Bioethics Matters

A Newsletter for the Friends of Biomedical Ethics at UVA

UNIVERSITY of VIRGINIA HEALTH SYSTEM

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Director's Letter

Warm greetings on this very warm June day! Things calm down around here during the summer—sort of. Our well-subscribed graduate courses (Foundations of Bioethics, Clinical Ethics, The Ethics of Human Subject Research) aren't offered in the summer; the new first-year medical school class has not yet started and last year's entering class is on break; vacation time takes one or two Center staff or faculty away each week. The Center is pretty quiet.

But there's lots going on in the midst of all this apparent calm. For one thing, we continue to try to fill the gap left by irreplaceable Walt Davis, who left us in June to accept a position in the Chippenham system in Richmond. He is much missed here—as teacher, consultant, and friend—but is, to all reports, thriving in his new role. Meanwhile, Ann Mills is toiling away at the innovative, one-of-a-kind ethics textbook for students of hospital administration that she, Prof. Pat Werhane, and others are preparing. Lois Shepherd and I are working on an invited essay for a palliative care journal that will be a trial balloon for the perspective on medical ethics we are presenting in our forthcoming book. Center faculty are critiquing and revamping courses for the next academic year. And, as we do throughout the year, we are continuing to hold regular ethics and humanities "workshops" with third-year medical students on various clinical rotations.

This week Marcia Childress, director of our programs in the medical humanities, and I led a discussion with several students in the midst of their two-week rotation in geriatrics and palliative care. The students' task is to bring to the table stories of encounters that have left them puzzled, concerned, moved, or outraged (or, often, all of the above). In this as in all our teaching opportunities with medical students, we seek to affirm and enhance their own considerable skills of discerning and analyzing such situations and to nurture their ability, as colleagues and teammates, to assist each other in finding reasonable, moral, and humane ways of responding. One of the students told of a witnessed encounter that left him "feeling sick" about the way patients are sometimes treated; it was a tale of a staff member reacting inappropriately (and ineffectively), with sarcasm and apparent anger, to a demanding nursing home patient.

The student's fundamental concern, one we hear with some frequency, was that he might turn into that staff member. He could easily understand her feelings of frustration with the patient, and wondered how he could manage to avoid having his good, compassionate vocational intentions distorted and suppressed by the consistent stress entailed in a profession of service. This, of course, is a very basic ethical question for the medical professions and for the administrators of medical facilities, a question that must look to theories of moral formation and virtue for help, and perhaps especially to the crucial role of the moral climate in which our work happens—the sense of mission, leadership, and solidarity that make the practice of thoroughly ethical medicine both expected and possible. Fostering this kind of climate is part of the work of the ethics-identified staff in any hospital. As we re-think the sorts of educational and skill-building support we can and should offer you, you can be sure that this question will be prominent among those to which we turn our attention.

In the meantime, best wishes for a fruitful summer—and for some relaxing time away from the good work you do to refresh and recharge for all that is to come!◆

Margaret Mohrmann

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Recent Faculty Publications/ Presentations/ Activities

Donna Chen

Presentations

+ "Recruiting, Informed Consent, and Therapeutic Misconception: Where Do the Problems Lie?" Association of Clinical Research Professionals, Central Virginia Chapter, Charlottesville, Va., January 27, 2011 (with Lois Shepherd).

+ Return of results. GARNET/ Genomics and Randomized Trials Network Steering Committee meeting. Bethesda, MD. May 20, 2011. (invited speaker)

Ann Mills

Publications

+Mills A. and Rorty M. (2011) "The Pre-Conditions for Building Capacity in Ethics Programs." HEC Forum 22:287-297. Published on-line Jan 7, 2011.

+Mills A. and Tereskerz P. (2011) "Projecting Human DNA Patent Numbers." Science 331(6022): 1264 (Letter to Editor).

Margaret Mohrmann

Presentations

+"Taking Responsibility, Holding on to Integrity, and Letting Go," Keynote Address, Conference on "Letting Go in the 21st Century: The Ethics of 'Heroic Care'," Peninsula Regional Medical Center and Salisbury University, Salisbury, MD, April 26.

+"Medicine, Ethics, and Spirituality: Integrity and Integration," Lecture Series in Religion and Ethics, School of Allied Health Sciences, Virginia Commonwealth University, Richmond, VA, March 23.

Lois Shephard

Presentations

+"Gen-ethics or Just Plain Old Ethics?" Second National Conference on Genetics, Ethics and the Law, University of Virginia, June 1, 2011.

+"Reasonable Limits to Autonomy at the End of Life," Carillion Clinic Annual Spring Ethics Workshop, Carillion Hospitals of Roanoke, Va., May 24, 2011.

+"Lessons Learned from the Schiavo Case," Gaston County U.C. Book Club, Gastonia, N.C., April 20, 2011.

+"If That Ever Happens to Me: Making Life and Death Decisions After Terri Schiavo," UVa Colonnade Club, March 29, 2011.

+"Recruiting, Informed Consent, and Therapeutic Misconception: Where Do the Problems Lie?" Association of Clinical Research Professionals, Central Virginia Chapter, Charlottesville, Va., January 27, 2011 (with Donna Chen).

Other

+Lois Shepherd was interviewed by Book TV about her book, "If That Ever Happens to Me: Making Life and Death Decisions after Terri Schiavo." The thirty-minute interview, which appeared on CSPAN2, can be found here.

+Organized and hosted in May the inaugural meeting of the Blue Ridge Health Law Professors Society, which brings together regional health law teachers for conversation about teaching and scholarship.

Patti Tereskerz

Publications

+Tereskerz, PM, Guterbock, TM, Kermer, DA and Moreno, JD. (2011) "An Opinion and Practice Survey on the Structure and Management of Data and Safety Monitoring Boards." *Accountability in Research*, 18 (1):1-30, 2011.

+Mills A. and Tereskerz P. (2011) "Projecting Human DNA Patent Numbers." *Science* 331(6022): 1264 (Letter to Editor).

Presentations

+Institute for Environmental Studies. Forum for a Civil Dialogue on Tobacco, Nicotine, and Alternative Products. Conflict of Interest Policies at U.Va. March 14, 2011.◆

In the News:

Leadership, The JC, and Blind-Spots

In 1995, The Joint Commission (then the Joint Commission on Accreditation of Healthcare Organizations) it expanded the "Patient Rights" chapter of its accreditation manual for hospitals to include requirements for "organization ethics." The standard required that hospitals conduct their business and patient care practices in an "honest, decent and proper manner."(1) "Honest, decent, and proper manner" manner refers to way in which a hospital carries out its activities. Thus, the mandate was directed at a hospital's culture and ethical climate.

This mandate survived several reiterations in The JC's accreditation manual for hospitals but until recently it was located in the manual's chapter on "Patient Rights." And assuredly, it was a misfit with other standards contained in the chapter. The chapter on Patient Rights (now called "Patient Rights and Responsibilities") was and is mostly concerned with standards on clinical issues the hospital should adhere to; specifically, clinical ethics issues.

In a little noticed shift, in 2009, The JC dropped this mandate from the chapter "Patient Rights and Responsibilities." It moved the mandate, dropping the term "organization ethics," to its chapter on "Leadership."

Standard LD.04.02.03 (previously associated with organization ethics) states: "Ethical principles guide the hospital's business practices." (2) The rational for the standard is:

> Although some leaders many not be involved in the day-to-day, hands-on operations of the hospital, their decisions and work affect either directly or indirectly, every aspect of the operations. They are the driving force behind the culture of the hospital. Leaders establish the ethical framework in which the hospital operates, create policies and procedures, and secure resources and services that support patient safety and quality care, treatment, and services. Policies, procedures, resources and services are all influenced by the culture of the hospital and, in turn, influence the culture. (2)

Leadership is now directly responsible as well as accountable for establishing the ethical framework which helps develop and sustain an institution's culture. But Treviño, Weaver and Brown found troubling results for leaders interested in establishing ethical frameworks. In the study, they randomly surveyed senior managers, and lower level employees in a financial services company, an industrial products company, and a public utility. Their goal was to identify and compare two types of employees' perceptions of ethics in their respective organizations. Their results suggest that that different identities and roles may lead to very different perceptions of ethics in an organization between senior managers and lower level employees. Senior managers consistently had a more positive view of the role of ethics and ethics infrastructures than lower level employees. Treviño, Weaver and Brown speculate that if "…senior managers believe that the ethical environment is already quite positive, they may do too little—provide too little executive ethical leadership or too few financial resources to support effective ethics management." (3)

The study points to the possibility that leadership in hospitals may also have a "blind spot" when it comes to the role of ethics and ethics infrastructures in their institutions. Hospital leadership should be aware of this possibility. They need to develop mechanisms to ensure that they aren't blinded in their perceptions of the ethical environment in their institutions so as to ensure appropriate decision-making in trying to fulfill the JC's mandates.◆

(1)Joint Commission for Accreditation of Healthcare Organizations. (1995). "Patient Rights and Organization Ethics." *Comprehensive Manual for Hospitals. Joint Commission for Accreditation of Healthcare Organizations*. p. 95 -96.

(2)The Joint Commission (The JC). (2011) *E-Edition*. Available through the University of Virginia's Medical Center at e-dition.jcrinc.com/ Frame.aspx

(3)Treviño L., G. Weaver, M. Brown. (2008) "It's Lovely at the Top: Hierarchical Levels, Identities, and Perceptions of Organizational Ethics." Business Ethics April 18(2):233-252.

Hospital Drive

"*Hospital Drive*" is the on-line literary and humanities journal of the University of Virginia School of Medicine

Daniel Becker, M.D., M.F.A, Director of the Center for Biomedical Ethics and Humanities conceived the idea of a journal that encourages original creative work that examines themes associated with health, illness, and healing. Dr. Becker serves as the journal's editor.

An editorial board and outside reviewers judge each submission anonymously. Poems, short fiction, essays, visual arts, and audio and video art are considered.

The current issue demonstrates the diversity of *Hospital Drive.* It offers poems, stories, and art from more than 30 writers and artists.

This newsletter has obtained permission to reprint a poem:

Kid Gloves

Susan Mahan*

When I was twelve years old,
Nana gave me
my first pair of leather gloves.
She called them kid gloves
and said they were the best.
They were supple and soft,
wonderfully scented
and lined with cashmere.
Those gloves kept my hands
from getting chapped
in our harsh New England winters.
When my husband died from
leukemia,
people treated me with kid gloves,
but that didn't help at all.
I bled from every pore.

If you are interested in submitting a piece to "Hospital Drive" or in reading the current issue, see http://hospitaldrive.med.virginia.edu◆

* Susan Mahan has been writing poetry since her husband died in 1997. She is a frequent reader at poetry venues, has written four books ("*Paris Awaits,*" "*In The Wilderness of Grief,*" *"Missing Mum," and "World View*"), and has been published in a number of journals and anthologies. She joined the staff of *The South Boston Literary Gazette* in 2002.

Ethics Conundrums: Empirical Evidence and Data and Safety Monitoring Boards: A Summary of Recent Work

Data and safety monitoring boards (DSMBs), also sometimes referred to as data monitoring committees, are commonly used in clinical trials involving life-threatening conditions and risks of major morbidity or mortality. DSMBs are responsible for advising sponsors about the continuing safety of trial subjects, the safety of potential recruits, as well as the continuing validity and scientific merit of the trial. But there is limited empirical data available which can be used by policy makers as well as persons serving on DSMBs as to "best practices" regarding how DSMBs are structured and managed. To help fill this gap, Patti Tereskerz and others undertook a study with a two-fold goal. The first goal was to obtain data about how DSMBs *are* structured and managed. The second goal was to solicit opinions as to how persons knowledgeable about DSMBs think DSMBS *should* be structured and managed.

Tereskerz et al. solicited information from three groups: Principal Investigators, Biostatisticians, and IRB Community Members. Principal Investigators (PIs) may or may not have served on DSMBs but regardless PIs would have knowledge about how DSMBs work. Biostatisticians are usually included on DSMBs and IRB Community Members served as a proxy for the general public.

The study uncovered startling differences between what these three groups thought *should* be the appropriate structure and management of DSMBs and what was *actually* happening. For instance, almost 70% of respondents believed DSMB members should have some formal training or serve as an apprentice yet few reported, again across all combined samples, receiving any training prior to serving on the board (14.9%). Moreover, there were significant differences between opinion and actual practice in several key areas including: payment of members to serve, keeping minutes of DSMB meetings, having rules in place for conflicts of interest and for course of action to follow when there is disagreement between the DSMB and sponsor, requiring sponsor blindness, using independent biostatistics centers, and having a community representative and bioethicist member as part of DSMBs. For each of these, respondents indicated that these practices should occur significantly more frequently than what was reported to occur in actual practice.

Given the importance of the role of DSMBs, particularly when a DSMB calls for a study to be terminated early, it is vital that DSMBs have guidance on best practices. Clearly, when DSMB member are open to and believe that practices *should* be more rigorous than they are, this suggests a compelling need for policy makers to consider developing further guidance on the structure and management of DSMB's.

Tereskerz and colleagues' work, "An Opinion and Practice Survey on the Structure and Management of Data and Safety Monitoring Boards," appeared in the January 18, 2011 ((1):1-30) issue of *Accountability in Research*.