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.

Valdez-Martinez E, Trumbull B, Garduno-Espinosa J, Porter JD. Understanding the structure and practices of research ethics committees through research and audit: A study from Mexico. *Health Policy* 2005; 74(1):56–68.

This paper reports on a series of studies conducted between 2001 and 2002 at the Division of Research Evaluation of the National Health Research Council, Mexican Institute of Social Security, Mexico City (Dirección de Prestaciones Médicas; Instituto Mexicano del Seguro Social; IMSS). These studies sought to determine the role, structure, and workings of the local research ethics committees (LRECs) within the IMSS. The IMSS, unlike other Mexican health institutions, has a formal committee system. Such committees operate under a regulatory system and are charged with scrutinizing all research proposals to ensure their scientific validity and to protect the rights and well-being of research subjects. These requirements are described in their publication, *Manual de Investigación Medica en el IMSS* (Mexico City: IMSS; 1999). IMSS officials wanted to know how the committees were functioning and if they needed improvements. Their studies found problems with committee composition, the process of project assessment, the continuing review process, and staff motivation. In addition, a qualitative study [Valdez-Martinez E, Turnbull B, Garduno-Espinosa J, Porter JDH. Descriptive ethics: A qualitative study of local research ethics committees in Mexico, *Developing World Bioethics*, in press] highlighted the focus of the committees on rules, regulations, and the law, with little understanding of the important individual role of members in complementing and adding to these structures and perspectives. It suggests that, both to support the staff and to protect research subjects, *the organizational structure, management, and decisionmaking process of the IMSS's LRECs ought to be audited on a regular basis*. To support the further development of the committees, the aim of these audits should be focused on education and development of the vision, perspectives, values, and working processes of each LREC.

Axtell-Thompson LM. Consumer directed health care: Ethical limits to choice and responsibility. *Journal of Medicine & Philosophy* 2005;30(2):207–26.

Because HMOs, PPOs, socialized medicine (e.g., Canada), and other innovations have not controlled healthcare costs, a number of authors have suggested going back to the "old days" before insurance systems and having consumers take more responsibility for their own healthcare costs. This author, from Hawaii's Blue Shield, describes one such method, "consumer directed health care (CDHC)." She warns that healthcare cost-control measures will likely become unavoidable and painful as costs continue to escalate, with external forces possibly rationing resources. She suggests that an alternative is to engage consumers to make their own allocation decisions through "self-rationing," wherein they are given greater awareness, control, and hence responsibility for their healthcare spending. CDHC is one such method to both control costs and enhance choices by combining financial incentives with information to help consumers make more informed healthcare decisions and appreciate the economic trade-offs of those decisions. Although CDHC is gaining attention in the popular press, business publications, and academic journals, the author acknowledges that it is not without controversy about its relative merits and de-

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merits. *CDHC raises questions regarding the ethical limits of consumer responsibility for their choices*. Although the emphasis on consumer choice implies that autonomy is the ruling ethical principle in CDHC, it must be tempered by justice and beneficence. Justice must temper autonomy to protect disadvantaged populations from further widening disparities in healthcare access and from outcomes that could arise from healthcare reform efforts. Beneficence must temper autonomy to protect consumers from unintended consequences of uninformed decisions. She thinks that "thoughtful paternalism" will allow CDHC plans to offer choices that are comprehensible to lay consumers, limited in their range of options, and carefully structured with default rules that minimize potential error costs. However, if the confusion and self-serving nature of the industry-led Medicare drug plans are an example, we must be wary of such quick fixes that put the onus on consumers.

Wendler D, Belsky L, Thompson KM, Emanuel EJ. Quantifying the federal minimal risk standard: Implications for pediatric research without a prospect of direct benefit. *JAMA* 2005;294(7):826–32.

The bioethics literature is becoming more critical of the pure bureaucracy inherent in institutional review boards (IRBs) and the increasing number of "hoops" to research posed by federal research rules. These authors describe the difference between the risks to children in daily life versus the typical IRB threshold to approve pediatric research that does not offer participants a "prospect of direct" benefit. Such IRB approval occurs only when the risks are minimal or a "minor" increase over minimal. The federal regulations define minimal risks based on the risks "ordinarily encountered in daily life or during routine physical or psychological examinations or tests." In the absence of empirical data, IRB members may assume that they are familiar with the risks of daily life and of routine examinations and tests, and rely on their own intuitive judgment to make these assessments. Yet, intuitive judgment of risk is subject to systematic errors, highlighting the need for empirical data to guide IRB review and approval of pediatric research. Current data reveal that car trips pose the highest risk of mortality ordinarily encountered by healthy children. On average, these risks are approximately 0.06 per million for children aged 14 years and younger, and approximately 0.4 per million for children aged 15 through 19 years. Riskier car trips (i.e., younger driver, rural roads, wet conditions) pose an approximately 0.6 per million chance of death for children aged 14 years and younger and an approximately 4 per million chance of death for children aged 15 through 19 years. Participation in sports represents the upper end of the range of morbidity risks for healthy children. For every million instances of playing basketball, approximately 1900 individuals will sustain injuries, including 180 broken bones and 58 permanent disabilities. These findings suggest *IRBs are implementing the federal minimal risk standard too cautiously in many cases, suggesting a need to consider alternative standards*.

Newgard CD, Hui SH, Stamps-White P, Lewis RJ. Institutional variability in a minimal risk, population-based study: Recognizing policy barriers to health services research. *Health Services Research* 2005; 40(4):1247–58.

It is always interesting when researchers study a study. It is akin to the "making of" documentaries about a movie. These authors describe part of the IRB process during a multi-institutional research project of a prospective, observational, out-of-hospital study that attempted to validate a decision rule to identify seriously injured children involved in motor vehicle crashes in Los Angeles County. The primary study attempted to enroll 27 pediatric receiving hospitals between 2001 and 2004. Two federal research policies, the Privacy Rule and the requirement for federal-wide assurances, were implemented during the project.

The descriptive ethics study described (1) institutional variability in study approval and their willingness to obtain federal assurance documents for a federally supported, minimal-risk health services research project conducted during the implementation of the Privacy Rule and federal-wide assurances, and (2) the potential impact of such a policy on selection of research subjects and the generalizability of study results.

The 27 hospitals were sent identical research protocols requesting approval to review charts of children transported to their facility. The research protocol included strict confidentiality protections, was noninterventional, did not alter the standard of care at the scene or at the hospital, and

met requirements for waivers of both informed consent and the Health Insurance Portability and Accountability Act. Because it was a federally supported project, all participating hospitals were required to obtain a federal-wide assurance. Outcomes sought by these authors included hospital approval of the research protocol, total number of days to obtain study approval, and successfully obtaining a federal-wide assurance.

Overall, 6 of 27 hospitals (22%) refused to participate in the trauma study, all of which were community hospitals. The median time from submitting an application to study approval was 118 days (interquartile range 34–254, range 12–960 days) and time to get study approval differed when hospitals were categorized by type and the presence of an institutional review board ($p = .053$). No institutional review resulted in a change in the basic study protocol, although one hospital required paramedic consent. Following intensive efforts to secure federal-wide assurances, 12 of 27 hospitals (44%) possessed the necessary assurance to conduct the study. If all patients transported to hospitals that failed to obtain such an assurance were omitted, the sample size would have been reduced by 62% and would have excluded all children transported to community hospitals. This led these authors to conclude that *there is substantial institutional variability in approval of minimal-risk observational studies and in their willingness to obtain a federal-wide assurance, particularly among community hospitals. Federal research policy involving patient privacy and institutional assurances may be contributing to this variability, which can adversely affect research subject selection, disrupt population-based study designs, and threaten the generalizability of study results.*

Roth R, Barsi E. The community need index. A new tool pinpoints health care disparities in communities throughout the nation. *Health Progress* 2005;86(4):32–8. More information and charts available at: http://www.chwhealth.com/stellent/groups/public/@xinternet_con_sys/documents/webcontent/084757.pdf

The Community Need Index (CNI) is a new tool to help healthcare organizations, not-for-profits, and policymakers identify and address barriers to healthcare access in their communities and to identify specific areas (generally zip codes) in need of more healthcare resources. Catholic Healthcare West, San Francisco, developed this tool along with an information products company. The CNI aggregates five socioeconomic indicators long known to contribute to health disparity: income (impoverished elderly, impoverished children, impoverished single-parent households), culture/language (percentage minorities, no or limited English-speaking proficiency), education (lacks high school diploma), housing status (rents house or apartment), and insurance coverage (lacks health insurance, unemployed). They then applied these factors to every zip code in the United States. Each zip code received a score ranging from 1.0 (low need) to 5.0 (high need). Residents of communities with the highest CNI scores were twice as likely to experience preventable hospitalization for manageable conditions—such as ear infections, pneumonia, or congestive heart failure—as communities with the lowest CNI scores. The CNI provides compelling evidence for addressing socioeconomic barriers when considering health policy and local health planning. The tool highlights healthcare disparities between geographic regions and illustrates the acute needs of several notable geographies, including inner city and rural areas. Further, *the CNI should enable healthcare providers, policymakers, and others to strategically allocate resources where they are most effective in maintaining a healthy community, using a standardized, quantitative tool.*