1524–8.

Similar to the United States, Sweden discovered that women are underrepresented in their research trials. Although researchers have tried to address the issue, women are still excluded as subjects of medical research on diseases that are prevalent among both men and women, with only a slight improvement over the past two decades. This author attempted to assess the reason for this bias. The institutional research ethics committee (IRB equivalent) requested a written explanation for this exclusion from the investigators for 26 studies where women would seem to be appropriate subjects. These were culled from the studies submitted to them for review during 1997–1999 (2% of the total number of applications during the period). (A 1998 Swedish Medical Research Council policy document stipulates that research ethics committees can require additional information concerning choice of study population.)

Most researchers had more than one reason for excluding women. Qualitative analysis revealed that their explanations could be grouped into three categories: scientific, historical, and economic. The scientific reasons centered on a lack of knowledge of the physiology and metabolism of women of childbearing age. Consequently, researchers felt that their study results would lack external validity if these women were included. The author suggests that the lack of knowledge of women's physiology and metabolism could be explained by a lack of female experimental animals in preclinical studies—and could be easily remedied. However, investigators also expressed a general concern (moral or legal?) not to harm women of childbearing age. The historical reasons were that the investigators wished to compare their study results to prior study populations that did not include women. Some researchers based their choice to exclude women on "tight research budgets," although the relevance of this explanation is unclear. The author

concluded that this study demonstrates an avoidable occurrence of gender bias in medical research.

Whitney SN, Brown BW, Brody H, Alcser KH, Bachman JG, Greely HT. Views of United States physicians and members of the American Medical Association House of Delegates on physician-assisted suicide. *Journal of General Internal Medicine*. 2001; 16(5):290–6.

The American Medical Association (AMA) purports to speak for American physicians, but it is increasingly out of touch with practicing doctors. Although that has been intuitively clear for a number of years, this study centered on the AMA's support for banning physician-assisted suicide emphasizes that fact. To assess whether the AMA's position on the legalization of physician-assisted suicide corresponded to the position of practicing United States physicians, they mailed a confidential questionnaire to a random national sample of physicians of all ages and specialties, as well as all members of the AMA House of Delegates as of April 1996. The House of Delegates is the elected leadership group that sets general organizational policies.

The authors received a usable response from 658 of 930 eligible physicians in the nationwide random sample (71%) and 315 of 390 eligible physicians in the House of Delegates (81%). In the national sample, 44.5% favored legalization (16.4% definitely and 28.1% probably), 33.9% opposed legalization (20.4% definitely and 13.5% probably), and 22% were unsure. Opposition to legalization was strongly associated with self-defined politically conservative beliefs, religious affiliation, and the importance of religion to the respondent ($p < .001$). Among members of the AMA House of Delegates, 23.5% favored legalization (7.3% definitely and 16.2% probably), 61.6% opposed legalization (43.5% definitely and 18.1% probably), and 15% were unsure; their views differed significantly from those of the nationwide random sample ($p < .001$). Very reasonably, a majority of both groups would prefer no law at all, with physician-assisted suicide being neither legal nor illegal. The authors conclude that although members of the AMA House of Delegates strongly oppose physician-assisted suicide, rank-and-file physicians show no consensus either for or against its legalization. Although the debate is sometimes adversarial, most physicians in the United States are uncertain or endorse moderate views on assisted suicide. This study suggests that the positions on ethical issues taken by the AMA might not be consistent with the majority of practicing physicians' views.