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Statement of Financial Disclosure: Arthur R. Derse, MD, JD (Board Member), Allison Mechem Weaver (Editor), Coles McKagen (Associate Publisher), and Jill Robbins (Managing Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

MAY 2008
VOL. 24, NO. 5 • (pages 49-60)

Psychiatric advance directive: Patients plan for when they're not competent

Advocates say advance planning gives mentally ill patients autonomy

When the first psychiatric advance directives (PADs) began to appear in state legislation more than 20 years ago, they were largely considered to be an end-of-life tool, much like general advance directives. But as more states have passed PAD laws — 25 states now have laws specifically providing for PADs — their usefulness has expanded.

A PAD is a witnessed legal instrument that documents a person's specific instructions or preferences regarding future mental health treatment, in preparation for the possibility that the person may lose capacity to give or withhold informed consent to treatment during acute episodes of psychiatric illness. To be binding, a PAD must be executed when the person is mentally competent. PADs often are used in concert with a general advance directive for health care to ensure that an individual's wishes regarding care and hospitalization are known and acted upon.

"Psychiatric advance directives were originally developed for use in the context of end of life, but now they are also being promoted as a way to enable patients with severe mental illness to retain control over their care if they become seriously impaired [regardless of whether they are at the end of life or not]," according to **Susan Bowers**, MBA, director of the Veterans Health Administration (VA) Integrated Service Network in the Southwest. "Advocates say [PADs] not only respect patient autonomy and choice, but can provide benefits to patient care in other ways."

By bolstering autonomy, PADs can improve care

Bowers, who spoke recently as part of a VA Ethics Center teleconference on PADs, says that, specifically, PADs have proved to be useful by:

- increasing patients adherence to therapy;
- decreasing the need for involuntary treatment.

PADs, like advance directives for health care, trace their roots to the Patient Self-Determination Act (PSDA) of 1991, which introduced a

new set of federal requirements intended to implement advance directive policies at all health care facilities that receive federal funding through Medicaid and Medicare programs. Ethicists, attorneys, health scholars, and consumer advocates soon began talking about PSDA's implications for psychiatric treatment, and the act became part of the patient empowerment armament.

Specifically, the PSDA requires all hospitals — both general hospitals and psychiatric facilities — to:

- Inform patients of their rights to determine their own care, including right of refusal.
- Document the presence or absence of an advance directive.
- Have in practice policies for implementing patient rights.
- Comply with state laws on advance directives.
- Educate staff and the community about advance directives.

PDSA's intent — that patients have the right to declare *in advance* what their preferences for care are should they become incapacitated — applies equally to those suffering from mental illness who are competent or have periods of competency in which they can execute a directive letting their providers and representatives know their wishes.

Federal law does not require any form of advance directive, and it expressly forbids requiring an advance directive as a requirement for treatment.

Health care advance directives, particularly ones executed using a generic template, are not specific to mental illness, and in some cases are not even effective until a patient is determined to be terminally ill, according to **William Van Stone**, MD, associate chief for psychiatry for the VA.

A PAD can contain any stipulation that the individual might encounter as part of treatment. For example, it can include consent to, or refusal of, particular medications or inpatient admission; spell out who can or cannot visit the person when he or she is hospitalized; or designate who can make decisions regarding treatment when the patient is not competent to make those decisions on his or her own.

In all states, involuntary commitment to a treatment facility takes priority over the wishes expressed in a PAD about hospitalization; for example, a request "never to be involuntarily committed" would not be a viable, legal inclusion in a PAD. However, preferences regarding medication and treatment while hospitalized should be followed during an involuntary commitment.

According to the National Resource Center on Psychiatric Advance Directives (NRCPAD), PADs can make patients feel more in control and confident in the care they'll receive during a mental health crisis, and, therefore, might lead to greater compliance with treatment.

Advantages to a PAD, according to NRCPAD, include:

- the individual has more control over what happens to him during periods of crisis;
- providers and others will know what the person wants even when he can't express himself well;
- case managers and others can draw on the PAD for information as they craft a treatment plan;
- confidence that state law requires providers to respect what is included in a mental health

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media 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 740059, Atlanta, GA 30374.

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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.)

Editor: **Allison Mechem Weaver**.
Senior Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcmedia.com).
Associate Publisher: **Coles McKagen**, (404) 262-5420, (coles.mckagen @ahcmedia.com).
Managing Editor: **Jill Robbins**, (404) 262-5557, (jill.robbins@ahcmedia.com).

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Editorial Questions

Questions or comments?
Call **Jill Robbins**
at (404) 262-5557.

SOURCES

For more information, contact:
- **Susan Bowers**, MBA, director, Veterans Health Administration Integrated Service Network 18 (VISN 18), Mesa, AZ. Phone: (602) 222-2681.
- **Michael Ford**, JD, National Ethics Committee, VA National Center for Ethics in Health Care. Phone: (202) 501-0364.
- **William Van Stone**, MD, associate chief consultant for psychiatry, VA Mental Health Services, Washington, DC. Phone: (202) 273-5400.

advance directive to the fullest extent possible.

"We respect autonomy when we respect decisions made when the patient had decision-making capacity," says Van Stone.

Check for expiration

While health care advance directives never expire (unless they're revoked by the person who executed them), 10 states have legislated that advance directives for psychiatric care expire after a period ranging from two to five years. **(See table, this page.)**

Michael Ford, JD, an attorney for the National Ethics Committee at the National Center for Ethics in Health Care in Washington, DC, says mental health advocates have taken issue with the expiration provision of some PADs.

"When a [PAD] expires, the patient has to execute a new one, and if it expires and the patient isn't aware of it, he or she might lose the ability to guide their own treatment when they lose decision-making capacity," says Ford. "We're not aware that there's evidence that a patient with a mental illness should be treated differently [than a physically ill patient] by letting their advance directive expire. That seems ethically unjustified, and seems unfair to single out mentally ill patients when advocates are trying to reduce the stigma attached to mental illness."

Another concern among mental health advocates is that if a PAD is in place, it could lead to coercion into treatment of a patient by his or her appointed representative. For that reason, 24 of the 25 states that have PAD legislation have restricted who can be a witness to the PAD, excluding family members and members of the person's treatment team, to avoid potential coercion from those groups.

Whether their state imposes a mandatory expiration, individuals in any state are permitted to revoke their PADs at any time they are competent.

Ford says some clinicians have expressed concern that their patients will revoke their PADs after they lose decision-making capacity, based on the fact that all states permit patients with general advance directives to revoke them at any time.

But Ford points out that 18 of the 25 states with PAD laws allow revocation of PADs only when

States that have enacted psychiatric advance directives

State		Valid Period
Arizona	Montana	Until revoked by person it applies to
Hawaii	New Jersey	
Idaho	New Mexico	
Indiana	North Carolina	
Kentucky	Oklahoma	
Maine	South Dakota	
Maryland	Washington	
Michigan	Wyoming	
Minnesota		
Pennsylvania		Up to 2 years
Tennessee		
Illinois	Ohio	Up to 3 years
Oregon	Texas	
Utah		
Louisiana		Up to 5 years

Source: National Resource Center on Psychiatric Advance Directives

the patient is determined to have decision-making capacity; some states allow individuals to indicate that they wish to have revocation powers even if not deemed competent.

(Editor's note: For more information on psychiatric advance directives, go to the web site of the National Resource Center on Psychiatric Advance Directives, www.nrc-pad.org.) ■

Center to pursue ethical, informed vaccine policies

Balancing patient autonomy, public safety key

The life cycle of a vaccine — from discovery and production through distribution, rationing, and replacement — can span a quarter-century, involve health professionals worldwide, and raise ethical issues every step of the way. But there was no centralized effort to promote policy and ethics around vaccine discovery, use, and global public health — and so the Center for Vaccine Ethics and Policy was created.

"As a number of new vaccines are entering public health and clinical practice, it is more important than ever to have clear, accurate information about vaccines and their critical role in public health," according to **Paul Offit**, MD, a founding member of the center and head of infectious diseases at Children's Hospital of Philadelphia. The center, he adds, "will make an important contribution to clear thinking about vaccine policy, safety and ethical issues, and by doing so, help parents, patients, clinicians, and public health professionals make informed choices and use vaccines more effectively."

The center is the offspring of the 18-month-long Ethics of Vaccine project begun at the University of Pennsylvania School of Medicine's Center for Bioethics. The project aimed to examine the field of vaccine development and use, and propose an ethical framework to help guide researchers, pharmaceutical companies, public health agencies, health care providers, and citizens regarding vaccines and their safe, effective, and ethical use.

"The new Center for Vaccine Ethics and Policy will engage the entire vaccine life cycle from a global perspective," says **David Curry**, executive director of the center. Importantly, he adds, the center also will address the policies that prevent vaccines from actually being used for years as developers negotiate the required maze of approval.

"Particularly frustrating is the time it takes for getting a vaccine to the people," Curry says. "It may take 20 to 25 years — an entire generation — before a vaccine is making the impact it could or should be making.

"In an age when you can FedEx a vaccine and have it someplace overnight, something's amiss when policy and government impede the impact that vaccines can make. That seems like something that should be addressed and improved on."

Pandemics obvious, but not only, focus

When the Ethics of Vaccine project was introduced in 2006, its founder, **Arthur Caplan,** PhD, of Penn's Center for Bioethics, commented that just as Hurricane Katrina revealed the nation's weaknesses in emergency preparedness, the threat of avian influenza was pointing out potential weaknesses in our approach to vaccines.

Curry, in discussing the new Center for Vaccine Policy and Ethics, says vaccines designed to curb pandemic diseases are certainly one of the center's areas of interest — but that's only part of the center's mission.

"We saw influenza as a good lens through which to look at vaccines, but our interests are not solely on that," Curry says.

There is an ethical imperative for policy to accelerate the development and delivery of needed vaccines of all kinds, Caplan says, to provide safe, affordable, and effective access for all people, regardless of circumstance or geography.

The idea of ethics in vaccine is not new, but is picking up steam as an integral part of the vaccine cycle, Curry says.

Staff for the vaccine ethics project at the Penn Center for Bioethics recently contributed a chapter

SOURCES

For more information, contact:

- **David R. Curry**, MSLS, executive director, Center for Vaccine Ethics and Policy; visiting scholar, Center for Bioethics, University of Pennsylvania. Phone: (267) 251-2305.
- **James C. Thomas**, MPH, PhD, associate professor of epidemiology, University of North Carolina School of Public Health, Chapel Hill. E-mail: jim.thomas@unc.edu.

on ethics for the 5th edition of *Vaccines* (Plotkin, Orenstein, Offits, eds; Elsevier, 2008). This is the first time a chapter on ethics has been included in the internationally consulted reference text.

The Penn Center is not alone in noting the potential for ethical crises surrounding vaccines. In 2007, **James C. Thomas**, MPH, PhD, an epidemiologist at the University of North Carolina School of Public Health, Chapel Hill, published research into the pandemic preparedness plans of all 50 states, the District of Columbia, and the federal government, and found some critical weaknesses shared by all — notably a plan for addressing, ahead of time, the ethical issues that might arise. **(See "Pandemic plans address vaccines but not ethics," *Medical Ethics Advisor*, June 2007.)**

"When a crisis happens, it exacerbates disparities, and people who are vulnerable are, by definition, vulnerable, and they need to be given extra vigilance," according to Thomas. Working against their favor, he notes, is the "two-list" model of ensuring vaccines and antivirals for the physically vulnerable and those needed for public order, both of which stand to overlook other vulnerable populations.[1]

And the thought given to what to do in the time between when a virus is identified and when the antivirals and vaccines are available for it "is disproportionate to the number of issues we'll be facing," Thomas adds.

Such questions are just what Curry and other center staff hope can be addressed by this coordinated effort.

"The area of vaccine ethics generally has not had the kind of attention that ethics in other [clinical] areas has had — it's somewhat of a new field," he notes. "So we're trying to attract visiting scholars, post-doctoral [candidates], to make sure vaccines and immunizations are given adequate focus."

Challenged by crisis of confidence

Another important challenge faced in the area of vaccines is public misunderstanding and fear about vaccines, Curry says.

"To help address this challenge, among our early programs is a series of public forums [in partnership with the Franklin Institute] around vaccines," he says. At the first of the forums, held in early 2008, patient autonomy and freedoms vs. public responsibility to curb the spread of disease was explored. Specifically, the issue of government mandates for certain childhood immunizations and immunization of health care workers was addressed.

The forums — and the center — will provide a mechanism for those on the front lines of public health to contribute to policy debates and ethical discussions that emerge across a vaccine's life cycle, Curry added.

"There is a trendline that suggests that with easy ways to opt out or be exempted from immunization requirements, public health stability is being eroded, leading to things like the outbreak of measles that we saw in San Diego," Curry continues.

The Centers for Disease Control and Prevention, in the Feb. 29, 2008, issue of *Morbidity and Mortality Weekly Report* (*MMWR*), noted that 12 cases of measles had been reported in San Diego within a one-month period (January and February).[2]

"The San Diego import-associated outbreak, affecting exclusively an unvaccinated population and infants too young to be vaccinated, serves as a reminder that unvaccinated persons remain at risk for measles and that measles spreads rapidly in susceptible subgroups of the population unless effective outbreak-control strategies are implemented," according to the *MMWR*.

(Editor's note: Information about the center can be found at www.centerforvaccineethicsandpolicy.org.) ■

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Physicians urge protections against genetic discrimination

ACP policy to protect against work, insurance bias

The availability of genetic testing is expanding rapidly — so rapidly that information is available before there are safeguards in place concerning how it can be used. In recent months, home test kits, with which users are told they can determine genetic predisposition to bipolar disorders or determine paternity, have come on the market.

In an effort to describe the need for federal pro-

tections against discriminatory use of genetic information in the workplace and by insurers, a national physicians group has drafted a list of six policy positions it believes Congress should act on to protect Americans' genetic information.

"While they're not quite there, Congress does continue to move closer to passing federal legislation that protects the use of genetic information in employment and insurance coverage decisions," says **David C. Dale**, MD, FACP, president of the American College of Physicians (ACP), which issued the position monograph in March 2008.

A survey conducted in March 2007 by researchers at Johns Hopkins Genetics and Public Policy Center in Baltimore found that while most survey participants trust their physicians and genetic researchers with access to their genetic information, that trust does not extend to health insurers and employers.[1] One-fourth of those surveyed said they don't trust health insurers not to misuse their genetic information by discriminating against them — limiting or denying insurance — if the insurers have the information.

The ACP defines "genetic information" as information about an individual's genetic tests; genetic tests of that individual's family members; or the manifestation of a disease or disorder in the family members of that individual.

A "genetic test," by ACP guidelines, is "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes."

The six position points drafted by the ACP are:

Position 1: Insurance providers should be prohibited from using an individual's genetic information to deny or limit health coverage or establish eligibility, enrollment, or premium contribution requirements.

Position 2: Insurance providers should be prohibited from establishing differential premiums based on an individual's genetic information or request for genetic screening.

Position 3: Employers should be prohibited from using an individual's genetic information in employment decisions, such as hiring, promoting, or terminating an employee or establishing the terms, conditions, and benefits of employment.

Position 4: Insurers and employers should be prohibited from requiring individuals and families to undergo genetic testing.

Position 5: Insurers and employers should be prohibited from collecting and/or disclosing an individual or family's genetic information. Written and informed consent should be required for each disclosure of genetic information and should include to whom the disclosure is made.

Position 6: Congress should establish comprehensive and uniform federal protection against genetic discrimination that closes the gaps in protection due to varying state laws. Federal protection should also cover ERISA (Employee Retirement Income Security Act) health plans.

The entire 12-page policy monograph, "Establishing federal protections against genetic discrimination," is available on-line at www.acponline.org/advocacy/where_we_stand/policy/gen_dis.pdf.

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Massachusetts seeks ban on pharma gifts to doctors

Would be most restrictive in United States

Some lawmakers in Massachusetts have introduced legislation that would make the state the first in the nation to impose an outright ban on all pharmaceutical marketing gifts to physicians. The bill also seeks statewide adoption of electronic medical records.

The ban on gifts would forbid pharma representatives from offering gifts, and physicians from accepting them. The proposed ban extends to physicians' staff and family, but would permit distribution of drug samples for exclusive use of patients.

Gifts, as defined by the bill, would include payments, entertainment, meals, travel, honorariums, subscriptions, and office supplies with drug company logos imprinted on them. Violation of the ban would carry a $5,000 fine, two years in prison, or both.

The Massachusetts Medical Society (MMS) immediately issued a statement praising the intent of the proposed legislation, but taking strong issue with how it would accomplish its aims.

"While understanding the intent of this provision to prevent undue influence by drug companies on the prescribing patterns of physicians and sharing that concern, the Society believes this proposal would have the unintended conse-

quences of limiting support for legitimate continuing medical education programs," the MMS stated. "It would also potentially curtail the distribution of scientifically accurate information in medical and scientific publications."

Current MMS policy states that gifts accepted by physicians "should be related to a patient benefit or the physician's work and must be modest in nature." The current MMS stance on gifts to physicians aligns with policy or guidelines held by most medical associations, including the American Medical Association, which permit gifts of continuing medical education sponsorships and small gifts (office supplies, models, etc.) that are practice-related and modest in cost.

Less-restrictive legislation has been passed in other states, most of which set dollar limits on the value of gifts to physicians from the pharmaceutical industry. ■

Uninsured research subjects raise multiple ethical issues

What is the 'moral obligation'?

Nearly 47 million Americans lack health insurance, leaving them without regular access to health care — and making them a potentially vulnerable population in health care research.

From the possibility of undue influence to how to deal with research-related injuries, uninsured subjects raise ethical issues that researchers must consider when reviewing protocols, says **Daniel Vasgird**, PhD, CIP, director of research compliance services for the University of Nebraska-Lincoln.

Vasgird says the Belmont Principles of beneficence and justice underlie research boards' responsibility to subjects who lack ready access to health care.

"You have a moral obligation there to make sure that the individual would benefit from the specific study — that it's not just something that you can rationalize out and say you're doing it for the greater benefit of mankind," Vasgird says.

According to the U.S. Census, 15.8% of all Americans reported being uninsured during 2006, the highest percentage since 1998. For some groups, the percentages are even higher: 20% of African-Americans and 34% of Hispanics reported being uninsured during 2006.

Important subject pool

In his previous position as chair of the institutional review board (IRB) at the New York City Department of Health, Vasgird saw many uninsured patients.

He says the department was an inviting place for researchers, particularly during the 1990s when the HIV epidemic was in full swing and tuberculosis cases were on the rise.

"The department has well over 100 clinics scattered throughout the city, with tens of thousands of people receiving treatment in those clinics — STD clinics, tuberculosis clinics, and the like," Vasgird says. "Researchers want to have access to that subject pool, so the Department of Health IRB is an important one."

He says his interest in uninsured research subjects was piqued by a study that sought to look at the effectiveness of the powerful antibiotic class quinolones.

"An individual had gotten funding from a pharmaceutical company and wanted to use the tuberculosis and STD clinics to recruit subjects," Vasgird says. "Some of [the quinolones] have some very extreme side effects, and as I was reading through the protocol and consent form, I realized after I got to the end, that there was no provision made if anybody was injured, or if they had serious side effects."

Vasgird says he consulted physicians on his board, who all advised that the sponsor be required to provide free medical care or compensation if subjects were injured in the course of the study.

But the researcher balked at the idea, pointing out that the federal regulations require only that participants be told whether health care is available, not that it be mandated.

"In other words, all you have to do is let people know that they're not going to be cared for if something goes wrong — it's a very, very minimal standard," Vasgird says. "We told him yes,

SOURCE

For more information, contact:
- **Daniel Vasgird**, PhD, CIP, director, research compliance services, University of Nebraska-Lincoln. Phone: (402) 472-1837.

we're aware of that, but I pointed out to him that the IRB can raise the bar, if they feel it's ethically necessary to do it. In this case, we felt it was ethically necessary."

Ultimately, Vasgird says, the researcher and sponsor agreed to the provision and the study went forward.

He says a study that presents more than minimal risk to subjects should take similar steps to ensure that uninsured subjects are protected in case something goes wrong.

He notes that in some cases, health care for those injured in research is paid for through the institution's liability insurance.

"So my first word of advice is to double-check with your general counsel to make sure that you don't have those provisions in place in an insurance policy," Vasgird suggests.

Other ethical issues

Beyond concerns about research-related injury, the inclusion of uninsured subjects poses other ethical challenges, Vasgird says:

• *Undue influence.* Vasgird says some uninsured subjects may be signing up for clinical trials because they are trying to receive health care and medication that they can't get elsewhere.

"Their income levels are modest at best," he says. "So they're more susceptible to coercion. It's possible that people would be making a decision to be involved in a study that they normally wouldn't do. They're not thinking seriously about what it could mean for them down the line in terms of their well-being."

He says review boards should be alert to that possibility when reviewing protocols that are likely to recruit a large number of uninsured patients.

• *Post-trial benefits.* Vasgird says vulnerable groups such as uninsured patients shouldn't be expected to contribute to research that can't benefit them later, if they're unable to access the study drug because of lack of health insurance.

It's a concept that applies not only to uninsured subjects in this country, but increasingly to research subjects in developing countries.

"If at all possible, you're supposed to provide so the individual can receive care," he says. "Certainly from the standpoint of the developing countries, they want to make sure that the medical care and other things are going to be provided after the people leave."

Vasgird says that review boards that routinely deal with uninsured subjects should take special care to involve representatives from that community on the board.

"You should try to make a point of not just having somebody unaffiliated," he says. "You should be going beyond that to find individuals who can really be representatives for these particular groups — a minister, a social worker, a principal, or teacher who comes from that community and who can speak for them." ■

Do staff speak up when patient safety is at issue?

Openness must be made part of system culture

The health care community has long endorsed staff and patients speaking up when necessary to protect patient safety, but in the heat of the moment, a staff member can be intimidated by superiors and fearful of rocking the boat.

How can you tell if your colleagues will speak up? Finding the answer requires some digging, according to **Grena Porto**, RN, MS, ARM, CPHRM, senior vice president with Marsh, a health care management company in Philadelphia. Employees quickly get the message that the correct response when patients are at risk is to speak up, but that doesn't mean they really feel empowered to do so, she points out.

"A lot of people want to just say, 'We'll train the nurses, tell them what to do, and they will do it.' In fact, they don't," Porto says. "The culture really needs to support what you're telling them to do. Organizations that want to put all their focus on training the staff are missing the boat, because you have to create a systemwide culture."

Nurses and other staff are astute observers of the employer's culture and will respond accordingly, she says. They are quick to recognize that leaders are preaching about the virtues of speaking up for safety but at the same time dismissing staff concerns or even punishing those who speak. "It only takes one or two instances to undermine your whole effort. The staff say they're not going to speak up because they saw what happened to someone else who opened their mouth," Porto says. "Of course, they'll still tell you that they will do the right thing and speak up, because that's what you want to hear. I

SOURCES

For more information, contact:
- **Christy Dempsey**, BSN, MBA, CNOR, senior vice president of clinical operations, PatientFlow Technology, Boston. Phone: (617) 358-5060. E-mail: cdempsey@patientflowtech.com.
- **Lori A. Paine**, RN, MS, patient safety manager, Johns Hopkins Medicine, Baltimore. Phone: (410) 955-2919. E-mail: lapaine@jhmi.edu.
- **Grena Porto**, RN, MS, ARM, CPHRM, senior vice president, Marsh, Philadelphia. Phone: (215) 246-1144. E-mail: grena.porto@marsh.com.

see that a lot."

For a "stop-the-line" culture, in which even the lowest-ranking employee can intervene when patient safety is threatened, to succeed, that attitude must be modeled across the board, up to the highest levels of management, Porto says.

Local culture can be important

The effort to encourage nurses to speak up is worthwhile because each instance of an error, near miss, or policy violation is an opportunity to improve patient safety, says **Lori A. Paine**, RN, MS, patient safety manager at Johns Hopkins Medicine in Baltimore.

"If we merely see nurses as the executors of provider orders, we miss the opportunity for the nurses to be that final check," she says. "That's how we see nurses, as a vital part of the system, sometimes the last gatekeeper for safety. If they are not empowered to speak up and if we don't listen to them, the organization misses a huge opportunity to improve safety."

Paine points out that, while organizational culture is important, the "local" culture of a staff member's unit or work area can be the driving factor in whether someone speaks up. Even if the overall culture of an organization is on the right track, there may be considerable variability from one unit to another, she says. "We see this sometimes in our event reporting, which we watch carefully and mine for any signs of problems that we need to address," Paine says. "Sometimes we will see reports that a nurse or supervisor is resistant to reporting from others, or we may also see a sharp discrepancy in the number of event reports coming from one unit. That can suggest that the staff in that particular unit are feeling discouraged from reporting these events to us."

Paine also notes that there are continuing concerns among some staff about the risk manager's role and what will happen if a concern is reported to the risk manager. Some staff may fear the intervention of a risk manager more than punishment from their supervisors, she says. "Risk managers can help by tearing down some of those walls and showing what you can do to help in those situations," she says.

Staff must be assured that they will be supported by the institution when they act on behalf of a patient, says **Christy Dempsey**, BSN, MBA, CNOR, previously vice president and director of perioperative services at St. John's Regional Health Center in Springfield, MO, and now senior vice president of clinical operations for PatientFlow Technology, a health care consulting firm in Boston.

"From a management perspective, that's what I did to encourage people to speak up and act," she says. "I told them that as long as they followed the proper procedures and acted in the best interests of the patient, I would stand by them completely and support their actions. I wanted them to feel that they weren't going to be out there by themselves if they stuck their necks out." ■

Free drug samples might be costly 'gifts' in the long run

Samples often newer, more expensive drugs

Before you hand patients free samples of prescription drugs, consider that the sample that saves them money now may end up costing them in the long run, according to research that indicates patients who receive free drug samples from their doctors have significantly higher out-of-pocket prescription costs than those who don't.

"Our findings suggest that physicians should use caution in assuming that the use of free samples ultimately reduces patients' out-of-pocket prescription cost," according to **G. Caleb Alexander**, MD, assistant professor of medicine at the University of Chicago Medical Center and author of the research findings.[1]

According to Alexander, patients who never received free samples had estimated out-of-

pocket prescription costs of $178 over six months, while patients who did receive samples spent an estimated $166 for a six-month period prior to getting free samples, $244 for the six months in which they received samples, and $212 for the six-month period after they received samples.

Previous surveys have found that free samples can lead to overuse of newer drugs over their older counterparts, but the earlier studies did not examine the costs associated with sample receipt.

"We believe our study is one of the first to look at the economic consequences of sample receipt," Alexander said. "Samples may be particularly valuable in providing patients economic relief when they are used short-term and not followed up with long-term prescription for the same medicine. However, all too often, physicians and patients end up continuing the medicines initially begun as samples, even though older, less expensive alternatives may exist."

Samples are often newest, most expensive

Alexander and his colleagues followed 5,709 patients for up to two years. The mean age of patients was 48 years, 84% were white, and 76% had private insurance.

The authors found that there were important differences in the characteristics of patients who received samples and those who did not. The odds of sample receipt were lower among those who were older and also among those who had Medicaid as their source of insurance coverage.

The study was not designed to identify the exact reason that sample users have higher prescription costs after sample receipt. However, the authors hypothesize two main possibilities for this surprising finding.

First, those who received samples may have been more seriously ill than those who did not. But underlying health status, say the authors, explains only a part of the difference in out-of-pocket costs.

Equally important, they suggest, is that patients who receive free samples may end up paying for a prescription for the medicine initially begun as a free samples. The medicines that are given as free samples are often the newest and the most expensive.

"Regardless of the degree to which these different mechanisms account for our findings," Alexander said, "patients and physicians should consider complementary ways to reduce patients' burden from out-of-pocket prescription costs, such as using more generic medicines, stopping non-essential treatments, and using three-month rather than one-month supplies."

For policy makers and researchers, their findings provide an opportunity to consider the complexity of issues raised by sample use.

"Further research is needed to examine patient-physician communication about samples," suggests Alexander, "as well as how physicians decide who needs samples and how samples are distributed across different types of physician practices."

Reference

1. Alexander GC, Zhang J, Basu A. Characteristics of patients receiving pharmaceutical samples and association between sample receipt and out-of-pocket prescription costs. *Med Care* 2008;46:394-402. ■

NEWS BRIEFS

'Dr. Death' seeks to become Rep. Kevorkian

The former physician who went to prison as "Dr. Death" in 1999 has announced he will seek election as a Congressman from Michigan. Jack Kevorkian, who was released from prison in 2007 after serving eight years of a 10- to 25-year sentence for second-degree murder, said in announcing his bid for office that he would seek to bolster the 9th amendment, which he claims gives Americans the right to, among other things, assisted suicide.

Kevorkian must gather 3,000 signatures from registered voters by July to win a spot on the November ballot, but being a convicted felon won't restrict him from running for office. The

CME answers

17. A; 18. C; 19. B; 20. D.

only requirements to run for Congress are age (at least 25) and residency in the state. In announcing his bid for office, Kevorkian said he would run without any party affiliation for the seat, which represents a suburban area of Detroit.

Kevorkian claimed to have assisted in the suicides of more than 130 people between 1990 and 1998, but he was charged and convicted only in the death of Thomas Youk, a California man with Lou Gehrig's disease. A condition of Kevorkian's parole is that he not assist in any more suicides. ▼

Antibiotics and end-of-life in dementia patients

Antibiotics are frequently prescribed to nursing home patients with advanced dementia in nursing homes, posing two potential ethical dilemmas — both in the treatment burden placed on patients at the end of life and the spread of antimicrobial resistance in the nursing home community — a research group reports.

Erika D'Agata, MD, MPH, of Boston's Beth Israel Deaconess Medical Center and Harvard Medical School, led a team that studied 214 residents with advanced dementia living in 21 nursing homes. Each patient was followed up, after an initial review, for up to 18 months; during that time, 99 of the residents died, and of those, 42 (42.4%) received antibiotics during the final two weeks before they died.

"The proportion of residents taking antimicrobials was seven times greater in the last two weeks of life compared with six to eight weeks before death," the authors write. Thirty of the 72 courses (41.7%) in the last two weeks of life were administered intravenously rather than by mouth, a method that may be uncomfortable for patients with advanced dementia.

"This extensive use of antimicrobials and pattern of antimicrobial management in advanced dementia raises concerns not only with respect to individual treatment burden near the end of life but also with respect to the development and spread of antimicrobial resistance in the nursing home setting," the authors write. The results support "the development of programs and guidelines designed to reduce the use of antimicrobial agents in advanced dementia." (D'Agata E, Mitchell SL. Patterns of antimicrobial use among nursing home residents with advanced dementia *Arch Intern Med* 2008;168:357-362.) ▼

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided at the end of each semester and return it in the reply envelope provided to receive a credit letter. When your evaluation is received, a credit letter will be mailed to you. ■

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After reading each issue of *Medical Ethics Advisor*, you will be able to do the following:

- discuss new information about hospital-based approaches to bioethical issues and developments in the regulatory arena that apply to the hospital ethics committee;
- stay abreast of developments in bioethics and their implications on patient care, risk management, and liability;
- learn how bioethical issues specifically affect physicians, patients, and patients' families. ■

COMING IN FUTURE MONTHS

- Haleigh Poutre: 'PVS' child abuse victim awake, helping prosecutors
- Truth-telling to cancer patients can foster hope
- Doctors, ethicist, clergy struggle to define end of life
- Organ donations take hit over allegations doctor hastened death

CME Questions

17. Twenty-four of the 25 states that have enacted laws providing for psychiatric advance directives have restricted who can be a witness to the document, excluding:
A. family members and members of the patient's treatment team.
B. only family members with whom the patient lives
C. attorneys
D. only the patent's adult children

18. The American College of Physicians' policy monograph, "Establishing federal protections against genetic discrimination," lists six position points aimed at prohibiting misuse of genetic information by:
A. insurers
B. employers
C. both a and b
D. neither a nor b

19. Proposed legislation in Massachusetts would ban all pharmaceutical industry gifts to physicians, and is in line with similar bans suggested by the American Medical Association and other physician organizations.
A. True
B. False

20. According to Alexander, who studied of out-of-pocket drug costs and their potential tie to free drug samples, some suggested ways to reduce patient out-of-pocket costs include:
A. use of more generic medicines
B. stopping non-essential treatments
C. using three-month rather than one-month supplies
D. All of the above

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