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.

Lemiengre J, de Casterle BD, Van Craen K, Schotsmans P, Gastmans C. Institutional ethics policies on medical end-of-life decisions: A literature review. *Health Policy* 2007; 83(2–3):131–43.

These authors used a literature review to examine the ethically sensitive administrative practices surrounding medical end-of-life decisions. They looked at the prevalence, content, communication, and implementation of these written institutional ethics policies using a literature review. Their review included the major databases (PubMed, Cinahl, PsycINFO, Cochrane Library, FRANCIS, and Philosopher's Index) and a further review of reference lists for relevant papers. Relevance meant that the study was empirically based and that it focused on the prevalence, content, communication, or implementation of written institutional ethics policies concerning end-of-life decisions. They found 19 American, Canadian, Dutch, and Belgian studies. The majority of studies dealt with do-not-resuscitate (DNR) policies (prevalence: 10%–89%). Only Dutch and Belgian studies dealt with policies on pain and symptom control (prevalence: 15%–19%) and policies on euthanasia (prevalence: 30%–79%). The studies' focus was primarily on the procedural and technical aspects, rather than on defining the specific roles of parties involved in these decisions. Little attention was given to exploring ethical principles that question the ethical function of policies. In ethics policies on euthanasia, significant consideration was given to procedures that dealt with physicians' and nurses' conscientious objections. *These authors concluded that despite their importance in clinical ethics, empirical studies about the implementation of ethics policies are scarce.* Existing studies show that DNR and euthanasia policies do provide support to physicians and nurses, although primarily through specifying technical and procedural guidelines. They make it obvious that further research is needed.

Miller FA, Giacomini M, Ahern C, Robert JS, de Laat S. When research seems like clinical care: A qualitative study of the communication of individual cancer genetic research results. *BMC Medical Ethics* 2008;9:4.

Research ethicists have belatedly discovered that research participants want to know the outcomes of the studies in which they participated. The issue was first raised by native people who felt used by outside researchers over many decades; informing participants of results is now an ethical imperative. In some cases, information provided to participants is limited to communicating the study's general findings or conclusions. However, in other cases, it extends to disclosing individual research results, especially when these results are perceived to have clinical relevance to the patient. A debate has raged over this practice, with several scholars advancing critiques of the obligation to disclose individual research results. They question whether ethical goals are served by disclosure or violated by nondisclosure, and whether the communication of research results respects ethically salient differences between research practices and clinical care. Empirical data on these questions are limited. Available evidence suggests, on the one hand, growing support for disclosure, and on the other, the potential for significant harm. Using a set of interviews with key players, these authors explore the implications of the disclosure of individual research results concerning research-based cancer genetic testing in Ontario, Canada. Their findings led them to three conclusions: First, the communication of individual research results makes research practices seem like clinical services. Second, while valuing the way in which research enables clinical access, the

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interviewees found that these quasi-clinical services were inadequate. Finally, the authors recognized that although research needs influenced the quasi-clinical interaction with patients/subjects, they influenced them in different ways. This led the authors to conclude that the hybrid state created through the disclosure of research results that are perceived to be clinically relevant to individuals may produce neither sufficiently adequate clinical care nor sufficiently ethical research practices. They question the extent to which research can, and should, be made to serve clinical purposes, and *suggest the need for further deliberation regarding any ethical obligation to communicate individual research results*.

van den Borne F. Using mystery clients to assess condom negotiation in Malawi: Some ethical concerns. *Studies in Family Planning* 2007;38(4):322–30.

This paper serves as an example of how bending ethical rules potentially helped save thousands of people from the suffering brought on by HIV/AIDS, as well as more common STDs. To halt the HIV/AIDS epidemic in Malawi, the government promoted safer sex among female prostitutes in and around bars. In 1996, a qualitative study explored the changing dynamics of concurrent sexual partnerships, using a variety of researchers and methods. Although most international ethical research codes prescribe the informed consent of research subjects, the author, as principal investigator for that study, included the mystery-client method, which omits informants' consent. Five trained, pilot-tested, and closely supervised male researchers contacted 101 bar girls and "freelancing" women in trading and urban centers to assess the women's ability to negotiate condom use. The men posed as clients but were instructed not to have sex with their informants. This approach provided important contextualized information to improve HIV transmission-prevention programs, yet it raises ethical concerns. This article contributes to the dialogue and debate on ethical research involving mystery clients and encourages other researchers to share their ethical dilemmas and show how they have addressed them.

Duley L, Antman K, Arena J, Avezum A, Blumenthal M, Bosch J, Chrolavicius S, Li T, Ounpuu S, Perez AC, Sleight P, Svard R, Temple R, Tsouderous Y, Yunis C, Yusuf S. Specific barriers to the conduct of randomized trials. *Clinical Trials* 2008;5(1):40–8.

These authors have written an essay asking for some rational thinking in the requirements surrounding clinical trials. It's about time. Large randomized trials are required to provide reliable evidence of the typically moderate benefit of most interventions. To be affordable, such trials need to be simple; to be widely applicable, they need to be close to normal clinical practice. However, current regulations and guidelines have hugely increased trial complexity, effectively becoming barriers to their design and conduct. Key barriers include inadequate funding, overly complex regulations producing needlessly complex trial procedures, excessive monitoring, overrestrictive interpretation of privacy laws without evidence of subject benefit, and inadequate understanding of methodology. Complex regulations result in multiple ethics approvals for a multicenter study, unnecessary complexity in the study protocol, delays in securing regulatory approval, and cumbersome regulatory procedures, even for drugs widely used in clinical practice. The type of detailed safety monitoring currently needed in trials of new drugs is being applied indiscriminately to all studies. A simpler, more basic level of monitoring, which constitutes good practice in most trials, could be agreed on, with that level being exceeded only in specific instances. More evidence about the pros and cons of alternative approaches to data quality monitoring would help inform this process. Complex procedures in the form of multiple-page consent forms, overzealous monitoring of side effects and adverse events, source data verification, and overrestrictive approaches to protocol amendments can impede, rather than facilitate, trial objectives. Finally, further education on the nuances and functions of randomization would facilitate trial conduct, and reduce the need for burdensome complexity. *A radical reevaluation of existing trial guidelines is needed, based on a clear understanding of the important principles of randomized trials, with the objective of eliminating unnecessary documentation and reporting without sacrificing validity or safety.* Researchers should encourage public debate about how best to strike the balance between regulation and cost.

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