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 editors Kenneth V. Iserson and Barry Morenz at bmorenz@email.arizona.edu.

Anscher MS, Anscher BM, Bradley CJ. The negative impact of Stark Law exemptions on graduate medical education and health care costs: The example of radiation oncology. *International Journal of Radiation Oncology* 2010;76(5):1289–94.

The Stark Law is federal legislation prohibiting physicians from referring Medicare and Medicaid patients to entities with which they have a financial relationship. "Radiation therapy services and supplies" are regulated under the Stark Law. The law contains several exemptions, including the In-Office Ancillary Service Exemption (IOASE), which, in essence, provides a way to legally bypass the selfreferral prohibition as it pertains to radiation therapy services by allowing radiation therapy services to be incorporated into the practices of nonradiation oncologists, usually urologists. Such arrangements can be profitable to urology groups by allowing them to maximize financial rewards by collecting the technical component of more expensive treatment modalities. A literature review by the authors suggests that ownership of radiation oncology facilities by nonradiation oncologists is associated with increased utilization and increased costs but does not necessarily improve access to services. Given that financial interests may play a role in referral and treatment patterns, the authors aimed to evaluate the impact of urology/radiation oncology IOASE arrangements on radiation oncology residency training programs at academic centers. A survey was sent to directors of all 81 U.S. radiation oncology residency training programs. Seventy-three percent of surveyed program directors responded. The number of resident trainees in responding programs ranged from 4 to 28, with the median being 6. Fifty-three percent of the directors reported that practice arrangements taking advantage of the IOASE for radiation oncology existed in their communities. Such practice arrangements occurred in a number of different

states and in both larger and smaller metropolitan areas. One program was excluded from further analysis because it was participating in an IOASE practice arrangement. Of those remaining directors who reported that IOASE business practices existed in their areas, 87% indicated that such arrangements reduced patient volumes at their institutions, and 27% believed that the reduction in patient referrals had negatively impacted resident training in their programs. The programs who reported a negative influence trained a total of 44 residents, nearly 10% of the total number of radiation oncology residency positions at the responding institutions. For radiation oncology trainees to successfully complete residency training, they must perform a minimum number of radiation procedures as designated by the American Council on Graduate Medical Education. The study implies that certain Stark Law exemptions have a negative effect on residency training in the field of radiation oncology by shifting patients away from academic centers to community practices in which radiation services are owned by nonradiation oncologists. Current Stark Law exemptions may have important implications for graduate medical education, treatment and utilization patterns, and healthcare costs.

Halac J, Halac E, Moya MP, Olmas JM, Dopazo SL, Dolagaray N. Bioética perinatal: ¿Eutanasia o decisiones sobre terminación de la vida? Análisis del Protocolo de Groningen. [Perinatal bioethics: Euthanasia or end-of-life decisions? Analysis of the Groningen Protocol]. [Spanish] *Archivos Argentinos de Pediatría* 2009;107(6):520–6.

Dutch faculty at the University Medical Center in Groningen developed the now controversial "Groningen Protocol" as a framework to discuss neonatal euthanasia, publishing it in English in 2005. Although euthanasia is not an option in most places in the world, the protocol suggests a useful structure for discussions with the parents of extremely ill neonates and clinical actions for these neonates.

This paper's authors, Argentinean physicians and ethicists, along with additional physician and nursing staff, analyzed the protocol in English and Dutch and then using their Spanish translation. They reached a consensus that the protocol identifies three neonatal groups to which it might be applied: (1) infants with physical deformities or chromosomal abnormalities clearly incompatible with life; (2) infants who survive intensive treatment, but whose expected quality of life is poor (e.g., severe asphyxia or cerebral abnormalities); (3) infants who survive without technological interventions, but will suffer greatly-and there is no known way to ameliorate that (e.g., severe forms of epidermolysis bullosa, progressive paralysis).

They then presented their assessment and proposed method for using it in discussions with parents about the clinical condition of their critically ill babies to their hospital's ethics committee; the committee made additional recommendations. Euthanasia was not an option. The authors then selected four extremely ill infants that met one of these criteria. Their parents were interviewed at least twice daily during the child's hospital stay. In the course of these interviews, the authors identified three interventional stages. The first stage was promoting all possible treatments, the second was a guarded and cautious request for the staff to evaluate "suffering," and the last was when requests were made to reduce therapeutic efforts to provide the child with a "dignified death." A week after their infant's death, the parents were shown the protocol. In all four cases, the parents suggested that they would have chosen ending their infant's life to avoid undue suffering, once the ultimate outcome was evident. The authors recommend that the protocol must not be viewed as a guideline for euthanasia in newborns, but rather as a means to discuss infants' critical conditions with parents. Limitations when applying it are the definition of what is considered "unbearable suffering" in newborns and how to ascertain when the infant has "no prospect." They emphasize the benefits of working with the Ethics Committee and of obtaining "second opinions" from experienced physicians.

Guyatt G, Akl EA, Hirsh J, Kearon C, Crowther M, Gutterman D, et al. The vexing problem of guidelines and conflict of interest: A potential solution. *Annals of Internal Medicine* 2010;152:738–41.

As the concept of evidence-based medicine (EBM) has been introduced and incorporated into virtually every aspect of the practice of medicine, organizations and committees across specialties have struggled with the problem of financial and intellectual conflicts of interest (defined as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation"), especially as they relate to clinical guidelines shaping how physicians practice their trade and standards of care in their respective fields. Much has been written both academically and in the mass media about how even the appearance of conflicts of interest can create significant doubt about the appropriateness and trustworthiness of formal practice guidelines. This has led many to more thoughtfully consider membership of these committees, as well as how to manage conflicts of interest in the long and arduous process of producing these documents.

The American College of Chest Physicians (ACCP) has published "Antithrombotic Guidelines" for "the use of antithrombotic agents to prevent and treat venous and arterial thrombosis" eight times in the past 20-plus years. In reviewing previous revisions of these guidelines, an executive committee determined prior contributors had "problematic" conflicts of interests despite previous attempts to manage these conflicts openly. In preparation for the ninth revision of this work, the Health Science and Policy Committee (HSP) of this organization was given the task of determining new requirements for participation in guideline development. They implemented three unique conditions to improve the independence (and, thus, perceived quality) of these guidelines, including (1) explicitly defining and placing equal emphasis on intellectual and financial conflicts of interests as a way of more closely controlling the participants in the process, (2) employing "methodologists" without "important conflicts of interests" as editors with primary responsibility for each specific portion of the document, and (3) allowing participants with significant intellectual or financial conflicts of interest to be involved in the collection and interpretation of evidence, but excluded from discussion and ultimate development of recommendations for specific guidelines.

Although not without its own set of problems, the ACCP's HSP Committee for

the production of the "Antithrombotic Guidelines" has proposed and implemented requirements much more cumbersome and substantial for its participants than most other organizations provided with the task of developing specific guidelines for clinicians in practice. These conditions still allow for participation by those with intellectual and financial conflicts of interest (as, in many cases, these individuals are experts in their fields and have knowledge and experience of value to the committees charged with the task of guideline development) but limit their involvespecifically prohibit their ment and influence in the actual production of the recommendations. This method is unique and could become a model for other organizations striving for more transparent and evidence-based guidelines that are less influenced (intentionally or unintentionally) by conflicts of interest.

Shabanowitz RB, Reardon JE. Avian flu pandemic—Flight of the healthcare worker? *HEC Forum* 2009;21(4):365–85.

A major medical disaster, such as a pandemic flu, will put all healthcare workers in a conflict of interest position between their role as healthcare providers and personal safety concerns. A critical issue in planning for a disaster, such as a pandemic flu, is identifying the healthcare workers who are able and willing to provide the needed care. Whether there is a "duty to treat" remains a controversial question. There are a variety of legal, professional, and ethical guidelines that could help inform debate about a duty to treat, but to date there are no clear directives that mandate healthcare workers provide care in the face of a dangerous medical disaster. There is no doubt that individuals will need to participate in collective action for the ultimate good of the community in the face of such a disaster lest anarchy ensue. Some have advocated creating penalties for healthcare workers unwilling to work in the face of medical disasters or creating legal obligations to work in the face of such disasters. Others have advocated incentives, such as making sure that healthcare workers who expose themselves to risk caring for others during a pandemic are the first to receive vaccines and antiviral drugs and are provided supplemental life/disability insurance.

The authors, who are working with the Geisinger Pandemic Influenza Prepared-

ness Group, decided to survey their healthcare workers to gain their perspectives on these issues. Geisinger Medical Center is located in Pennsylvania and serves a population of more than 2.5 million people across 41 predominantly rural counties. The Geisinger Health System has 10,000 employees and is the largest hospital in the area, which would likely receive a substantial influx of patients if a severe pandemic flu were to occur. The authors developed an online survey that was distributed by the institutional e-mail system to over 10,000 employees. One thousand three individuals responded to this survey, which was approximately a 9% response rate. There were 12 questions, 4 concerning healthcare workers' responsibilities, 7 concerning volunteerism, and a final question that asked whether the respondent would or would not volunteer in the event of a pandemic flu. Ninety-five individuals were removed from the original data because they started the survey but never completed it.

Survey respondents did acknowledge a "duty to treat." More than 60% did not believe it was ethical to abandon the workplace during a pandemic, yet 65% felt they should have the power to decide for themselves whether they would work during an avian flu disaster. Further, approximately 79% did not think it appropriate to terminate someone who refused to work during a pandemic. Responses regarding requirements for parents of children were mixed, with about 45% indicating that childless workers should not necessarily be the primary source of caregivers for victims of a pandemic. Over 99% believed that protective equipment and training regarding handling infectious disease were "extremely important" or "important." Incentives, such as the availability of vaccines and antiviral medications, along with personal financial help, were also believed to be extremely important or important in approximately 78%–96% of study participants. Most importantly, 79% of people said they would volunteer if they received all of the protective options/incentives that were offered. Younger workers were more likely to feel it was ethical to abandon the workplace during a pandemic to protect their families.

The authors emphasized that most experts believe it is only a matter of time before another deadly pandemic occurs. The Spanish flu of 1918 was believed to have killed an estimated 20–100 million people worldwide;

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however, no expert can say when or how severe the next epidemic will be. The authors underscore the many concerns that have to be considered in planning for a pandemic, including "quarantines, allocation of scarce resources, compulsory vaccinations, autonomy and liberty rights." The authors are of the opinion that cooperation, including cooperation of healthcare workers, will only occur in an atmosphere of openness, inclusion, and transparency, which will require the "utmost trust and solidarity." The authors review recent efforts, such as those of a group of scholars who developed an ethical framework for a collaborative pandemic plan after the 2003 Toronto SARS outbreak.

These Abstracts of Note were written by Aimee Kaempf, Ken Iserson, Steven T. Herron, and Barry Morenz.