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.

American College of Obstetricians and Gynecologists Committee on Ethics. Nonselective embryo reduction: ethical guidance for the obstetrician-gynecologist. *International Journal of Gynecology and Obstetrics* 1999;65:216–9.

Sterilization of women, including those with mental disabilities. *International Journal of Gynecology and Obstetrics* 1999;65:317–20.

Ethical issues related to expert testimony by obstetricians and gynecologists. *International Journal of Gynecology and Obstetrics* 1999;65:321–2.

With these three papers, the American College of Obstetrics and Gynecology's (ACOG) Committee on Ethics continues its excellent development and updating of ethical positions important to the specialty.

The first of these, "Nonselective embryo reduction," reviews the ethical issues involved in terminating one or more embryos in a multiembryo pregnancy during the first trimester. Because its purpose is to increase the chance of the remaining embryos surviving and to decrease maternal risk, to many people it is different from abortion. Indeed, women often undergo this procedure to *increase* their chance of delivering a child. Yet physicians may choose not to participate in the procedure.

The incidence of multiembryo pregnancy has risen with the use of potent ovulation-inducing drugs and assisted-reproduction technologies (e.g., in vitro fertilization). Perinatal mortality and morbidity and maternal morbidity increase as the number of embryos increases over two. ACOG recommends several methods to prevent multiembryo pregnancies, suggests better ways to counsel parents considering nonselective embryo reduction, and clearly lays out each option (abort all embryos, attempt to carry all embryos to term, terminate some embryos) and its potential consequences. In part, the decision rests with how much risk, both for the mother and for the potential children, the parents are willing to accept. For those who are counseling parents faced with this difficult decision or for those physicians concerned with the ethics of this procedure, ACOG's paper will be extremely helpful.

The second paper, on the sterilization of women, emphasizes that this elective procedure, often requested more for social than for medical reasons, has permanent and far-reaching consequences. Physicians involved in counseling women have a responsibility to avoid making recommendations based on nonmedical factors, although if they cannot participate in this procedure for personal reasons, they may explain their reasons to the patient—if asked. They must still refer the patient to another practitioner if the procedure is desired.

Patient vulnerability and sterilization are this paper's main thrust. Women in several circumstances may be subject to coercion either to be or not to be sterilized—from their family, physicians, insurers, and the government (restrictive laws). Women with mental disabilities can also be coerced into getting sterilized or they may be prohibited from getting the procedure when it is medically indicated. A long discussion suggests ways of avoiding these pitfalls and assessing patients' decisionmaking capacity. It emphasizes that neither IQ nor specific mental-illness categories directly relate to the capacity to consent. Even when consent is impossible, assent (as with children) should be obtained, when possible. When all else fails, ACOG recommends a series of guidelines to follow before performing sterilization, to help protect the rights of everyone involved.

The third paper, which discusses the ethical issues related to expert testimony, makes three key points. First, specialists who testify as expert witnesses should do

Cambridge Quarterly of Healthcare Ethics (2000), **9**, 580–582. Printed in the USA.

so in an unbiased fashion based on the case's merits. They should have experience and knowledge in the medical areas on which they are providing testimony, should not exclude any relevant information, and should not condemn practices that fall within the accepted standard of care. Second, there is a difference between medical malpractice, substandard practice that causes harm, and medical maloccurrences (bad outcomes that are unrelated to the quality of care provided). Examples of maloccurrences include unavoidable risks of appropriate medical care and unpredictable and unavoidable complications. Third, they suggest that any expert testimony should be subject to peer review. ACOG supports the concept of appropriate and prompt compensation for any medically related injury but would see society (i.e., government) pay for those injuries not related to malpractice. This paper addresses an important issue, because there are so many physicians now prostituting themselves as "hired guns," testifying to anything that earns their salary. Ethical issues are involved in this area that has been too long left solely to the lawyers. It's time ethicists had something substantial to say. This paper is a good start.

Forsythe M, Calnan M, Wall B. Doctors as patients: postal survey examining consultants and general practitioners adherence to guidelines. *British Medical Journal* 1999; 319:605–8.

How well do physicians follow the ethical dictates not to treat themselves and their families? Not well. In a survey of British general practitioners and consultants, the authors found that the guidelines adopted by the British Medical Association in 1995 were largely not being followed.

More than two-thirds of those queried responded after several mailings. Most (96%) had a general practitioner (GP), although few used them. About one-fourth (26%) of all GPs had as their primary care physician someone else in their own group, with one-third of male GPs using their partners but only 15% of women GPs doing so. However, 9% of the male GPs and 4% of the women said that they would never consult a GP before seeking a specialist's advice. Nearly one-fourth (24%) of specialists said that they would never consult a GP.

Nearly three-fourths of all respondents (71% of GPs; 76% of consultants) admitted prescribing for themselves. For 10% of GPs and 15% of consultants, this included prescribing opiates, anxiolytics, antidepressants, and hypnotics. Most (83% of GPs; 70% of consultants) also prescribed for their families.

Using a series of vignettes describing illnesses that the respondent might have (e.g., hematuria, depression, suspected gastric ulcer), only about half of the respondents indicated that they would seek a formal consultation. Many would self-medicate, seek informal consultation, and keep working. Some of the barriers to physicians seeking treatment are time pressures, perceived lack of confidentiality, and, although not specified in this article, physicians' egos that suggest that they cannot be ill and if they are ill, they know how to treat themselves better than anyone else. These authors suggest that barriers to physicians receiving appropriate medical treatment (and care) be removed, which may actually be easier to do in the British system than in many others.

Anon. Proposed revision of the Declaration of Helsinki. World Medical Association. *Bulletin of Medical Ethics* 1999;(147):18–22.

The presumably august body known as the World Medical Association (WMA), composed of expense-accounted leaders of many nation's medical associations, seems to have needed a further excuse for their existence. Their one claim to fame is the Declaration of Helsinki, a frequently cited but now-outdated document governing biomedical research on human subjects. Therefore, accompanied by their spouses and other ethically challenged luminaries, they settled in a beautiful international site and decided to rewrite their document. Unfortunately, as several component medical societies subsequently pointed out, they lacked the capacity to do the job. The editor of the *Bulletin of Medical Ethics*, for example, wrote, "others might share the editor's alarm that wholesale rewriting of such an important document by the WMA without external consultation was potentially very damaging."

With egg on their faces (again), the WMA submitted their draft to small working groups with consultation from many national medical associations.

One of the most contentious areas may be that of "waiver of consent." Although it is in concert with current U.S. regulations, most other countries have not bought into

the concept of or need for nonconsent research in emergency or critical care situations. Perhaps that is why this British author disdainfully notes that the WMA committee is "again with an American chair to collect views." Now that they have been exposed, the new Declaration may be in for some substantial alterations based on real international discourse and the WMA itself may be in for a housecleaning to make it a worthwhile entity before it is forcefully dissolved.

Dal-Ré R, Espada J, Ortega R. Performance of research ethics committees in Spain. A prospective study of 100 applications for clinical trial protocols on medicines. *Journal of Medical Ethics* 1999;25: 268–73.

When pharmaceutical companies write articles for ethics journals, we should be very wary. This piece, authored by SmithKline Beecham Pharmaceuticals in Madrid, is, as might be expected, a nice review of research ethics committee (REC) activity, primarily centered on the most active Spanish regions for clinical studies, Madrid and Catalonia. However, buried within its presentation is a not-so-veiled threat for Spain and other European nations to improve their RECs if they want to continue to get research funding from drug companies, which sponsor 90% of all Spanish clinical trials.

This study formally reviews the first 100 applications the company made for clinical pharmaceutical trials after Spanish regulations concerning human-subject studies changed in 1993. These applications involved 12 drugs in 15 protocols (phase II, III, and IV trials). Twelve were multinational trials that now comprise about 70% of all Spanish drug trials. The study designs included both controlled trials and open-label follow-up studies on a wide variety of medications. A total of 41 RECs were involved, with study sites being teaching hospitals, primary care centers, and clinics in 25 cities.

The authors' biggest complaint was the amount of time it took for the RECs to review the studies and, even when they did not raise additional questions, the time for researchers to hear that they had gotten approval. The mean time from submission to the arrival of the approval documents was 85 days (range 23–238 days). RECs, though, raised questions about more than one-third of the applications. Perhaps most disturbing is that different committees did not raise the same questions. More than half dealt with protocol-related issues and more than a third with ethical issues. Three applications were rejected, although other RECs approved the same projects. Of interest to IRBs in other countries, more than two-fifths of Spanish RECs charge (£200–560) for their reviews, although it doesn't seem to correlate with efficiency.

These authors summarize with a threat, "[Spanish RECs] should realize that the time needed to assess and approve clinical trials is one of the factors which is being carefully considered by research-based companies when they are deciding in which countries a study should take place." It's unfortunate that a bioethics journal let itself be used to wield this stick.