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Relationship with patient is asking for trouble

The blurring lines between personal and professional relationships between physicians and patients have raised multiple ethical and legal concerns for the healthcare field.

If a physician is dating a former patient and continues to treat the patient in some way, that physician is "now in a very difficult position," says **Arthur R. Derse**, MD, JD, FACEP, professor of bioethics and emergency medicine at the Medical College of Wisconsin.

If the physician refilled a prescription for narcotics for that former patient as a favor, the patient could later claim he or she became addicted to the medication as a result of the erosion of the boundary of the doctor-patient relationship, says Derse.

"Conversely, the patient may claim that you inadequately treated the patient's pain because of your relationship," says Derse. "There is a potential for legal action on both sides of that scenario."

Those legal concerns are seconded by **Jennifer Lawter**, RN, JD, vice president of risk management at Emergency Physicians Medical Group (EPMG) in Ann Arbor, MI. If a physician continues to treat a patient after a social relationship has developed, he or she faces significant legal risks, Lawter says. "It is much more difficult to be certain you are providing appropriate and objective care if you are treating someone with whom you have a social relationship," she explains. "You are leaving yourself open to inferences that you would not otherwise have to deal with in a litigation environment."

In the case of a physician prescribing narcotics or other more significant forms of treatment to a person he or she is dating, Lawter says "that's just asking for trouble."

The blurring of the doctor-patient relationship can become a legal issue, affirms **John Burton**, MD, chair of the Department of Emergency Medicine at

"There are potential legal risks if a patient contacts you via social media."

Carilion Clinic in Roanoke, VA. This issue is particularly troublesome if the physician is prescribing scheduled substances, Burton says. Many states have laws requiring any physician caring for a patient to have a formal doctor-patient relationship and medical records.

"If I'm dating you and I write you a prescription, then now I'm in trouble twice," he says. "We don't have a doctor-patient relationship, and there are no records." *(For more information on legalities of dating a patient, see story, p. 63.)*

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Legal problems can result from 'friending'

When putting your identifying information onto a social network, remember that you can be found not only by friends, but by people you don't want to find you, including past or current patients. "There are potential legal risks if a patient contacts you via social media," says **William Sullivan**, DO, JD, FACEP, director of emergency services at St. Margaret's Hospital in Spring Valley, IL, and a Frankfort, IL-based practicing attorney.

Sullivan says that he joined Facebook to find out about high-school and college friends, until a patient posted a message on his "wall" to complain that he wouldn't prescribe her narcotic pain medications. "I immediately deleted my account," he says. "If patients post medical questions on your Facebook wall, there may still be a question as to whether they have given you consent to discuss their medical care in this open forum."says Sullivan. "'Friending' a patient will allow the patient access to all your personal photos and to all your other friends," he says. "Is that something you want to happen?"

If a physician "friends" a patient, "the normal boundary in the patient relationship starts getting eroded," Derse says. If that patient ends up suing for malpractice, the attorney will be able to discover these postings, he says. "If the physician said something that seemed funny while chatting online, it may now seem flippant," Derse says. "Now, all of that is fair game for the attorney."

For example, a comment on a patient's Facebook wall such as, "I told you it would probably turn out to be nothing!" can be used to demonstrate that the physician wasn't really taking the client's problem seriously, says Derse. "The attorney could use that to set the stage for how the patient encounter went overall," he says.

If a patient sends you a "friend" request, Derse recommends replying, "Sorry, I can't 'friend' patients or former patients."

It's all discoverable

Increasingly, organizations are taking stances against use of social-networking sites, Burton says.

"They are saying that physician employees should not be in any kind of relationship with patients, including on the Internet," he says. "A 'friend' request might start out as a very simple thing, but usually goes over the line to unethical behavior."

Recently, Burton was contacted by a waiter who served him at a restaurant, who found his contact information on the hospital web site and wanted help finding a psychiatrist. "This was a potentially explosive situation," he says. "The person seemed to be stable in my limited interaction with him, and I'm also an empathetic person and wanted to help."

Burton sent the man some referral information, but it raised the issue of what he would have done if the request had been different. "What if he emailed that he needed a new lithium prescription?" asks Burton. "Do I help him with that? Of course not, but how do I respond?"

Online communication is allowing patients to break down traditional barriers in contacting physicians, says Burton. "You have to be very careful, because you can get into legal and certainly ethical areas on both sides," he says.

You likely feel an ethical responsibility to offer help as a physician if you see a motor-vehicle accident with obviously injured people, says Burton, while a patient's email request for help is not as clear-cut. "You are clearly not legally obligated to provide a service to an individual who contacts you via social media," says Burton. "Remember that this is all discoverable in the event of a lawsuit."

Lawter says that many hospitals around the country have developed no-tolerance policies with respect to social networking. "Nurses and physicians have been fired for discussing patients on Facebook, even when names were not mentioned," she says.

In November 2010, the American Medical Association issued a policy on professionalism in the use of social media, including a recommendation that physicians should separate personal from professional information. "These will likely be used against physicians in lawsuits if they do not comply," Lawter says. "They specifically mention that, as a general rule, physicians should not accept 'friend' requests from patients, especially if your only relationship with them, at that point, is as a patient."

SOURCES

For more information contact:

• **John Burton**, MD, Chair, Department of Emergency Medicine, Carilion Clinic, Roanoke, VA. Phone: (540)266-6331. E-mail: JHBurton@carilionclinic.org.
• **Arthur R. Derse**, MD, JD, Professor, Bioethics and Emergency Medicine, Institute for Health and Society, Medical College of Wisconsin, Milwaukee. Phone: (414) 955-8498. E-mail: aderse@mcw.edu.
• **Jennifer Lawter**, RN, JD, Vice President, Risk Management, EPMG, Ann Arbor, MI. E-mail: jlawter@epmgpc.com.
• **Matthew Rice**, MD, JD, FACEP, Gig Harbor, WA. Phone: (206) 790-5371. Fax: (253) 853-5617. E-mail: mricemd@gmail.com.
• **William Sullivan**, DO, JD, Frankfort, IL. Phone: (708) 323-1015. E-mail: wps013@gmail.com. ■

Legal risks arise when dating a patient

Don't arm counsel with ammunition

Developing personal relationships with patients involves ethical as well as possible legal implications, says **William Sullivan**, DO, JD, FACEP, director of emergency services at St. Margaret's Hospital in Spring Valley, IL, and a Frankfort, IL-based practicing attorney.

"Some ethicists have questioned whether it is wise to merge one's social and professional lives," Sullivan says.

The best practice for physicians is to consider patients and former patients to be off limits for personal relationships, says **Arthur R. Derse**, MD, JD, FACEP, professor of bioethics and emergency medicine at the Medical College of Wisconsin in Milwaukee, says. Several medical examining and licensing boards specifically state that having an inappropriate relationship with a patient violates their codes, Derse notes. "In some of these, a patient is defined as up until two years after medical care was provided," he says. "There is a large potential danger area."

While these codes generally are meant to apply to ongoing doctor-patient relationships, as in psychiatry, says Derse, "a savvy lawyer could use this in a malpractice lawsuit, as evidence that a physician was acting inappropriately." *(For more information on relationships with patients, see story p.64.)*

> ***"Some ethicists have questioned whether it is wise to merge one's social and professional lives."***

All hospitals, surgery centers, and office-based surgery facilities accredited by The Joint Commission must have a code of conduct that defines acceptable, disruptive, and inappropriate behaviors. They also must have a process for dealing with the defined inappropriate behaviors.

Evidence against the doctor

If you date a patient, "the first place where you'd get into trouble is not necessarily legally, but with the state board of medicine," says **John Burton**, MD, chair of the Department of Emergency Medicine at Carilion Clinic in Roanoke, VA.

Most complaints against physicians alleging an improper relationship with a patient ultimately end up at the state board of medicine or the hospital ethics board, which often reports to the hospital executive board, notes Burton.

If a patient complains to the medical examining board, says Derse, this complaint might be used as evidence against you in a subsequent malpractice lawsuit.

If your behavior is sanctioned, this sanction will be on your record and most likely would get reported out to the National Practitioner Data Bank, Burton warns. "These things are increasingly being investigated aggressively and reported out to boards, which have very little tolerance for these kinds of activities," Burton says. "And if the board investigates it, you'd better get a lawyer because your whole career is on the line."

Most medical and nursing societies have guidelines and/or rules that they enforce when it comes to moral and ethical obligations of their members, says **Jennifer Lawter**, RN, JD, vice president of risk management at Emergency Physicians Medical Group (EPMG) in Ann Arbor, MI. "Physicians and nurses need to be concerned about these expectations, as well as the various state-licensing organizations, so that they do not run afoul of the requirements," she says.

Most insurance coverage for medical-malpractice litigation doesn't typically cover licensing investigations, which can be costly, adds Lawter. "You may find yourself with licensing-violation allegations or perhaps be kicked out of professional societies," she says. "While this may not be as scary as a medical-malpractice lawsuit at first glance, it can lead to more problems than you may be prepared for. These issues will nearly always show up in any future litigation." ■

Placing barriers between patient and professional

There are certain barriers you have to place between you and the patient, as a professional, says **Matthew Rice**, MD, JD, FACEP, former senior vice president and chief medical officer at Northwest Emergency Physicians of TEAM Health in Federal Way, WA. "When those barriers start to break down, huge problems occur."

Rice notes that Washington state has taken a serious stand on this issue, with its Medical Quality Assurance Commission establishing written boundaries on appropriate behavior.

"Actions will be taken against you as a professional if you cross over the boundaries we believe to be there," says Rice. "This is critical for those people who think they can be a physician and casually associate with their patients."

If a patient decides, at any point in time, to bring an action for medical malpractice, the nurse or physician named in the lawsuit would be at a significant disadvantage if a personal relationship ever existed, says **Jennifer Lawter**, RN, JD, vice president of risk management at Emergency Physicians Medical Group (EPMG) in Ann Arbor, MI. "Past mates make vengeful plaintiffs," she says. "If you're going to get romantically involved with a patient, ideally it should be later in time, after treatment has terminated." ■

Stroke trials pose ethical challenges

Researchers voice diverse opinions

Acute stroke trials pose unique ethical challenges to researchers. Stroke interventions are extremely time-sensitive, meaning that decisions about treatment and research participation often must be made quickly.

Some symptoms of stroke affect the patient's cognitive abilities and even the ability to know that he or she is suffering a stroke, which raises consent issues. And because the degree of impairment can vary widely from patient to patient, hard-and-fast rules about how to handle consent of stroke patients is difficult, says **Enrique Leira**, MD, MS, assistant professor of neurology at the University

of Iowa in Iowa City.

"It's very difficult to generalize the regulations about, for example, waiver of consent, in a situation like this that is so heterogeneous," he says.

Leira and his colleagues recently surveyed stroke investigators in 15 countries to get their opinions about various ethical questions related to stroke research.[1] He says what they found was a wide diversity of opinion among researchers and review boards about how to handle some of the most pressing ethical questions related to stroke research: While 73% of investigators said that their review boards allowed surrogate consent in stroke trials, only 18% reported that they were allowed to obtain that consent by telephone, and 20% reported that they were allowed to obtain that consent by fax. 22% reported that there was an established procedure agreed to by review boards for assessing competency in stroke patients. Language ability and judgment of consciousness ability was evaluated using a variety of models.

That diversity of opinion can lead to delays in getting multisite international stroke trials off the ground, Leira says. He hopes that the group's recently published article will start a conversation in the stroke research community that leads to more standardized procedures for stroke trials. "Given that this is very time-dependent and that time is of the essence, if we could agree on some framework for determining eligibility for example, that would be ideal," Leira says.

A 'time-dependent emergency'

Leira says that in his own experience, review boards' requirements for conducting acute stroke trials are so onerous that they can sometimes delay the start of interventions.

"I think the most important thing for review board members to understand when evaluating an acute stroke research protocol is that this is a time-dependent emergency," he says. "The outcome of any intervention, including the intervention that is being tested, is going to be dependent on how soon that intervention is started. So while all the requirements on safety of research have to be maintained, we also have to understand that this particular research cannot be delayed too long because if it is, we enter another ethical problem, which is if we are testing interventions at too late a stage, then they are less efficacious or they are not efficacious at all."

In other types of research into emergency interventions, physicians have been able to use established procedures, including provisions in the federal regulations for emergency exception from informed consent. But Leira says there are important differences between stroke research and other types of emergency research. In some other emergency situations, a patient is unconscious, which makes the decision of how to obtain consent more cut-and-dried.

In that case "it is obvious when the patient and potential subject cannot provide consent, and a waiver of consent through community consultation can be approved," he says. "In stroke research, this is a little more complicated because we are talking about a variety of neurological deficits and degrees of impairment. There may be persons with mild cognitive impairment, no cognitive impairment at all, or totally impaired." *(For more information about consent, see story below.)*

In fact, some stroke patients might suffer from a condition known as anosognosia, meaning they don't recognize that they are impaired, "in which case getting informed consent for research or treatment can be challenging because the patient is not aware of having any problems," Leira says.

REFERENCE

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Consider the option of surrogate consent

In cases in which a person has been judged to be incapable of giving consent, surrogate consent is always an option. However, according to **Enrique Leira**, MD, MS, assistant professor of neurology at the University of Iowa in Iowa City, the time pressure involved in a stroke adds complications there, particularly for investigators such as him who work in rural areas.

"Patients often are evacuated by helicopter, and they often arrive much earlier than the relatives who usually come by ground," Leira says. "By the time the relatives become physically present, it may be too late to enroll the patient in the protocol."

He says many review boards, including his own, will not allow phone consent from a surrogate for

research. "The requirement is that the informed consent has to be obtained with a legal document on paper. For an acute time-dependent trial in a rural center, that's going to be a problem."

While Leira says that a consensus on how to handle ethical issues in stroke research would need to come from the stroke research community, understanding the issues can help review boards to better facilitate these trials. As an example, he notes the complexity of required language in consent forms.

"It's important to really make an honest assessment of how long it would take to go through a complete standard consent form in an acute situation like this and be sure that true consent can be obtained without delaying the process," Leira says. "I personally think for an acute stroke situation, the consent forms are a little bit too legalistic and long. While that may be appropriate for studies where a person has more time to decide on participation, in a situation like this, it can really defeat the purpose." ■

Research group updates ethics training

Focus: Community obligations, informed consent

The new edition of a widely used human subjects protection curriculum has an increased emphasis on community engagement and the importance of ongoing informed consent, says one of its developers.

Changes to the Research Ethics Training Curriculum (RETC) for Family Health International (FHI) came in response to feedback from people around the world who've used it since its introduction in 2001, says **Roberto Rivera**, MD, a senior advisor for FHI, which conducts research throughout the developing world in areas that include reproductive health and infectious diseases. "We've trained hundreds of people ourselves, and people have used the [first edition of the] curriculum by the thousands," he says. "We were constantly receiving feedback from the people using it, so we had many ideas that we wanted to incorporate in a new edition."

> ***"After you obtain consent, you have to maintain communication with the participant regarding informed consent issues."***

The new RETC has been recognized with an Award for Excellence in Human Subjects Protection from the Health Improvement Institute (HII). In 2005, FHI won two awards from the HII: one for the first edition of the RETC and one for an ethics training curriculum for community representatives.

Rivera says the original RETC was developed to train personnel who participate in its international research projects. Since that time, it has come to be used by other organizations including the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO). In addition, Rivera says, many U.S. institutions use the RETC to provide an international component for their ethics training.

"They use the CITI as the primary tool, and then they use our curriculum for people who are going to do international research," he says. The CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

Community and consent

When it came time to update the curriculum, Rivera says his group made several changes but he sees two as particularly important:

- **Community impact.**

The first edition of the RETC interpreted the basic Belmont principles — respect for persons, beneficence, and justice — only as they applied to individuals, Rivera says.

"This is still the most common perception of these three principles: that they apply to a particular person — respect for a person, benefits and risks for the person, justice for the person," he says. "In this [new] edition, we tried to make an important point that equally important is the community. You owe respect not only to the person, but to the community where the research is being conducted. You have to think of the benefits and risks that are going to come out of the research for the community. The community has to be justly treated."

In accordance with that principle, the curriculum has a new section on community participation, looking at the role of the community engagement in research projects, Rivera says.

• **Informed consent.**

Rivera says that informed consent is too often seen as a single interaction between participants and researchers. The new edition looks at informed consent more as a process, he says.

"It's not one point in time, it's something that begins before the research is initiated," he says. "You have to collect information that is necessary to develop the informed consent. After you obtain consent, you have to maintain communication with the participant regarding informed consent issues."

In addition, he says, the developers of the new RETC have expanded the case studies section, a selection of real studies that raise particular ethical questions for students to discuss, to include examples from outside FHI. They now include studies reviewed by research ethics commissions in countries such as Colombia, Indonesia, and India. "Someone might say that the [FHI cases] aren't the best cases to talk about the research that they do or the ethical issues that they encounter," Rivera says. "So now we have a variety of case studies." ■

Too much information in informed consent?

Study raises issue: what to tell participants

Can the informed consent process actually provide too much information? That's the contention of HIV researcher **Susan Allen**, MD, MPH, DTM&H, director of the Rwanda Zambia HIV Research Group, based at Emory University in Atlanta, who points to a recent study she tried to conduct in Zambia of participants' knowledge about contraceptive options.

Allen says additions to the informed consent gave away too much of the educational content of her study, which made it impossible to discern how much participants learned about contraceptive methods from the program she was testing. When reviewing studies such as this one, which test participants' knowledge, attitudes and behaviors, review boards need to be alert to the possibility of contaminating the group being studied, she says.

"I have always been above and beyond the call of duty when it comes to what education you provide" in informed consent, she says. "But when you're actually trying to test an intervention and then you muddy the waters by having to give information like that in the consent, it's really a problem."

Allen's experience with the study in question occurred with a review board at another institution. She was studying knowledge about contraceptive options among two types of couples in Zambia: those where both partners were infected with the HIV virus, and those couples in which one partner was infected and the other wasn't (called sero-discordant couples). *(For more information about couples HIV testing, see story, p. 68.)* The plan was to test couples' baseline knowledge of different contraceptive methods, including pills, injectables, implants, intrauterine devices, tubal ligation and vasectomy.

The couples were randomized to interventions that included a video showing family planning information and a control group video that provided other health information. Participants then were retested to see how well the family planning education worked.

Adding to the consent

The Zambian review board approved the study without reservations, Allen says. However, the American review board raised concerns that some participants would not receive family planning information during the study. As a result, the review board required that contraceptive information be disclosed to all participants in the informed consent video they viewed beforehand.

"We said, 'Wait a minute, that's part of the intervention,'" Allen says. "If educating people about the different family planning options is included in the informed consent, then we're really not going to have a control group."

She noted that even if participants didn't view the family planning video, they were being provided with an alternate video that talked about important health issues such as nutrition and malaria prevention. However, the review board argued that in a low-resource country such as Zambia, this study might be participants' only opportunity to receive family planning information. "Their position was that since they could not

get those methods elsewhere, it would be unethical to withhold that information," Allen says.

Therefore, Allen's team went forward with the study as approved by the review board, but the team also found a way to create a control group to look at the effects of the changed informed consent, by looking at results from a separate observational study of sero-discordant couples in Zambia. That group had not been given family planning information in their informed consent.

The results were as Allen had predicted: Despite any significant differences between the two groups of couples, those who had viewed the family planning study's informed consent video had much higher levels of knowledge about some of the contraceptive methods. By creating that higher baseline knowledge in those who watched the family planning informed consent video, it became impossible to accurately measure the effects of the later family planning video education, she says. "The informed consent changed things before the intervention even began," she says.

In discussing the aftermath of the study, Allen says that it might have been possible to craft a debriefing after the family planning study that could have brought control group participants up to speed on contraceptive methods without contaminating the sample.[1] However, this study is an example of a more widespread tendency among American review boards to want to give research participants in poor countries such as Zambia greater access to health care resources found in countries such as the United States, even to the detriment of research that might improve public health in those poorer nations, she says.

"Review boards need to get comfortable with the idea that in low-resource settings, people are not getting a lot of things," Allen says. "The standard of care in these settings is often pretty poor. Your research study is going to change that for a couple thousand people, but it's not going to change it for the other 2 million people. Asking researchers to make a little cocoon for the 2,000 people while doing a disservice to the 2 million is not a good thing."

REFERENCE

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Voluntary couples HIV testing

Susan Allen, MD, MPH, DTM&H, director of the Rwanda Zambia HIV Research Group, based at Emory University in Atlanta, lobbies vigorously for enhancing informed consent in HIV studies in Africa and says that it should include information about voluntary couples HIV testing, which she calls a low-cost, high-impact intervention.

Compared to interventions such as male circumcision and vaginal microbicides, couples testing works just as well, she says. But Allen says informed consents for trials of these other interventions usually fail to discuss couples testing as an option.

"How can you enroll women into your study when you know that 75% of them are married and that their greatest risk of getting HIV is from their husbands?" she asks. "I've really been trying to advocate that you must include two or three sentences in your informed consent that say: 'If you are married, your greatest risk of HIV comes from your spouse. We strongly encourage you to be tested with your spouse, and we will either provide that service for you, or we will refer you to a place that provides it.'" ■

Guiding seniors through EOL

Seniors covered by BlueCross BlueShield of Tennessee's Medicare Advantage plan are guided through the end-of-life (EOL) processes and are being empowered with the education, resources, and assistance they need to make their own decisions about what kind of care they want to receive at the end of life.

The Chattanooga-based health plan end-of-life planning program received a bronze award in fall 2010 at the Best Practices in Health Care Consumer Protection and Empowerment awards ceremony from URAC, a Washington, DC-based organization that promotes healthcare quality through its accreditation, education, and measurement programs. (formerly known as Utilization Review Accreditation Commission.

The program began in 2009 after the health plan started its Medicare Advantage program in

2006, says **Alice Greer**, RN, BSN, CPHQ, quality research analyst in quality management. "As we worked with the Medicare population, we realized that end-of-life concerns are a big issue. We found that even though some of the members knew they were facing a potentially terminal illness, they hadn't thought about end-of-life plans, or if they had, they didn't have a legally appropriate form or had not shared their wishes with their family or their physician," Greer says.

At the same time, the insurer determined that many staff members were uncomfortable initiating a conversation about EOL considerations and needed education to learn how to approach members about their choices. "We looked for ways to assess our Medicare population to identify people who needed the program and to aid the case managers in bringing up the subject with members and leading them through the process," Greer says. *(For more information on the assessment process, see story, right.)*

The case managers who work with the Medicare Advantage members have been trained on how to approach the subject and have information at their fingertips to educate the members. The health plan also collaborated with the non-profit Tennessee End-of-Life Partnership and sponsored a daylong educational program for case managers and the health plan's providers.

When seniors sign up for Medicare Advantage, the health plan sends them the health needs assessment. They can return it by mail and have it scanned into the computer program, or they can call and complete the assessment over the telephone.

Referrals come from the health needs assessment, from the utilization management department, from claims data that show members with multiple hospital admissions, and from the health plan's predictive modeling. The Centers for Medicare and Medicaid Services (CMS) requires Medicare Advantage to conduct an initial health needs assessment. "We tweaked our assessment and configured our computer system so it would automatically send out a referral when someone had a condition that indicated they might benefit from an end-of-life discussion," Greer says.

Medicare Advantage members who are referred to the program are asked if they have EOL plans and if they would like to discuss the subject. Those who meet the criteria for needing immediate EOL support are offered a more intensive care plan, Greer says. Criteria for the intensive care plan include debility, failure to thrive, cancer patients with a terminal diagnosis or uncontrolled symptoms, advanced heart disease patients, advanced pulmonary diseases, dementia, end-stage liver or renal disease, and neurological disorders.

The utilization management department has a trigger list of criteria. If someone calls to obtain approval for a procedure and the patient falls into one of the diagnosis categories, those nurses are trained to send a referral, she says. Outreach calls are then made to all members who are eligible for the intensive care planning program. The services the health plan offers are explained the services, how the EOL planning will occur, and how they can be empowered to make their own decisions. ■

EOL program assessment process

If senior members consent to participate in the BlueCross BlueShield of Tennessee's Medicare Advantage end-of-life (EOL) plan, a thorough assessment is made that includes their current health status; their present functional status; resources they have; their caregivers; their understanding of their current level of health, diagnosis, and prognosis; information on their socioeconomic status; and any educational or language barriers.

The Medicare Advantage staff includes two social workers who help people complete the forms over the telephone or, if the member prefers, will meet with them at the health plan's Silver Life Center in Chattanooga, TN. Consent to notify the member's primary care provider is then obtained to collaborate with the physician as well as the caregiver so everyone is on the same page.

One of the goals of the EOL program is to overcome the negative impression many older people have of hospice care by educating them. Some members aren't aware of the hospice benefits they have. Others don't take advantage of them because

One of the goals of the EOL program is to overcome the negative impression many older people have of hospice care by educating them.

of their perception of what hospice means, says **Alice Greer**, RN, BSN, CPHQ, quality research analyst in quality management.

"Length of stay in hospice is incredibly short with our Medicare population," Greer says. "If somebody doesn't get into hospice until the last two days of their life, they've lost the opportunity to increase the quality of life, have gone through unnecessary procedures, and increase the stress on the family. Knowing about hospice and what it means saves people a lot of panic-mode trips to the emergency room for interventions and makes them feel more in control." ■

New guidelines for ethical conduct

The American Society of Plastic Surgeons (ASPS) recently adopted guidelines concerning ethical conduct for surgeons when dealing with medical device and pharmaceutical manufacturers.

No matter how big or how small, it is no longer permissible for doctors to accept gifts from industry sources that are not directly related to educating healthcare providers or patients. These gifts include but are not limited to dinner, sporting events, tchotchkes, flowers, and the like. This ban also includes take-out meals left in physician's offices and healthcare facilities. The new guidelines permit meals provided for surgeons and their staff during educational presentations, as long as they are not part of an entertainment activity. The guideline also consents to society members accepting educational items as long as they are worth less than $100.

Building on the information presented during a recent Compliance Summit, the ASPS Board of Directors approved guidelines for members' interactions with industry. An all-inclusive document, titled "Considerations for Interactions with Industry," aligns with AdvaMed and PhRMA industry guidelines to ensure ethical relationships between physicians and industry. The document details standards related to the acceptance of gifts, educational products, meals and entertainment from industry; protocols for seeking industry support for educational programs; consulting arrangements; promotional speaking, and the regulations associated with each. A free copy of the new guidelines can be found at http://www.psnextra.org/Articles/Compliance-Guidelines.html. ■

Cow's blood saves a life

The life of a Melbourne, Australia, woman was spared after a life-saving transfusion was performed using hemoglobin-based oxygen carrier HBOC-201, a product manufactured from cow's blood. Ten units of the blood substitute were flown to Melbourne from the United States, where it is manufactured by the U.S. Navy.

The patient, **Tamara Coakley**, had been in a medically induced coma since a car accident in October. Because of her Jehovah's Witness faith, 33-year-old Coakley's family refused a conventional blood transfusion but was willing to accept blood substitutes. Jehovah's Witnesses have long been known for their rejection of blood and blood-component transfusion, even when it is necessary to save life. But in a notable change in policy, the Witnesses' governing body announced in the June 15, 2000, issue of its official church publication *The Watchtower*, that members may now accept fractions of any of the primary components of blood. This includes hemoglobin-based HBOC-201, derived from bovine (cow) blood.

After the ethics committee at Melbourne's Alfred Hospital approved the import, the blood arrived within 48 hours. Doctors at the hospital administered five units of the manufactured blood over two days. The patient did experience complications, including fever and pneumonia, but her hemoglobin levels remained at a healthy level. It was the first case reported in which a synthetic blood product reversed cardiac hypoxia and anemia in a patient.

The blood product does not require cross-matching and can be stored at room temperature for up to three years. Coakley said in an interview that she was overwhelmed by the doctor's efforts to save her life while respecting her personal wishes. Researchers have high hopes that in synthetic products will help the worldwide shortage of donor blood. ■

Medical center sponsors EOL forum

In honor of National Healthcare Decisions Day on April 16, 2011, Wake Forest Baptist Health in Winston Salem, NC, along with the Bioethics Committee of Lexington (NC) Medical Center, sponsored a forum on end-of-life (EOL) issues.

Although public awareness of the need for advance care planning has increased a great deal over the last few years, studies on the subject indicate that many individuals have not taken advantage of their right to make pre-emptive decisions concerning healthcare, in the event that they cannot speak for themselves. The forum shed light on this initiative and was open to the entire community. The sole purpose to inform participants about relevant healthcare decisions that individuals tend to face at the end of life.

The **Rev. Lee Duke III**, DMin, chaplain and pastoral counselor at Lexington Medical Center and organizer of the event, said that people are able to live a more meaningful life when they are informed and have made critical decisions about the end of life. The Rev. Jay Foster, DMin, chaplain supervisor at Wake Forest Baptist Medical Center, opened the forum with a short presentation highlighting end-of-life choices. Foster has published an article titled "Clarifying patients' wishes at the end-of-life" in the *North Carolina Bar Association Elder Law Newsletter* (2006; 11:5-8). Following his presentation, Duke lead a panel discussion about the day's topic. The panelists included Helen Fitzgerald of Hospice of Davidson County, NC, and the following persons from Lexington: Terry Arnold, MD, an internist with Lexington Internal Medicine, Jack Briggs, president and owner of Davidson Funeral Home, the Rev. Ray Howell, DD, of First Baptist Church, David Inabinett of Brinkley-Walser law firm, Dennis Marton, a respiratory therapist at Lexington Medical Center, and Donna Miller, case management coordinator, also with Lexington Medical Center. ■

NJ surgeons fined for ethics violations

According to published reports, the state Board of Medical Examiners has penalized three orthopedic surgeons for failing to disclose their financial interest in a medical device while participating in clinical trials.

The board reprimanded Richard A. Balderston, MD, of Cherry Hill, NJ, Thomas J. Errico, MD, of Summit, NJ, and Jeffrey A. Goldstein, MD, FACS, of New York, for failing to disclose to their research institutions the financial interests they held in the ProDisc spinal disc device, which was developed to eliminate the need for spinal fusion surgery.

The state board discovered that surgeons Goldstein and Errico indicated they had not received monetary compensation while conducting

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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 with the June issue, you must complete the evaluation form provided 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.

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.

COMING IN FUTURE MONTHS

- Ethical, legal and social issues of the Human Genome Project
- Health system reforms: economic restraints and ethical and legal values
- Recommendations for best approach to organ donation
- The risks and benefits of re-consent

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clinical studies of the spinal disc device at the NYU Langone Medical Center and Hospital for Joint Disease, New York City, and Balderston neglected to reveal his financial interest to the Hospital of the University of Pennsylvania, Philadelphia, while he was the clinical investigator of the device.

According to the published report, Errico was fined $60,000 in civil penalties and $17,500 to reimburse investigative costs, and Goldstein must pay $30,000 in civil penalties and $10,000 in cost reimbursements. Additionally, all three surgeons must complete a refresher ethics course. ■

CME QUESTIONS

21. What does Dr. Leira advocate as another option to use for informed consent in cases in which a person has been judged incapable of giving consent?
    A. Surrogate consent
    B. Proxy consent
    C. Telephone approval
    D. None of the above

22. In what two areas did Family Health International (FHI) make important changes to their Research Ethics Training Curriculum (RETC)?
    A. Processes and ethical questions
    B. Community engagement and research questions
    C. Community impact and informed consent
    D. Reproductive health and infectious diseases

23. What is a goals of the BlueCross BlueShield of Tennessee's Medicare Advantage end-of-life (EOL) plan?
    A. To increase the users' socio-economic status and to lift any educational and language barriers.
    B. To overcome the negative impression many seniors have of hospice care by educating them on hospice benefits.
    C. To ensure all seniors have an EOL plan.
    D. All of the above.

24. True or False: In November 2010, the American Medical Association issued a policy on professionalism in the use of social media, including a recommendation that physicians should separate personal from professional information.
    A. True
    B. False

Answers: 21. A; 22. C; 23. B; 24. A