MEDICAL ETHICS ADVISOR®

For 25 years, your practical guide to ethics decision making

November 2012: Vol. 28, No. 11
Pages 121-132

IN THIS ISSUE

Statement of Financial Disclosure:
Arthur R. Derse, MD, JD (Consulting Editor), **Shelly Morrow Mark** (Executive Editor), and **Leslie Hamlin** (Managing Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

AHC Media

Making ED organ transplant feasible puts providers in "difficult ethical territory"

Pilot project generated ethical debates

At the start of leading an 18-month pilot project to explore organ donation for patients who died in the emergency department (ED) at University of Pittsburgh Medical Center, **Clifton W. Callaway**, MD, believed the team was "creating, in reality, what the general public already thought existed." "In reality," he explains, "there is no established mechanism for patients who die in the ED to donate organs." "I think, in large part, the public expected that if they were in a car crash and died suddenly, and despite our best efforts could not be resuscitated, that was exactly when they *would* donate organs," he says. "We always notified the organ procurement organizations when we had a death, but that was the end of the process."

This is because all resuscitation efforts stop when a patient is pronounced dead by the ED team, and nothing is done to maintain organs for possible transplant. "We all walk away and talk to the family, and the organs have no blood flow," says Callaway, a professor of emergency medicine at the University of Pittsburgh. "Without blood flow, the kidney begins to suffer, and after about 30 minutes, we would expect the

EXECUTIVE SUMMARY

A pilot project exploring organ transplant in the emergency department (ED) setting at the University of Pittsburgh Medical Center identified the challenges of this practice, including few potential organ donors dying in the ED and difficulty meeting timeframes. Families and hospital staff reported no ethical concerns, but the project did not continue due to logistical difficulties and lack of funding.

- There is currently no established mechanism for patients who die in the ED to donate organs.
- The cost of keeping a team continually available is significant.
- Public fears about new donation practices can be allayed with education.

recipient would not do well. So there is a group of organ donors who currently don't have the opportunity to donate when they die."

Team always on call

The majority of organ donations occur when it becomes clear that an intensive care unit (ICU) patient's injury is not survivable, and the process occurs on a "more gentle time scale" than in the ED, says Callaway. "It's quite challenging to front load this into an ED setting, when somebody goes from being healthy to an organ donor in 60 minutes time. Fortunately, that is a rare situation. So there is not a huge untapped pool of potential donations."

No one involved in the care of a patient who might become a donor was involved in the donation process, stresses Callaway. The only change in ED practice was to prioritize the call to the organ procurement organization. If the patient was an organ donor, a second physician, different from the emergency physician, then began a procedure to pump cold fluids to lower the temperature of the organs that might be donated, in order to "buy time" until a surgeon could be available to procure any organs that would be donated. "We had a pretty pure separation between emergency care and donation," he says. "We had no concerns expressed by the public that there was anything different about our care or practice, and we really had no concerns from the hospital staff," he says.

Donation was attempted for only five patients who died in the ED during the 18-month pilot, which began in 2010 and was funded by a $321,000 grant from the Department of Health and Human Services, and none of the organs were transplanted. "We had two kidneys that looked usable on the pump, but were not matched to a recipient. None of the families were concerned about the ethical aspects of the donation," Callaway says. "From an ethical standpoint, we were extremely conservative in how we approached it."

The infrastructure cost of keeping a separate team available 24 hours a day, seven days a week, for an event that could occur at any time is one reason the project didn't continue. "Logistically, it was very difficult. When a potential organ donor dies five times in 15 months, that meant we had a team available on call for something that happens once every two or three months," says Callaway. "That is a tremendous resource to have, and it was not something we could sustain after the demonstration project was complete."

Delays are obstacle

Since the ED team made sure nothing was initiated until the first phone call was made informing the organ procurement organization that a donor had been pronounced dead, this decreased the chances that organs would be usable. "With a delay up to an hour, the transplant surgeon would not be enthusiastic about using that organ in another patient," he says. "We found it was tremendously challenging to make the time cutoffs that we said would be our benchmarks of success."

Cutting those delays means getting into "difficult ethical territory," however, says Callaway. "It would be much easier if we called when the resuscitation is still ongoing, but we felt that would be potentially unethical. We would not want to initiate anything prior to somebody being pronounced dead," he says, noting that Spain has a longstanding practice of continuing chest

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Medical Ethics Advisor®, P.O. Box 105109, Atlanta, GA 30348.

AHC Media is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media designates this enduring material for a maximum of *18 AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is intended for acute care physicians, chiefs of medicine, hospital administrators, nurse managers, physician assistants, nurse practitioners, social workers, and chaplains. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $83 each. (GST registration number R128870672.)

Senior Vice President/Group Publisher: **Donald R. Johnston**.
Managing Editor: **Leslie Hamlin** (404) 262-5416 (leslie.hamlin@ahcmedia.com)
Executive Editor: **Shelly Morrow Mark** (352) 351-2587 (shelly.mark@ahcmedia.com).

AHC Media

EDITORIAL QUESTIONS

Questions or comments? Call Leslie Hamlin at (404) 262-5416.

compressions after someone is pronounced dead. The team considered this practice, but ultimately rejected the idea.

"We were uncomfortable with the ethics of that. If you are doing chest compressions, it means you are still trying to save the patient in front of you, not just trying to save some organs for another patient," says Callaway. "To stop [cardiopulmonary resuscitation] for a little while, and then start it again in order to keep organs usable was something we had never done. We felt uncomfortable about instituting that into our program."

Callaway is still in favor of donation in the ED setting, but says current efforts are focused on improvements in resuscitation. "If nothing else, I think we identified the barriers to doing this and some areas for public discussion over the next few years to see what we should do in the ED and what should be off limits," he says.

The process by which informed consent is granted to donate an organ, how to allocate available transplantable organs to those on the waiting list, and ensuring that the possibility of organ donation does not adversely affect the care that a sick patient receives, are three ethical concerns with organ donation in any context, says **Kevin G. Munjal**, MD, associate medical director of prehospital care at Mount Sinai Medical Center in New York City. "These issues are amplified in the often high-pressure environment surrounding death in the emergency room," he says.

Since the advent of donation, there has been an ongoing effort to educate the public on the donation process, the dead donor rule, and how death is declared, says **Alexandra K. Glazier**, Esq., vice president and general counsel at New England Organ Bank in Waltham, MA, and chair of the Organ Procurement and Transplant Network/ United Network for Organ Sharing Ethics Committee. "As long as the death declaration process is made clear and the dead donor rule is maintained, public fears on new donation practices can be allayed," says Glazier. "However, the possibility of public misperception of new donation techniques, especially within the ED environment, should not be underestimated." *(See related story on misconceptions, p. 123.)* ■

SOURCES

• **Clifton W. Callaway**, MD, PhD, Professor, Executive Vice-Chair, Department of Emergency Medicine, University of Pittsburgh (PA). Phone: (412) 647-9047. E-mail: callawaycw@upmc.edu.
• **Alexandra K. Glazier**, Esq., Vice President and General Counsel, New England Organ Bank, Waltham, MA. Phone: (617) 558-6615. E-mail: Alexandra_Glazier@neob.org.
• **Kevin G. Munjal**, MD, Associate Medical Director of Prehospital Care, Department of Emergency Medicine, Mount Sinai Medical Center, New York City. E-mail: kevin.munjal@mountsinai.org.
• **Raquel M. Schears**, MD, Associate Professor of Emergency Medicine, Mayo Clinic, Rochester, MN. E-mail: Schears.Rocky@mayo.edu.

Public might worry that care will be compromised

Conflict of interest is issue

It was bioethicists who first called for firewalls to be erected between doctors determining death of donors and surgeons waiting to transplant the donated organs to recipients, says **Raquel M. Schears**, MD, associate professor of emergency medicine at Mayo Clinic in Rochester, MN. "The conflict of interest haunted the experiences of those involved in the earliest days of transplantation. They were called to make the determination of death, with a transplant surgeon at their elbow urging hasty judgment to assure the best possible organ viability for chosen recipients," she says.

The transplant pioneers relied on donation after cardiac death methods, which predated clinical brain death determination for organ donation purposes, says Schears. U.S. doctors and patients rapidly adopted brain death determination in the hospital as equivalent with human death and abandoned the practice of donation after cardiac death.

It is very important that efforts to resuscitate a patient aren't compromised, and don't even appear to be compromised, by the prospect of the death of one patient benefitting another who is waiting for an organ donation, warns **Kevin G. Munjal**, MD, associate medical director of prehospital care at Mount Sinai Medical Center in New York City. One method of doing this, which was embraced in certain European models, was to maintain a separation of those responsible for caring for a patient and determining death and others responsible for assessing the patient and discussing the prospect of organ donation with the family, he says.

The acceptability of presumed consent for procedures on the newly dead involved in donation after circulatory death procurement has not met with public endorsement, notes Schears. "Perhaps the strongest indication about worry regarding death and donation personally comes in comparing survey results about whether or not people support organ donation in general," she says. Roughly 80% reply in the affirmative, yet less than half of those respondents follow through on their assertions and become a designated donor using existing mechanisms such as organ donation registries, and fewer than 20% of Americans have an advance directive, including the small subset of people who agree to posthu-

mously donate their bodies to medical science, notes Schears.

"Within six months after Texas put the organ donation question as a 'no' checkbox on their driver's license forms, so many people elected the negative, they had to redo the question to avoid collapsing the state's donation election rate among those applying for license renewal," she adds.

Munjal says that in his experience, the public has been "overwhelmingly positive" about developing a mechanism for patients who die from cardiac arrest to donate their organs if they wish to. "In all our community outreach, the most striking thing was that even amongst religious and other groups that were not willing to be organ donors themselves, most were surprised to learn that the overwhelming majority of people that sign up or express an interest in being organ donors will not have their kidneys, livers, and other solid organs donated simply because they did not die in a hospital or did not die via brain death," he says. ■

EHR use growing fast, but ethical concerns are, too

Confidentiality is "inviolate obligation"

Access to the electronic health record (EHR) of an individual patient as well as what the person looking at the record does with that information remain concerns for all professionals and institutions involved in patient care. Confidentiality, in particular, remains "a major ethical concern," according to **Stephen T. Miller**, MD, MACP, Pearce Professor of Medicine at University of Tennessee and medical director of medical education and research at Methodist LeBonheur Healthcare in Memphis.

Institutions have used aliases and deception to assure that celebrities have privacy and their autonomy is not violated, underscoring ongoing concerns about confidentiality. "Education of all who have access to the EHR, and public reporting of penalties of those who do not follow the rules, have improved the atmosphere in which EHRs are used," says Miller. "There will be an ongoing need for professional education and reminders for all EHR users to keep confidentiality as an inviolate obligation for patient care."

Data stored in electronic format are susceptible to security breaches, such as health care providers who improperly access a patient's record, allow bystanders to gain access to unattended computer stations, or inappropriately provide their access codes to others. "Even access by authorized parties can lead to threats to privacy and confidentiality," says **Beverly Kopala**, PhD, RN, associate professor at Loyola University Chicago's Marcella Niehoff School of Nursing. "Data sharing is designed to promote quality and continuity of care. But as ease of access to health information and the number of parties with whom data are shared increase, the opportunities for security breaches increase as well." Additional threats arise when data are "lost" during transfer and when de-identified patient datasets become available for secondary use and are able to be re-identified.[1]

"Meaningful use" attestation, which obtains payments for those facilities that report meeting requirements, is another ethical concern for institutions and information technology administrators. "The accuracy of these reports is an ethical obligation," underscores Miller. Here are other ethical concerns involving EHRs:

Providers might be distracted during patient care encounters.

"The computer screen cannot become more important than the patient," says Miller. "Communications between providers and patients cannot suffer because the focus is on documentation rather than care of the patient. Distractions violate the principle of beneficence that guides patient care encounters," he says.

Providers might be overwhelmed by too much information.

"Avoiding patient harm is the substantive discus-

EXECUTIVE SUMMARY

Compromised patient confidentiality due to security breaches, accuracy of meaningful use attestation, distracted providers, and inaccurate information are some of the ethical concerns involving electronic health records. Providers should be aware that:
- Obscured information might harm patients.
- Communications with patients should not suffer due to distraction.
- Incorrect or irrelevant information can negatively impact decision making.

sion that clinicians should have about clinical documentations that may be wonderful notes for billing when viewed by coders, but are barriers to patient safety," says Miller.

Can patients be harmed because useful information is hidden by all of the "clutter" that can be collected in an EHR? Miller says the answer is yes. "Copying and pasting to make the record look like something has been accomplished is an ethical error," says Miller. "Repetitious incorporation of laboratory and radiology reports into progress notes when they obscure 'What does the clinician think, and what is the clinician doing?' must be elevated to an ethical concern, if it is going to get the attention of professionals."

EHRs incur financial costs related to development, implementation, and maintenance, such as hardware, software, equipment, personnel, privacy protection measures, and record storage and retention requirements.

"These are substantial and ongoing," explains Kopala. "When limited financial resources must be reallocated to meet these needs, tough decisions about priorities are needed."

Data might be inaccurate.

This can result from intentional or unintentional entry of misinformation, loss or destruction of data when data are shared, and the presence of incorrect information and data that are no longer accurate or relevant to a patient's current status. "This places the patient at risk for harm, as provider decision-making can be negatively impacted," says Kopala. Systems might engender poor quality documentation by expecting overwhelmed providers to document time-consuming details that don't improve care.

"There was an old saying with computers — 'garbage in, garbage out.' I would take that to next level and say even more dangerous is 'garbage in, presumed truth out,'" says **Ida M. Androwich**, PhD, RN, BC, FAAN, professor and director of health systems management at Niehoff School of Nursing. "This can occur when the provider fails to listen to the patient and over-relies on electronic data, to the detriment of care." ■

REFERENCE

1. Sittig DF, Singh H. Legal, ethical, and financial dilemmas in electronic health record adoption and use. *Pediatrics* 2011:127;2010-2184.

SOURCES

• **Ida M. Androwich**, PhD, RN, BC, FAAN, Professor and Director, Health Systems Management, Niehoff School of Nursing, Loyola University Chicago, IL. Phone: (708) 216-9276. E-mail: iandrow@luc.edu.
• **Stephen T. Miller**, MD, MACP, Pearce Professor of Medicine, University of Tennessee, Medical Director, Medical Education and Research, Methodist LeBonheur Healthcare, Memphis. Phone: (901) 448-5770. E-mail: steve.miller@mlh.org.
• **Beverly Kopala**, PhD, RN, Associate Professor, Marcella Niehoff School of Nursing, Loyala University Chicago (IL). Phone: (773) 508-2896. E-mail: bkopala@luc.edu.

Screening test might *not* be the ethical choice

Patients biased in favor of testing

In general, patients think of a screening test as a good thing, says **Arthur L. Caplan**, PhD, director of the Division of Medical Ethics at NYU Langone Medical Center in New York, NY. "Patients aapproach this thinking that it is better to test than not test, and doctors have to be aware of that bias," he says. "Unless a test hurts a lot, patients don't see any danger." The doctor has an ethical obligation to give accurate information about the risks and benefits of a test, including the fact that a test might be very inaccurate, he says.

The U.S. Preventive Services Task Force's 2009 guidelines say mammograms should not be done routinely for women ages 40-50. "The data doesn't seem to support it. But testing is still going on, even though the current recommendation is *not* to test women annually," Caplan says. "In the face of risk in our culture, we feel doing something is better than doing nothing." The same is likely to happen with PSA testing for prostate cancer, he adds, despite the United States Preventive Services Task Force's May 2012 recommendation that the widely used test no longer be used routinely for men of any age.[1]

EXECUTIVE SUMMARY

Patients typically are biased in favor of screening tests, but providers have an ethical obligation to educate them about risks including accuracy rates and what is done with false positives, and to consider updated recommendations for mammograms and PSA testing. Providers should:
• Consider whether they are practicing defensive medicine.
• Fully inform patients of risks and benefits.
• Take individual patient preferences into account.

Screening tests are useful to detect conditions with serious consequences in which there is a treatment that can change the course of a disease, and in which that treatment is more effective if the condition is diagnosed before symptoms occur or early in the disease process, according to **Virginia L. Hood**, MB.BS, MPH, MACP, professor of medicine at the University of Vermont and immediate past president of the American College of Physicians.

Hood says that an example of a "good" screening test is a colonoscopy to look for colon cancer in adults older than age 50 and some younger people with risk factors. Colon cancer is the second leading cause of cancer deaths in the United States, and screening has been shown to save lives by detecting cancers at an early stage or conditions such as polyps that can lead to colon cancer and can be removed before cancer develops, she explains.

"An example of a bad screening or diagnostic test is doing radiological imaging looking for the cause of uncomplicated low back pain," says Hood. Research indicates that these tests do not lead to better outcomes in terms of pain, function, quality of life, or overall well being, and were associated with documented harms such as low level irradiation, clinically irrelevant findings that lead to more unnecessary tests, and increased costs.[2] Here are ethical considerations involving screening tests:

Physicians need to make it acceptable for the patient to conclude they *don't* want a test.

"Most people are going to assume the correct answer to 'Should I be tested?' is always going to be 'yes,'" says Caplan. "You need to document that discussion so there are no recriminations later. But in a way, you have to make it morally allowable to say no."

Doctors may need to explain, for instance, that a false-positive result means an intensive course of surveillance, including monitoring with potentially harmful biopsies and X-rays. "The doctor's job is to lay out the strengths and weaknesses of the test. At the end of the day, it's still up to the patient to decide how they want to proceed," Caplan says. "Some patients are going to say, 'Dying of prostate cancer is the worst thing I can imagine. I want to be tested, and I don't care if you have to monitor me with biopsy or risk impotence and incontinence.'"

Doctors need to be comfortable themselves with *not* ordering a screening test.

"A significant amount of testing is done for the practice of defensive medicine. It is not done for the patient, but for the doctor," says Caplan. "The doctor's fears might need to be calmed. Both the doctor and the patient need permission to say, 'It's all right to forgo the test.'"

Physicians and patients both need to consider the implications of false positives.

"The two tests most in the news today are screening for ovarian cancer and prostate cancer. Both have false positives," says **Gregory R. Moore**, MD, MPH, senior director of Stamps Health Services at Georgia Institute of Technology in Atlanta. "False positives are a little more complicated than they may appear."

The chance of a false positive for any one patient depends on the incidence of the disease or condition in the population being screened, so false-positive rates vary, he explains. Since no screening test is entirely accurate, physicians need to consider what is done with false positives. A positive screen for ovarian cancer requires a surgical evaluation of the ovary in question, for example.

"This next step has very clear surgical risks. Similarly, a positive test for prostate cancer requires a biopsy, which has clear risks," Moore says. "Even with a confirmatory positive biopsy for prostate cancer, we are still very limited in determining just how aggressive that tumor may be." Surgery for prostate cancer often causes incontinence and impotence, he notes. "These are obviously complications we would like to avoid when the tumor is not particularly aggressive. Prostate cancers that are not particularly aggressive can go for years or even decades without causing serious illness," says Moore. *(See sidebar on ethical obligations involving patient education, p. 127.)* ■

REFERENCES

1. Screening for Prostate Cancer, Topic Page. U.S. Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm.
2. Chou R, Qaseem A, Owens DK, et al. Diagnostic imaging for low back pain: Advice for high-value health care from the American College of Physicians. *Ann Intern Med.* 2011;154:181-189.

SOURCES

• **Jeff Belkora**, PhD, Associate Professor of Surgery, Institute for Health Policy Studies, University of California, San Francisco. Phone: (650) 533-6965. E-mail: Jeff.Belkora@ucsf.edu.
• **Arthur L. Caplan**, PhD, Director, Division of Medical Ethics, NYU Langone Medical Center, New York, NY. Phone: 646-501-2514. E-mail: Arthur.Caplan@nyumc.org.
• **Virginia L. Hood**, MB.BS, MPH, MACP, Professor of Medicine, University of Vermont, Burlington. Phone: (802) 847-2534. E-mail: virginia.hood@vtmednet.org.
• **Gregory R. Moore**, MD, MPH, Senior Director, Stamps Health Services, Georgia Institute of Technology, Atlanta. E-mail: gregory.moore@health.gatech.edu.

Fully informing patients on tests: "Ethical imperative"

Paternalism "cropping up" in public health

Well-informed patients choose less invasive screening and treatment than those who are acting on poor information or ill-considered preferences, according to **Jeff Belkora**, PhD, director of decision services at the UCSF Breast Care Center and associate professor of surgery at the University of California, San Francisco's Institute for Health Policy Studies.

"Providers may protest that patient education takes time; it does. It's also a legal and ethical imperative known as informed consent, more properly thought of today as informed choice," says Belkora. "We must reform the financing of health care so that we are funding our legal and ethical mandates."

Fully informing patients might cost hundreds of dollars, acknowledges Belkora. "But we squander orders of magnitude more than that on waste in medicine. We can afford fully informing and involving patients," he says.

People may choose to do screening when fully informed, but it is not a prescription that fits everyone of any age or condition, says Belkora, and patient preferences matter, too. "We have mostly gotten past paternalism in medicine, but it is cropping up in public health," he says. "My ethical stance is that screening in general is overprescribed as a public health benefit. In fact, on an individual basis, there is usually some non-negligible risk of harm, while the chance of benefit is often low."

Doctors and patients need to weigh how they feel about the value, timing, and likelihood of screening outcomes, at different ages and life circumstances, says Belkora. "There is a simple way to think about whether decisions should be highly individualized to patient preferences and circumstances," he says. In rare circumstances in which the benefits of intervention, including screening, vastly outweigh potential harms; *and* there is a strong evidence base, *and* little variation in how patients and providers feel about outcomes, this can be defined as "effective" care that needs to be more broadly disseminated, says Belkora.[1]

"Examples of these three conditions are hard to find in medicine, but might include using beta blockers to treat heart disease," he says. In most circumstances in medicine, however, patients risk significant harm along with benefits, or there is not a strong evidence base to rely on, or patients vary significantly in how they feel about the value, timing, and likelihood of the outcomes, says Belkora. "These cases are defined as 'preference-sensitive,'" he says. "Recommendations should be individualized to patients using shared decision-making strategies, such as clear risk communication and preference elicitation."

If the patient is requesting a test that is clearly *ineffective*, in that harm vastly outweighs benefits, *and* there is a strong evidence base *and* there is a general consensus among well-informed patients and providers against the request, then the provider's obligation to beneficence may outweigh the provider's obligation to patient autonomy, according to Belkora. In that situation, the provider may refuse to administer the test out of a sense of professional responsibility.

"However, in cancer care, this is a somewhat unlikely scenario," he says. "More likely, the provider must address the fact that patients are autonomous and have a legal and ethical right in our society to self-determination." ■

REFERENCE
1. O'Connor AM, Wennberg JE, Legare F, et al. Toward the "tipping point:" Decision aids and informed patient choice. *Health Aff* 2007;26(3):716-725.

"Drug-seeking" label is sometimes wrongly applied

Some patients suffer unnecessarily

Is there clear and convincing evidence that an individual has no pain that would justify a prescription analgesic and is, therefore, seeking medication solely because of an addictive disorder, recreational use, or with the intent of diverting it to others? If so, then the provider may have a legitimate factual basis for identifying a patient as "drug-seeking" and denying requests for medication, says **Ben A. Rich**, JD, PhD, professor and School of Medicine Alumni Association Endowed Chair of Bioethics at University of California — Davis Health System.

"The implication of the label is that the patient has no legitimate medical need for the medication which they seek," says Rich. Nevertheless, even some patients legitimately labeled as drug-seeking may have other medical issues, including mental health issues, that explain their behavior and require further attention. "Simply showing the patient the door is not an ethical response," says Rich. "The key ethical problem posed is the facility with which the label is used without adequate factual justification. Doing so has profoundly negative implications."

Rich notes that the "drug-seeking" label is almost exclusively applied to individuals who present to medical institutions or providers seeking an opioid analgesic, and rarely to patients seeking antibiotics or other non-opioid medications. "There is nothing intrinsically wrong with seeking something for which one has a legitimate need," says Rich. "When we are hungry, we engage in food-seeking behavior. When we are in pain, we seek pain relief, which, in many instances, requires some form of analgesic."

Clinical judgment

Some drug-seeking patients are "very convincing," acknowledges **Kenneth W. Goodman**, PhD, professor and director of the Bioethics Program at the University of Miami and director of the World Health Organization's Collaborating Center in Ethics and Global Health Policy. "From migraines to backaches to kidney stones, patients will adopt all kinds of stratagems to try to convince busy clinicians to part with prescriptions for controlled substances," he says. "In some cities, emergency departments are frequent targets of such drug scammers."

It can be a very difficult judgment call when, in a busy emergency department, a patient seems disabled by pain and is requesting a drug known to be abused, says Goodman. The line between appropriate and inappropriate prescribing will not always be clear in this scenario, and busy clinicians must rely on their diagnostic acumen to make these decisions, he adds. "One could argue that it is better to give a controlled substance to an abuser than not to give one to someone in actual pain," he adds. "Telling the difference can be a challenge. Trying to tell the difference is an obligation."

Ethical use of prescribing authority and privileges requires a scientific basis for each prescription, says Goodman. "This does not mean a physician must know in advance that a particular drug will work in a specific case — only that there be some evidence or other good reason," he adds. "Proper prescription of drugs that can be habituating requires an appropriate clinical workup, and mindfulness of the possibility that a patient is malingering."

Red flags might mislead

There are a wide range of screening instruments that can assist prescribers in determining whether opioids are being used as prescribed and are addressing a legitimate medical purpose, says Rich, but most non-pain medicine specialists lack the basic knowledge and skills necessary to administer these instruments effectively. In addition, providers might wrongly suspect drug seeking simply because patients demonstrate a familiarity with analgesic medications and dosages. "If the person has been taking pain medications for a chronic condition, it should be neither surprising nor sinister that they have some familiarity with such medications and experience in which medications have helped them and which have not," says Rich.

Providers might suspect drug seeking simply because the patient is insistent or demanding in their demeanor, but this might be reasonable if patients want relief for pain and feel their truthfulness is being questioned. "There is a recognized phenomenon of 'pseudo-addiction,' in which patients whose efforts to achieve pain relief have been so frustrated by encounters with opiophobic physicians that they are driven to behaviors that mimic a drug-dependent patient in withdrawal," he says. "Such patients suffer unnecessarily, and are victims of untreated or undertreated pain and the negligent infliction of emotional distress." *(See related story, p. 129, on ethical practices for providers.)* ■

EXECUTIVE SUMMARY

If providers suspect a patient is drug-seeking, overlooking underlying mental health issues, and undertreatment of pain are two ethical pitfalls. Providers should keep in mind that:

- Patients may be familiar with dosages and medications due to chronic conditions.
- Patients may become demanding if they feel their truthfulness is being questioned.
- A thorough evaluation must be conducted.

SOURCES

- **Kenneth W. Goodman**, PhD, Professor and Director, Bioethics

Program, , University of Miami (FL). Phone: (305) 243-5723. E-mail: kgoodman@Miami.edu.
• **Peter Koo**, PharmD, Clinical Professor of Pharmacy, University of California — San Francisco. Phone: (415) 476-3055. E-mail: koop@pharmacy.ucsf.edu.
• **Ben A. Rich, JD, PhD,** Professor and School of Medicine, University of California — Davis Health System. Phone: (916) 734-6135. E-mail: barich@ucdavis.edu.

Uneasy providers can utilize these options

Thorough evaluation is key

Peter Koo, PharmD, a clinical professor of pharmacy and a pharmacist specialist in pain management at University of California — San Francisco, says that sometimes patients are doctor shopping because they are addicted, but often they are doing it because they are actually under-treated. Sometimes, it's a combination of the two. "Often, a patient really does need better pain management and isn't able to address it through the medications they've been prescribed," he says.

For example, patients with nerve pain after a surgical procedure might be prescribed opiates, which the provider knows might not adequately address nerve pain in the long term. "They may have successfully used opiates after the initial surgery, but the cause of their pain has changed to something that no longer responds to the medication they're on," says Koo. "So the patient keeps going back to the doctor to seek more pain control."

One compounding factor is that many physicians aren't trained in pharmacological pain management, or are only focused on interventional procedures, such as nerve blocks or local injections. "Sometimes, a simple shift in medications might actually be more effective in controlling the pain in the long run," says Koo. "In fact, some atypical analgesics, such as antidepressants and seizure medications, actually work very well for nerve pain — much better, in fact, than opiates."

Providers need to conduct a thorough evaluation with any patient before they prescribe medications, especially opiates, underscores Koo. "You really have to assess the patient. If you feel like you are running a circle around yourself in trying to treat a patient's pain, that's a good time to refer them to a pain specialist," he says. "If you truly believe a patient is playing you for medication, you also have several options." Koo gives these examples:

- Providers should ask, "Is the opiate indicated?" "Is the patient being followed regularly to assess their progress?" and "Are regulations on opiate prescriptions being followed?"
- Providers can offer treatment with the condition that they have the right to conduct a urine test, and conduct periodic reviews of drug-monitoring reports, which track every controlled prescription patients receive.
- If providers don't feel comfortable writing the prescription, they can recommend instead that the patient receive an evaluation from an expert.
- Providers can identify co-morbidities, such as depression or anxiety, indicating that patients may benefit from psychotherapy as well.
- Providers can set up a treatment agreement with the patient, which spells out that they will provide the medications under the condition that the patient may not receive medications from another provider without consulting with you first. "If they do, you reserve the right to terminate their care," says Koo.
- Providers can make it an office policy that they do not write for prescriptions for opiates on initial new patient visits. "This will prevent traveling prescription shoppers," says Koo. ■

Large-scale adverse events: Obligation to disclose?

If a provider tells patients they might have been exposed to a blood-borne pathogen when they actually weren't, then the patients worried needlessly when there was no actual health risk. There is also the risk that by *not* disclosing, a minority of patients will be harmed and have no idea, says **Denise M. Dudzinski**, PhD, MTS, associate professor and director of graduate studies in the Department of Bioethics & Humanities at the University of Washington School of Medicine. "On the other hand, by disclosing, patients can take behavioral steps to reduce transmission if they might have been exposed to an infectious agent," she says. Dudzinski argues that even if the risks are small or unknown at the time, disclosure is still required based on obligations to tell the truth, protect patients, and

provide for their health care.[1]

"Depending on the seriousness of the potential injury, disclosure might come from an office or phone visit by a treating physician or through a letter from the institution," she says. Dudzinski says disclosure should include the following:

- what occurred;
- what the institution knows and does not know about what occurred;
- information about the level of risk;
- actions taken to prevent the incident from happening again;
- information on how to get follow-up testing and treatment, such as a hotline staffed by trained clinicians to field health-related questions;
- an expression of regret;
- a description of the plan for investigating the issue; and
- a promise to provide follow-up information as it is discovered.

"Disclosure might also require proactive calls to media outlets by the health care institution," she adds. While both the physician and the organization have obligations to disclose both individual and large-scale errors, an institution does not have a discrete therapeutic relationship with an individual patient like the doctor, notes Dudzinski. "An individual doctor is likely to address the disclosure within that therapeutic relationship, often sitting down with the patient and explaining what happened. This may not be possible when hundreds of people are affected."

While the message may be tailored to individual patients by a physician, the message should be consistent and uniform when disclosing to multiple people, and a multidisciplinary group of staff working at the institution should provide input on how to disclose, advises Dudzinski. "An individual clinician might not enlist too many other people before disclosing, but the organization should because the process of addressing the harm is more complex with multiple patients," she says. ***(See related story on the American Medical Association's recommendations, p. 130.)*** ■

EXECUTIVE SUMMARY

Patients might be needlessly worried by disclosure of large-scale adverse events such as possible exposure to a blood-borne pathogen, but failing to disclose could harm patients and prevent them from taking steps to reduce transmission.

- Institutions should provide patients with additional information as it is discovered.
- Messages should be consistent and uniform.
- A multidisciplinary group should provide input.

REFERENCE

1. Dudzinski DM, Hebert PC, Foglia MB, et al. The disclosure dilemma — large-scale adverse events. *N Engl J Med* 2010;363:978-986.

SOURCE

• **Denise M. Dudzinski**, PhD, MTS, Associate Professor & Director of Graduate Studies, Department of Bioethics & Humanities, University of Washington School of Medicine. E-mail: dudzin@uw.edu.

AMA gives ethical guidance on disclosure

The *American Medical Association (AMA) Code of Medical Ethics* offers physicians guidance regarding an appropriate response to large-scale adverse events, says **H. Rex Greene**, MD, chair of the AMA Council on Ethical and Judicial Affairs. The issues are discussed in AMA ethical opinion E-9.032, "Reporting Adverse Drug or Device Events," which states that a physician who "suspects the occurrence of an adverse reaction to a drug or device has an obligation to communicate that information to the broader medical community."

"When there is a serious adverse event defined by death, hospitalization, or medical or surgical intervention, it should be reported to the FDA [Food & Drug Administration]," says Greene. When physicians are faced with ambiguity surrounding an adverse event, the AMA ethical opinion states that "certainty, or even reasonable likelihood, of a causal relationship between the drug or medical device and the serious adverse event will rarely exist and is not required before reporting the event to the FDA."

In these situations, the burden is on the physician to report the event, he underscores. "Physicians work every day to provide patients with the best care and to ensure their safety, but when mistakes occur, physicians should openly discuss them with their patients," says Greene.

AMA ethical opinion E-8.12 "Patient Information" states that in these situations, "the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred." "We understand that many

physicians fear that the acknowledgment of error can be used against them in the courtroom," says Greene. "However, studies show a clear benefit when physicians set aside liability concerns and openly discuss mistakes with patients."[1]

AMA ethical opinion E-8.121, "Ethical Responsibility to Study and Prevent Error and Harm," emphasizes an institution's responsibility to provide effective and confidential review processes for reporting adverse events and errors. "Doing so enhances patient safety by giving physicians an established method of handling these situations," says Greene. ■

REFERENCE

1. Boothman RC, Blackwell AC, Campbell DA, et al. A better approach to medical malpractice claims? The University of Michigan experience. *J Health Life Sci Law* 2009;2(2): 125-159.

CME INSTRUCTIONS

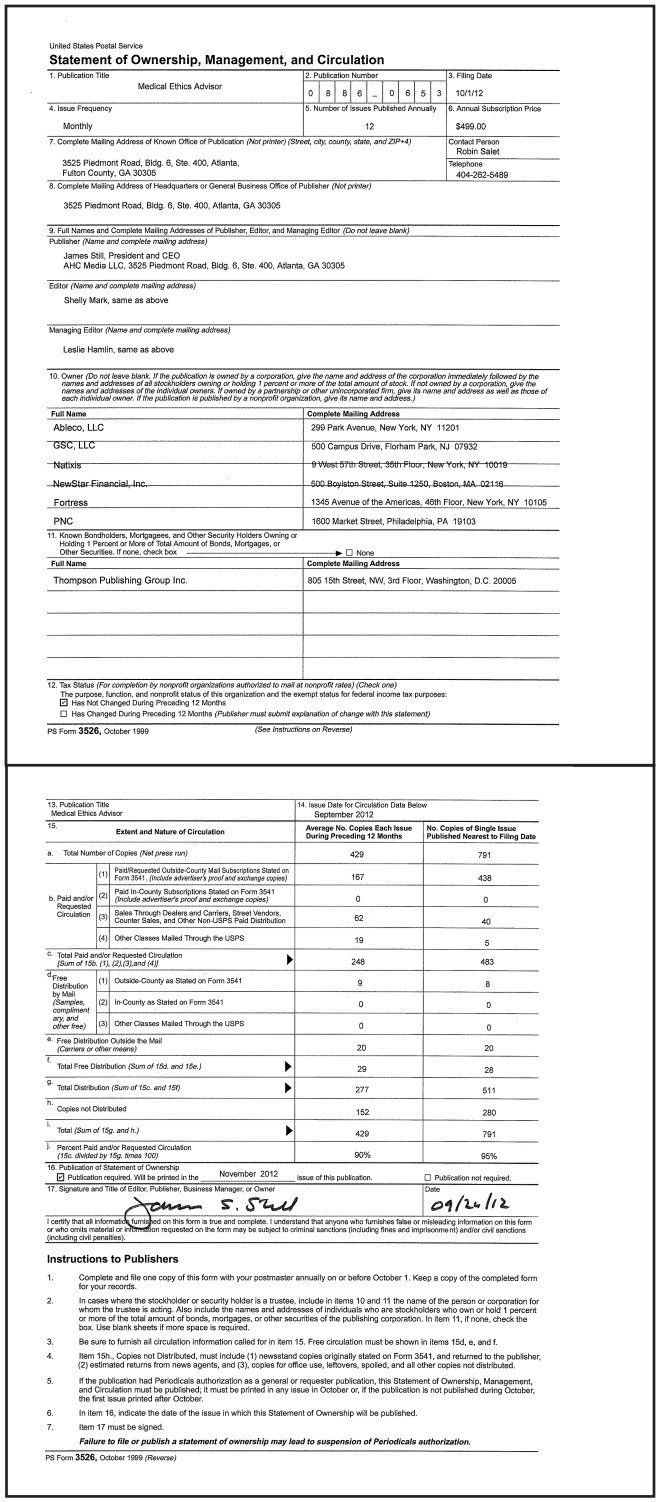
To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CME OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- Discuss new developments in regulation and health care system approaches to bioethical issues applicable to specific health care systems.
- Explain the implications for new developments in bioethics as it relates to all aspects of patient care and health care delivery in institutional settings.
- Discuss the effect of bioethics on patients, their families, physicians, and society.



United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication Number	3. Filing Date
Medical Ethics Advisor	0 8 8 6 _ 0 6 5 3	10/1/12
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$499.00

7. Complete Mailing Address of Known Office of Publication *(Not printer) (Street, city, county, state, and ZIP+4)*: 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, Fulton County, GA 30305 — Contact Person: Robin Saliet — Telephone: 404-262-5489

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not printer)*: 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do not leave blank)*

Publisher *(Name and complete mailing address)*: James Still, President and CEO, AHC Media LLC, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and complete mailing address)*: Shelly Mark, same as above

Managing Editor *(Name and complete mailing address)*: Leslie Hamlin, same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual owner. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
Ableco, LLC	299 Park Avenue, New York, NY 11201
GSC, LLC	500 Campus Drive, Florham Park, NJ 07932
Natixis	9 West 57th Street, 35th Floor, New York, NY 10019
NewStar Financial, Inc.	500 Boylston Street, Suite 1250, Boston, MA 02116
Fortress	1345 Avenue of the Americas, 46th Floor, New York, NY 10105
PNC	1600 Market Street, Philadelphia, PA 19103

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☐ None

Full Name	Complete Mailing Address
Thompson Publishing Group Inc.	805 15th Street, NW, 3rd Floor, Washington, D.C. 20005

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☑ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526,** October 1999 *(See Instructions on Reverse)*

13. Publication Title: Medical Ethics Advisor	14. Issue Date for Circulation Data Below: September 2012	
15. Extent and Nature of Circulation	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies *(Net press run)*	429	791
b. Paid and/or Requested Circulation (1) Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	167	438
(2) Paid In-County Subscriptions Stated on Form 3541 *(Include advertiser's proof and exchange copies)*	0	0
(3) Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	62	40
(4) Other Classes Mailed Through the USPS	19	5
c. Total Paid and/or Requested Circulation *(Sum of 15b. (1), (2),(3),and (4))*	248	483
d. Free Distribution by Mail *(Samples, complimentary, and other free)* (1) Outside-County as Stated on Form 3541	9	8
(2) In-County as Stated on Form 3541	0	0
(3) Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or other means)*	20	20
f. Total Free Distribution *(Sum of 15d. and 15e.)*	29	28
g. Total Distribution *(Sum of 15c. and 15f)*	277	511
h. Copies not Distributed	152	280
i. Total *(Sum of 15g. and h.)*	429	791
j. Percent Paid and/or Requested Circulation *(15c. divided by 15g. times 100)*	90%	95%

16. Publication of Statement of Ownership
☑ Publication required. Will be printed in the November 2012 issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: James S. Still — Date: 09/24/12

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including civil penalties).

Instructions to Publishers

1. Complete and file one copy of this form with your postmaster annually on or before October 1. Keep a copy of the completed form for your records.
2. In cases where the stockholder or security holder is a trustee, include in items 10 and 11 the name of the person or corporation for whom the trustee is acting. Also include the names and addresses of individuals who are stockholders who own or hold 1 percent or more of the total amount of bonds, mortgages, or other securities of the publishing corporation. In item 11, if none, check the box. Use blank sheets if more space is required.
3. Be sure to furnish all circulation information called for in item 15. Free circulation must be shown in items 15d, e, and f.
4. Item 15h., Copies not Distributed, must include (1) newsstand copies originally stated on Form 3541, and returned to the publisher, (2) estimated returns from news agents, and (3), copies for office use, leftovers, spoiled, and all other copies not distributed.
5. If the publication had Periodicals authorization as a general or requester publication, this Statement of Ownership, Management, and Circulation must be published; it must be printed in any issue in October or, if the publication is not published during October, the first issue printed after October.
6. In item 16, indicate the date of the issue in which this Statement of Ownership will be published.
7. Item 17 must be signed.

Failure to file or publish a statement of ownership may lead to suspension of Periodicals authorization.

PS Form **3526,** October 1999 *(Reverse)*

COMING IN FUTURE MONTHS

- ■ Ways to end patient-physician relationship
- ■ Concerns involving family caregivers
- ■ Identifying medical futility at end of life
- ■ Why predictive testing in minors might be unethical

CME QUESTIONS

1. Which is true regarding a pilot project exploring organ donation in the emergency department setting at University of Pittsburgh Medical Center?
   A. Most of the families involved reported significant ethical concerns.
   B. All ED team members involved in the care of a potential donor were involved in the donation process.
   C. No one involved in the case of a patient who might become a donor was involved in the donation process.
   D. Chest compressions were continued after someone was pronounced dead in order to increase the chances of usable organs.

2. Which is recommended regarding screening tests, according to **Virginia L. Hood**, MB.BS, MPH, MACP?
   A. Providers should not discuss accuracy rates of a particular screening test with patients.
   B. Screening tests are useful to detect conditions with serious consequences in which there is treatment that can change the course of a disease, and in which that treatment is more effective if the condition is diagnosed before symptoms occur or early in the disease process.
   C. Radiological imaging looking for the cause of uncomplicated back pain is an example of appropriate screening.
   D. It is unethical for providers to consider what is done with false positives when determining whether a screening test is appropriate.

3. Which is true regarding an ethical response to patients suspected of "drug-seeking," according to **Ben A. Rich**, JD, PhD?
   A. Even some patients legitimately labeled as drug seeking may have other medical issues that explain their behavior and require further attention.
   B. Ethical use of prescribing authority and privileges requires a physician to know in advance that a particular drug will work in a specific case.
   C. It is not ethical for non-pain medicine specialists to utilize screening instruments that can assist prescribers in determining whether opioids are being used as prescribed and are addressing a legitimate medical purpose.
   D. If providers don't feel comfortable writing the prescription, it is unethical for them to recommend instead that the patient receive an evaluation from an expert.

To reproduce any part of this newsletter for promotional purposes, please contact:
Stephen Vance
Phone: (800) 688-2421, ext. 5511
Fax: (800) 284-3291
Email: stephen.vance@ahcmedia.com

To obtain information and pricing on group discounts, multiple copies, site-licenses, or electronic distribution please contact:
Tria Kreutzer
Phone: (800) 688-2421, ext. 5482
Fax: (800) 284-3291
Email: tria.kreutzer@ahcmedia.com
Address: AHC Media
3525 Piedmont Road, Bldg. 6, Ste. 400
Atlanta, GA 30305 USA

To reproduce any part of AHC newsletters for educational purposes, please contact:
The Copyright Clearance Center for permission
Email: info@copyright.com
Website: www.copyright.com
Phone: (978) 750-8400
Fax: (978) 646-8600
Address: Copyright Clearance Center
222 Rosewood Drive
Danvers, MA 01923 USA