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.

Royal College of Physicians Committee on Ethical Issues in Medicine. Independent ethical review of studies involving personal medical records. *Journal of the Royal College of Physicians of London* 1994;28:439–43.

Good scientific practice requires using existing data, when possible, to answer questions. Is it ethical to use patient-generated data, including material from medical charts, without the patient's permission? Do these studies need institutional review board (ethical) review? The Royal College looked at these questions and divided them into two parts. The first part consists of studies used as medical audits, epidemiological surveillance, and outbreak investigations. They concluded that these constitute medical practice and require neither permission from patients nor an independent ethical review. The second part is research using existing medical records, health-related registers, or existing biological samples, but without direct patient involvement. These also do not require either consent or review, provided that the "official custodian" of the records or specimens gives consent, the recipient is a "senior professional person," confidentiality is assured, and anonymity exists in any publication or report. They conclude that only studies involving direct patient contact require consent or ethical review. The first group of cases seems indeed to be medical practice, and should not require any extra impediments. The second group, however, poses some problems. While this may expedite some research, we must wonder whether this exempts a bit too much clinical research from appropriate scrutiny. Only time will tell.

Wilks MF, Woollen BH. Human volunteer studies with non-pharmaceutical chemicals: metabolism and pharmacokinetic studies. *Human & Experimental Toxicology* 1994;13:383–92.

While discussions about the nature and ethics of using human volunteers in pharmacological trials are common, that is not true for nonpharmacological chemicals. Yet these tests not only occur frequently, but are also becoming more common as animal testing diminishes in many industries (cosmetics, personal care, and household products) under pressure from animal rights groups. These authors describe and make a case for the necessity of using human volunteers as subjects to test the metabolic pathways and target metabolites of nonpharmacological chemicals being introduced into the human environment. People encounter many chemicals (exhaust fumes, typewriter correction fluid, paint solvents) at home and at work. Safe-exposure levels have been established through trial and error and through the use of risk-benefit analyses balancing injury and loss of life against the consequences of not using the chemical. Animal toxicity studies (even if they are ethical to do) cannot be directly correlated with human metabolism or toxicity. Other measures of toxicity (accidental exposures and chemical use as pharmacologicals) are either too inexact or too rare to be of use, with hundreds of new chemicals introduced each year. The authors claim that they can follow accepted ethical guidelines for human subject research, use new analytical techniques to minimize subject exposure and danger, and produce information that will help determine nonpharmacological chemical toxicity to humans. Of interest is that they state that they would not perform any of these tests on women of childbearing age, or on women of any age if it could be avoided. (See next abstract for another view on women as experimental subjects.) The importance of this article for those in bioethics is that this is an area of human subject research that has been long neglected, being usually removed from the medical center environment. Perhaps we should be taking a closer look.

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McCarthy CR. Historical background of clinical trials involving women and minorities. *Academic Medicine* 1994;69:695–8.

As the outcry continues that women of childbearing years and minorities have been excluded as medical research subjects, Dr. McCarthy, who helped develop US research requirements, tries to put the debate in a historical perspective. Modern research ethics probably begins with the Nuremberg Code that, as he notes, was honored more in theory than in practice. In 1966, the US Public Health Service generated its first rules for the protection of human subjects after a series of research scandals became known. As these rules were revised, they increasingly emphasized the protection of vulnerable populations. He suggests that in that period research was widely regarded as dangerous and of little value to individual subjects. That, combined with the abortion debate, exposure of the Tuskegee syphilis study, and the "war on cancer" with its false hopes of quick success, deterred people from becoming research subjects. As a result of the first report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1975, regulations provided additional protections for pregnant women and fetuses. In 1977, the Food and Drug Administration prohibited phase I drug trials on pregnant women or women of childbearing potential. Fear of liability and a broad interpretation of the rule led to routinely eliminating women as subjects from virtually all drug trials (and much other research). Simultaneously, minorities feared participating as "guinea pigs" in research run by the White establishment. The 1980s saw major changes occur. While healthcare costs escalated and AIDS became America's most feared disease, people began to see clinical research studies as not only a way to get sophisticated medical care at relatively low costs, but also a way to obtain promising new medications. Simultaneously, a vocal women's movement finally pointed out that women potentially ran more risks from not having been part of drug testing than from having participated. This finally has led to a more equitable method of recruiting clinical research subjects. Yet, as Dr. McCarthy points out, we still do not know how to fairly describe the benefits and burdens of research participation to potential subjects.

Ethics Committee, American College of Obstetricians and Gynecologists. Sexual misconduct in the practice of obstetrics and gynecology: ethical considerations. *International Journal of Gynecology and Obstetrics* 1995;48:239–42.

Western medicine has a long tradition of prohibiting sexual contact with patients. This stems, in part, from the unequal power relationship between patient and physician, and the potential for abuse of that power. This prohibition must, it seems, be periodically reiterated. The American Medical Association's Council for Ethical and Judicial Affairs recently developed a report, "Sexual Misconduct in the Practice of Medicine," that condemned these practices, including the defense of "mutual consent." It also questioned some romantic relationships with former patients. With documented sexual contacts between obstetricians-gynecologists and their patients, the American College of Obstetricians and Gynecologists (following their Canadian counterpart's lead) endorsed the AMA report and added some additional caveats. They state that: sexual contact or a romantic relationship between a physician and a current patient is always unethical; sexual contact between a physician and a former patient may be unethical, depending upon the nature and timing of the professional relationship and residual feelings of dependency; physicians should not perform breast or pelvic examinations on their own minor children except in emergencies (nor should they be practicing medicine on any family member except in emergencies); and a request for a chaperone by either the patient or physician should be honored regardless of the physician's gender, but a separate opportunity for confidential discussions should be provided. They also state that the physician should only use the amount of physical contact required for diagnosis and therapy, and that should be accompanied by adequate explanation, avoiding sexual innuendos and provocative remarks. Finally, they do not completely depend on physician self-reporting, medical education, and professional reporting of misconduct to discover any problem. They encourage administrative physicians to develop clear and public guidelines for reporting instances of sexual misconduct, methods of prompt investigation, and disciplinary and remedial action. A very eloquent statement—now what?

Iserson KV, Kastre T. Are emergency departments really a "safety net" for the medically indigent? *American Journal of Emergency Medicine* 1996;14:1–5.

Are emergency departments really the medical "safety net" for America's indigents, as many claim? This study quantifies the willingness of emergency departments (EDs) and private primary care practitioners to see medically indigent patients. The authors developed three case scenarios to represent severe, moderate, and mild problems that typically confront emergency physicians. A female investigator made telephone calls using these scenarios, each time declaring herself to be medically indigent. All EDs received calls about all three scenarios, but she called private practitioners only with the least-severe scenario. The timing and order of all calls were randomized. A control survey of the same population of private practitioners was subsequently performed in which the caller related that she has third-party insurance and had a minimal (rash) problem. All 54 nonmilitary EDs in Arizona and 69 randomly chosen private primary-care practitioners in the same locales as the EDs were contacted. Calls to EDs were made during all time periods and days of the week; private practitioners were called only during their weekday office hours. Personnel answering the phone in the majority of EDs were willing to see medically indigent patients and recommended that the caller come to the ED immediately 76% of the time. This response did not vary by geography or the facility's size, although ED personnel suggested initial home treatment more commonly at smaller hospitals ($p = 0.02$), and more often suggested coming to the ED on weekends ($p < 0.02$). Some EDs, however, clearly did not comply with their own telephone-advice policies and some ED personnel failed to give medically appropriate advice. In contrast to the EDs ($p < 0.001$), 62% of private practitioners' staffs stated they were not taking new patients or required at least $30 in advance. Private practitioners in the largest communities were significantly more reluctant to see the medically indigent patient than were their peers in smaller communities ($p < 0.05$). For an insured caller 55% of the private practitioners would see the caller for less than $30 and only 35% were not taking new patients or provided referral. In contrast to most private primary-care practitioners, EDs are at least willing to serve as a triage point for the medically indigent and are often the primary-care safety net for the medically indigent patient.