MEDICAL ETHICS ADVISOR®

For 25 years, your practical guide to ethics decision making

January 2012: Vol. 28, No. 1
Pages 1-12

IN THIS ISSUE

Statement of Financial Disclosure: **Arthur R. Derse**, MD, JD (Board Member), **Joy Daughtery Dickinson** (Executive Editor), and **Felicia Willis** (Managing Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

AHC Media

Pay bone marrow donors, landmark court ruling says

In a groundbreaking decision, the Ninth U.S. Circuit Court of Appeals ruled that a technological breakthrough makes donating bone marrow a process nearly identical to giving blood plasma. This decision by the courts now makes it legal to compensate marrow donors, just as plasma donors are compensated.

The court differentiated between the classic technique of recovering bone marrow by aspirating it through a long needle from the hip and recovering stem cells by pheresis, which it likened to obtaining blood by donation. It stated that peripheral blood stem cells are a subpart of blood, and not of bone marrow, and hence not covered by National Organ Transplant Act (NOTA), as blood was specifically excluded as an organ by NOTA. "Donating stem cells by pheresis is nearly identical to donating platelets or plasma by pheresis, though most plasma is obtained by separating it from donations of whole blood, which is a much simpler, shorter, less uncomfortable, or time-consuming process," says **Michael E. Shapiro**, MD, FACS, chief of organ transplantation, vice chair of the Department of Surgery, Hackensack (NJ) University Medical Center, and associate professor of surgery, New Jersey Medical School, Stratford.

Before this overturning, the compensation of bone marrow was a crime punishable to up to five years in prison. The unanimous, three-judge panel of the court indicated that it remains a felony to compensate donors

EXECUTIVE SUMMARY

A U.S. Circuit Court has ruled that a technological breakthrough makes donating bone marrow a process nearly identical to giving blood plasma, therefore, it is now legal to compensate marrow donors, just as plasma donors are compensated.

- The court differentiated between the common technique of recovering bone marrow by aspirating it through a long needle from the hip and recovering stem cells by pheresis, which it likened to obtaining blood by donation.
- Peripheral blood stem cells are a subpart of blood, and not of bone marrow, and hence not covered by National Organ Transplant Act (NOTA), as blood was specifically excluded as an organ by NOTA.
- Before this overturning, the compensation of bone marrow was a crime punishable to up to five years in prison.

for undergoing an older transplant method, which extracts the actual marrow from the donors' bones.

"NOTA says it's a felony to receive 'valuable consideration' in return for human organs. This is clearly an important, viable law that should not be changed," says Shapiro. As noted in the appellate decision, it is important to obtain reliable information about a donor's medical and social history to ensure that the organs obtained are safe to transplant, and payment to individuals, potentially desperate for those funds, might induce a potential vendor (aren't considered a donor if they are selling rather than donating) to omit certain relevant information, or to lie. "There are many other moral, ethical arguments to be made in favor of banning the commodification of human organs, but the medical argument goes to the need for reliable information, the avoidance of coercion, and informed consent," Shapiro says.

The court has distinguished between bone marrow recovery by aspiration, which Congress prohibits under NOTA, and stem cell recovery by apheresis, which it believes is "blood donation" not "organ donation" and not covered by NOTA. "Many states have banned payments for blood donation for the same reasons — safety of the blood supply — that have been stated for the organ sale ban." Shapiro says. "I personally am not in favor of payment for blood products, so, being consistent, I would oppose payment for stem cell apheresis as well."

The court said the new technology isn't covered by the law because actual bone marrow isn't taken from the donor. According to the court, specialized cells that grow into marrow are taken from a donor's bloodstream, and it's basically a blood donation, not an organ transplant. The court also pointed out that two-thirds of bone marrow transplants employ the newer process.

Ethical effects

While the legal ruling enables payment, it doesn't require an ethical perspective. Presumably a hospital could decide whether to use paid donors in its transplant programs, and this decision would be an appropriate issue for hospital ethics committees to create a new policy.

Ann Mongoven, PhD, MPH, assistant professor, Center for Ethics and the Humanities in the Life Sciences, Michigan State University, East Lansing, says, "practically speaking, as the law becomes more settled, it will become harder for an ethics committee/individual hospital to require donor specifications not required by law. Crassly put, their hospitals will end up losing transplant market share if they do."

Advocates for paying donors believe that compensation will be an incentive for more donations. Shapiro says, "There certainly are people who will do certain things for money that they would not do under other circumstances." Some surveys have suggested an increase in people willing to sell their organs; other surveys have shown that at least some current altruistic donors would be negatively impacted by organ sales and might not donate. "We don't know how the balance would turn out," Shapiro adds. *(For an opinion of a post- transplant patient, see related story, p. 3).*

Another issue is whether risk is being considered adequately, and what risks are appropriate to incen-

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.)

Executive Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).
Managing Editor: **Felicia Willis** (404) 262-5446 (felicia.willis@ahcmedia.com)
Production Editor: **Kristen Ramsey.**

AHC Media

EDITORIAL QUESTIONS

Questions or comments? Call Joy Daughtery Dickinson at (229) 551-9195.

tivize through payment. Mongoven says, "The court is saying the new procedure is so low-risk, it is OK to pay. But the procedure involves significant drug-priming and time. Is it really so minimal risk? And if really so low risk, why not expect that we could get many to volunteer without payment?"

SOURCES

• **Ann Mongoven**, PhD, MPH, Assistant Professor, Center for Ethics and the Humanities in the Life Sciences, Michigan State University, East Lansing, MI. E-mail: ann.mongoven@ht.msu.edu.
• **Michael E. Shapiro**, MD, FACS, Chief, Organ Transplantation, University Medical Center, Professor of Surgery, Touro University College of Medicine, Hackensack, NJ. E-mail: MShapiro@humed.com. ■

Patient speaks out after transplant

We have an organ-donor crisis, need policy!

Post-transplant patient **David Courtney** says that America's present system of organ donation, which relies primarily on altruism, is failing miserably in meeting the demand for organs because the waiting list keeps increasing rapidly, now nearing 113,000, according to the United Network for Organ Sharing, the federally contracted operator of the U.S. Organ Procurement and Transplantation Network.

Media reports say that on average, one person who has been listed for transplant dies every 52 minutes. Courtney recommends a new organ-donor policy called 'presumed consent' that would mandate that all citizens are organ donors; however, each citizen retains the right of free choice and can opt out of the system at any time.

Courtney is the president of the Presumed Consent Foundation and a member of the FAIR Foundation's Board of Directors, whose 27 transplant surgeons, medical directors, and patient advocates support of the implementation of presumed consent policy. Courtney has intimate knowledge regarding the long wait for transplant. His life was close to ending after many years waiting for a double lung transplant.

"Although my life has been saved," Courtney states, I continue to fight for change from our present policies because so many others are needlessly dying; indeed, thousands of those lives can be saved."

"Making a choice," Courtney says, "remains the most important part of this policy as everyone is entitled to have their choice honored. This policy is presently in effect in 27 countries. It is the fastest and least expensive way to lessen the shortage of organs for transplantation."

Courtney states, "Studies by the Association of Organ Procurement Organizations and its members have shown that when faced with a decision at the time of a tragic event, many people do not consent to donation of their loved one's organs or tissue, simply because they don't know their loved one's choice. As a result, our current 'opt-in' system based on altruism is not meeting the demand for organs. Even with our state and federal governments having spent billions of dollars on educating our public on the need for donation, we still have the crisis of a death every 52 minutes."

Courtney has clarified in presentations throughout the United States to patient and civic groups, the United Network for Organ Sharing's Ethics Committee and the U.S. Department of Health and Human Service's Advisory Committee on Organ Transplantation, as well as many state and federal legislators and committees that the presumed consent policy in the United States should be implemented with integral capabilities as championed by the Spanish Model of Presumed Consent: notification, education, awareness, a central registry, program management, and legal protection for providers and oversight.

Courtney summarizes his position, "Yes, my life was saved by our present policy, but thousands of others are dying, and we must fight to help them with the implementation of presumed consent policy, which will provide many more organs for life-saving transplant." ■

Palliative care: Not just for end of life

Education is important for end-of-life care

Patients and caregivers often are not familiar with palliative care, or they misunderstand its purpose. Therefore, education on the reasons to make use of a multidisciplinary palliative care team and the benefits provided is important. *(For more information about educating people on palliative care, see related story, p. 4).*

For most, the word does not have a lot of meaning, or they worry that palliative care is end-of-life care, says **Steven Z. Pantilat**, MD, FAAHPM, SFHM, professor of clinical medicine and director

of the Palliative Care Program and Palliative Care Leadership Center at the University of California, San Francisco. It is care focused on improving quality of life for people with a serious illness such as heart failure, cancer, dementia, Alzheimer's disease, chronic lung disease, and chronic liver disease.

"People who may not understand what palliative care is can certainly relate to what palliative care does," says Pantilat.

Anyone with a serious and complex illness that needs help with pain or other symptom control such as fatigue, anxiety, sleeplessness, or shortness of breath benefits from palliative care, says **Nathan Goldstein**, MD, associate professor of the Brookdale Department of Geriatrics and Palliative Medicine, Hertzberg Palliative Care Institute, at Mount Sinai Medical Center in New York City. Palliative care also helps patients better understand their disease, develop goals for medical care, and tailor treatment to those goals.

Clinicians help patients and family members make decisions all the time, but the way a palliative care team helps is different, explains Goldstein. While physicians might ask patients if they want to continue with chemotherapy, members of a palliative care team work with patients to understand what is important to them at a given point in their illness. Also team members ask what their hopes and fears are, and they use the information to help patients make decisions. A palliative care team includes doctors, nurses, and other specialists such as social workers and chaplains.

Expertise in multiple issues

Often what is different about palliative care is the interdisciplinary nature of the team addressing medical, social, psychological, emotional, and spiritual issues that impact a patient's care in a comprehensive way.

"Experts who know how to talk with patients to help understand what their goals are and help ensure their treatment matches their preference," says Pantilat.

When a medical team focuses on disease management, issues that aren't addressed by this approach often get missed, he adds. Waking up in the middle of the night short of breath for someone who lives alone might have psychological implications. Adjusting medications is important, but it might not be the entire answer, says Pantilat. The patient might need someone to telephone or even someone to stay overnight.

It's important for staff to be educated on palliative care as well so the team can be set in place at the appropriate time, says Goldstein.

"The earlier we are called in, the better we can help patients cope with serious illness. The talking points of palliative care is not end-of-life care; it is care much earlier for patients to help them make complex decisions as well as support them during these really difficult medical situations," Goldstein explains.

SOURCES/RESOURCE

• **Nathan Goldstein**, MD, Associate Professor, Hertzberg Palliative Care Institute, Brookdale Department of Geriatrics and Palliative Medicine, Mount Sinai Medical Center, New York City. Telephone: (212) 241-1446. E-mail: Nathan.goldstein@mssm.edu.
• **Steven Z. Pantilat**, MD, FAAHPM, SFHM,, Professor of Clinical Medicine, Director, Palliative Care Program and Palliative Care Leadership Center Director, Palliative Care Quality Network Director, Hospice and Palliative Medicine Fellowship, Division of Hospital Medicine, University of California, San Francisco. E-mail: stevep@medicine.ucsf.edu.

• Web: www.getpalliativecare.org. Web site offers educational materials that help explain palliative care to patients, including answers to the six most frequently asked questions. Select "What is Palliative Care," "How to Get Palliative Care," or "Is Palliative Care Right for You?" The web site is sponsored by the Center to Advance Palliative Care at Mount Sinai School of Medicine in New York City. ■

Palliative care teams enhance education

Devoting time to quality-of-life issues

Physicians and nurses helping patients learn to manage disease such as heart failure often have no time to talk about patients' preferences for care, if continued interventions are consistent with their goals, and what is hampering their quality of life.

A discussion about a patient's goals and preferences can't be done in five minutes, says **Steven Z. Pantilat**, MD, FAAHPM, SFHM, professor of clinical medicine and director of the Palliative Care Program and Palliative Care Leadership Center at the University of California, San Francisco.

A palliative care team can fill this gap in education. Team members can take time to discuss options and gain an understanding of what is important to patients, what they value, and what kinds of outcomes and states of health are acceptable to them and which are not. Once this information is understood, the treatment can support their goals, he says.

"Gaps in education may be helping people understand goals of care and letting them know about the opportunity to document their goals and preferences for care," says Pantilat.

In addition, at University of California, San Francisco, a palliative care team assesses a broad range of symptoms that include emotional and psychological issues as well as physical. Patients who are not taking their medication successfully might not need instruction on the medication regimen but might need help with depression, says Pantilat.

Members of palliative care teams have special training in communication to help determine what a patient knows about their condition, what they understand, and what they want to know, says **Nathan Goldstein**, MD, associate professor at the Brookdale Department of Geriatrics and Palliative Medicine, Hertzberg Palliative Care Institute, Mount Sinai Medical Center in New York City. "We figure out where patients are in their understanding and then help them move along in terms of their understanding and their education," explains Goldstein. ■

Survival rates unaffected by end-of-life discussions

Results support initiating dialog

Discussing and documenting patients' preferences for care at the end of life does not cause them any harm, contrary to recent claims. A study[1] published in the *Journal of Hospital Medicine* found that patients who talk with their physicians about end-of-life care and have an advance directive in their medical record have similar survival rates as patients who do not have these discussions and documents.

The study included 356 patients admitted at three hospitals who had low or medium risks of dying within one year. Patients were followed from 2003 to 2009. During the study, there were no differences in survival for patients who had end-of-life discussions and those who did not; there also were no survival differences for those who had a living will in their medical record and those who did not.

"Our findings are reassuring. They support healthcare providers, who can initiate these discussions, and policymakers, who seek to reimburse these time-consuming discussions," said lead researcher **Stacy M. Fischer**, MD, assistant professor, University of Colorado School of Medicine. "Most importantly, our findings are reassuring for patients and families who desire these discussions with their healthcare providers. The term 'death panels' has sparked considerable controversy recently. It has undermined the efforts of clinicians who provide end-of-life care by scaring patients into thinking that their lives may be cut short for their families' or society's best interest." Fischer hopes the study provides data to help inform the national debate about advance directives for key stakeholders, healthcare providers, policymakers, and patients and families.

REFERENCE

1. Fischer S, Min SJ, Sauaia A, et al. "They're going to unplug grandma": Advance directive discussions and documentation do not decrease survival in patients at baseline lower risk of death. *J Hosp Med*; published online Sept. 29 2011, Doi: 10.1002/jhm.930. ■

Life expectancy estimating possible

Scores helps clinicians recommend care

A new scoring system that can more accurately predict the life expectancy of a patient with advanced cancer in terms of "days," "weeks," and "months" is described in a study[1] published in *British Medical Journal.*

This information is significant for clinicians as they evaluate appropriate care for terminally ill cancer patients. Current survival predictions based on clinicians' opinions are often unreliable, over-optimistic, and subjective, according to the authors. Researchers at St George's University of London developed a scoring system for patients with advanced cancer in different care settings that was as good or better than clinicians' best predictions.

The researchers evaluated 1,018 patients with advanced incurable cancer who no longer received treatment, and were recently referred to palliative care services across the United Kingdom. To predict patients' remaining life expectancy in "days" (0-13 days), "weeks" (14-55 days), or "months" (more than 55 days), the team developed two prognostic scores (PiPS-A and PiPS-B) by using a combination of clinical and laboratory variables and compared these with actual survival and clinicians' predictions.

They found that both scores were at least as accurate as a clinician's estimate, but PiPS-B, which required a blood test, proved to be significantly more precise than an individual doctor's or nurse's prediction.

According to the authors, this study is the first to benchmark a prognostic scoring system against current best practice, but further validation work is required before recommending the scales to be used in routine clinical practice.

REFERENCE

1. Gwilliam B, Keeley V, Todd C, et al. Development of prognosis in palliative care study (PiPS) predictor models to improve prognostication in advanced cancer: Prospective cohort study. *BMJ* 2011;343:d4920. ■

Informed consent experts advocate improvements

ANPRM plan to solve readability problems?

The ethics rule regarding biomedical and behavior research involving human subjects in the U.S., also known as the common rule, govern Institutional Review Boards (IRBs). In the proposed revision of the Common Rule, the Department of Health and Human Services (HHS) responds to years of complaints about informed consent documents: that they're too long, too complicated, and too full of boilerplate and risk management language. *(For more information on readability issues, see related story, p. 7)*.

The improvements proposed in the revision of the Common Rule address all of those points:

— mandating that certain content be included in consent forms, with more detail than is currently required and that other content be removed;

— limiting the length of certain parts of the forms;

— providing more detail about how information should be presented (what information belongs at the beginning of the form, for example, or what belongs in an appendix);

— reducing locally required content that doesn't protect subjects and primarily is intended to shield the institution;

— proposing creation of consent form templates, giving institutions a format that they can be confident will pass regulatory muster.

Those who have studied the challenges of providing appropriate consent say these proposals aren't new. **Michael Paasche-Orlow**, MD, MPH, associate professor of medicine at Boston University School of Medicine and a nationally recognized expert in health literacy, says he assisted in an initiative by the National Cancer Institute (NCI) that is taking on many of the same goals, including creating templates for consent documents. Furthermore, he says it's not even the first attempt by NCI. "I'm friends with people who were involved with the NCI informed consent effort that happened about 15 years ago," Paasche-Orlow says. "And they had some of the same recommendations back then that they did this last time. The issue is how come no one followed their recommendations?"

It's complicated

One obstacle is the sheer complexity of modern clinical trials, says **Mark Hochhauser**, PhD, a readability consultant who serves on a review board at North Memorial Medical Center in Robbinsdale, MN.

"It used to be that you would see a study that involved, say, an experimental drug vs. a placebo," Hochhauser says. "And you have a clinical trial now that has maybe three or four research parts to it. That's complicated and hard to understand even for IRB members."

He says it's hard to limit the length of documents when there are so many required elements that have to be communicated. "You've got somewhere around 20 topics that have to be covered in the consent form. You can't ignore 15 of them and just do five. You have to do all of them."

Hochhauser says that removing some of those elements to focus on what patients truly need to know would be an improvement.

Adding to the murk of an informed consent document is that many groups involved in its development often have goals in addition to informing subjects, Paasche-Orlow says. "The organizational goals have to do with risk management," he says. "Until there's a much stronger hand from the regulators, the risk managers for the organizations are going to fear changing what they're currently doing. Because what they're currently doing is considered acceptable, appropriate, and defendable."

Paasche-Orlow says previous efforts at simplifying informed consent had input from regulators, but the agencies were reluctant to give templates their official "approval." He says he's happy that the advanced notice of proposed rulemaking (ANPRM) provides for the creation of templates. However, he and Hochhauser say templates won't solve readability problems by themselves. Hochhauser notes that a template can only provide a general outline of the information in a specific study.

"The problem is that the template will start off with some sample language, and it's to be filled in

by the researcher," he says. "That's where it all falls apart. It's the to-be-filled-in part that winds up being written in incomprehensible legal and regulatory language."

Paasche-Orlow notes that even when forms actually are written plainly, it might be difficult to get certain concepts across to subjects. As an example, he points to language he was testing to be included in an informed consent toolkit developed by the Agency for Healthcare Research and Quality. He was trying to find the simplest way to tell subjects they would not be compensated for injuries they might suffer in a study.

"It turned out that actually it was very common for people to assume that we were saying the opposite," Paasche-Orlow says. "Because, in fact, the assumption is, 'Of course, if I'm injured in your study, you would pay for that. How could you not pay for that?'" ■

Flexibility, evaluation of informed consent docs

In the proposed revision of the Common Rule, which is the ethics rule regarding biomedical and behavior research involving human subjects in the U.S. and governs Institutional Review Boards (IRBs), the Department of Health and Human Services (HHS) responds to the many complaints about informed consent documents. There are steps HHS could take that could improve the informed consent process, according to **Mark Hochhauser**, PhD, a readability consultant who serves on a review board at North Memorial Medical Center in Robbinsdale, MN, and **Michael Paasche-Orlow**, MD, MPH, associate professor of medicine at Boston University School of Medicine and a nationally recognized expert in health literacy.

Paasche-Orlow says, "The form itself is just a piece of the puzzle. There are a lot of things that even with best language in your documents will need to be supported by a process." Their suggestions:

• Use real forms.

Instead of templates, Hochhauser would like to see HHS take existing drug and device trial consent forms and simplify them, to give researchers a better jumping-off point for their own forms.

"I don't think a template is going to do it," he says. "People need to see real consent forms from real projects. Change any of the proprietary language, and show it in 'before' and 'after' versions: the before version, which is long and complicated and hard to understand, and the simplified version. Paasche-Orlow also suggests that researchers feel free to take the simplified form and adapt to their needs.

• Allow for flexibility.

Giving developers of consent forms flexibility to get their information across in different ways might not necessarily shorten documents, but can make them clearer. For example, Hochhauser argues for a table of contents in consent documents. Since participants rarely read the whole form, he says, it makes sense to direct them easily to the most important parts.

Paasche-Orlow promotes the use of tables and figures and images to help explain difficult concepts. But he's found opposition to adding such tools, because incorporating them would require further review board approvals. "When you're dealing with complicated concepts like percents and rates, which are broadly misunderstood, the adult education literature shows that there are ways to improve how we talk to people about these things," Paasche-Orlow says. "Really, the whole system has to be much more flexible and amenable to the use of various kinds of teaching aids."

• Evaluate understanding.

The advanced notice of proposed rulemaking (ANPRM) asks whether, in certain types of studies, investigators should assess how well potential subjects comprehend the information before allowing them to enroll.

Paasche-Orlow says this would be an appropriate requirement, particularly in concert with a shorter form that focuses only on the most important information.

"This is not like some sort of memory test where you say, 'How long is the third study visit?' That's not the crucial component here," he says. "The crucial components are things like understanding that this is voluntary, that this will not impact their relationship with their doctor." Paasche-Orlow says that these are the critical things. Having a shorter template can substantively help the process, by focusing on the ethically relevant ideas. And that would put us in a good position to say, "And yeah, confirm comprehension of those things." ■

Human study examines medical marijuana

In the first human study[1] of its kind, research from the University of California, San Francisco (UCSF) suggests that patients with chronic pain might experi-

ence greater relief if their doctors add cannabinoids — the main ingredient in cannabis or medical marijuana — to an opiates-only treatment. The findings, from a small-scale study, also suggest that a combined therapy could result in reduced opiate dosages.

More than 76 million Americans suffer from chronic pain, which is more people than diabetes, heart disease, and cancer combined, according to the National Centers for Health Statistics.

"Pain is a big problem in America, and chronic pain is a reason many people utilize the health-care system," said the paper's lead author, **Donald Abrams**, MD, professor of clinical medicine at UCSF and chief of the Hematology-Oncology Division at San Francisco General Hospital and Trauma Center (SFGH). "And chronic pain is, unfortunately, one of the problems we're least capable of managing effectively."

In a paper published in *Clinical Pharmacology & Therapeutics*, researchers examined the interaction between cannabinoids and opiates in this one-of-a-kind human study. They found the combination of the two components reduced pain more than using opiates alone, similar to results previously found in animal studies.

Researchers studied chronic pain patients who were being treated with long-acting morphine or long-acting oxycodone. Their treatment was supplemented with controlled amounts of cannabinoids, inhaled through a vaporizer. The original focus was on whether the opiates' effectiveness increased, not on whether the cannabinoids helped reduce pain.

"The goal of the study really was to determine if inhalation of cannabis changed the level of the opiates in the bloodstream," Abrams said. "The way drugs interact, adding cannabis to the chronic dose of opiates, could be expected either to increase the plasma level of the opiates, or to decrease the plasma level of the opiates, or to have no effect. And while we were doing that, we also asked the patients what happened to their pain."

Abrams and his colleagues studied 21 chronic pain patients in the inpatient Clinical & Transitional Science Institute's Clinical Research Center at SFGH: 10 on sustained-release morphine and 11 on oxycodone. After obtaining opiate levels from patients at the start of the study, researchers exposed them to vaporized cannabis for four consecutive days. On the fifth day, they looked again at the level of opiate in the bloodstream. Because the level of morphine was slightly lower in the patients, and the level of oxycodone was virtually unchanged, "one would expect they would have less relief of pain, and what we found that was interesting was that instead of having less pain relief, patients had more pain relief," Abrams said. "So that was a little surprising." The morphine group came in with a pain score of about 35, and on the fifth day, it decreased to 24, which is a 33% reduction. The oxycodone group came in with an average pain score of about 44, and it reduced to 34, which is a drop of 20%. Overall, patients showed a significant decrease in their pain. "This preliminary study seems to imply that people may be able to get away perhaps taking lower doses of the opiates for longer periods of time if taken in conjunction with cannabis," Abrams said.

As a cancer doctor, Abrams was motivated to find safe and effective treatments for chronic pain. Patients in the cannabis-opiates study experienced no major side effects such as nausea, vomiting, or loss of appetite. "What we need to do now is look at pain as the primary endpoint of a larger trial," he said. "Particularly I would be interested in looking at the effect of different strains of cannabis."

For example, Delta 9 THC is the main psychoactive component of cannabis, but cannabis contains about 70 other similar compounds with different effects. One of those is cannabidiol, or CBD. It appears to be very effective against pain and inflammation without creating the "high" created by THC.

"I think it would be interesting to do a larger study comparing high THC versus high CBD cannabis strains in association with opiates in patients with chronic pain, and perhaps even having a placebo as a control," Abrams said. "That would be the next step."

REFERENCE

1. Abrams D, Couey P, Shade S, et al. Cannabinoid–opioid interaction in chronic pain. *Clin Pharm Therapeutics* 2011; 90:844-851. ■

Hospice caregivers need care interventions

Hospice family caregivers are "second order patients" themselves and require their own unique care needs, according to a study[1] led by the University of Kentucky researcher **Elaine Wittenberg-Lyles**, PhD.

The study, published in *Qualitative Health Research*, assessed the individual stressors that caregivers experience. The researchers recorded discussions between hospice caregivers and the intervention team. The caregivers were asked to identify and describe the

most pressing problems or concerns they faced.

The study enrolled hospice caregivers who were 18 years of age or older and who did not have functional hearing loss, had mild to no cognitive impairment, and had at least a sixth grade education. In addition, all participants had to have access to a standard phone line. In total, the team collected discussions from 81 participants.

Using a theoretical framework called Assessing Caregivers for Team interventions (ACT), the researchers coded participants' responses in one of three categories: primary stressors, which included talk that related to the performance of caregiving tasks; secondary stressors, talk about the personal impact of performing caregiving tasks; and intrapsychic stressors, talk about their thoughts, feelings, and awareness of the caregiving role.

The ACT framework has been proposed as a way to understand caregiver strain and develop customized caregiver interventions to positively affect the caregiving experience and improve outcomes. The goal of the study was to describe the variances among stressors, while targeting specific concerns for caregivers.

The study further proved that caregivers are like patients themselves and should be routinely assessed for these stressors so that interventionists may help them with personalized resources and coping strategies, says Wittenberg-Lyles, who holds a joint appointment in the United Kingdom (UK) College of Communications and the UK Markey Cancer Center. "It doesn't matter how well educated you are," said Wittenberg-Lyles. "When someone you love is dying and you are in a position to care for them at home, your home turns into a hospital room, and key decisions need to be made hourly. Clinicians should assume that anyone going through the stress and chaos of caring for a terminally ill family member has low health literacy and high needs for education and support."

Hospice is provided to patients who have an estimated life expectancy of six months or less. About 69% of hospice patients in the United States receive care at home from a family caregiver.

The study showed that nearly one-third of the hospice patients had a cancer diagnosis, and 21% had a primary or secondary diagnosis of Alzheimer's disease or dementia. Nearly 43% of caregivers were adult children of the patient, and roughly one-third were spouses/partners. In addition, an overwhelming majority of caregivers (79%) were women.

REFERENCE

1. Wittenberg-Lyles E., Demiris G, Parker D. Stress variances among informal hospice caregivers. *Qualitative Health Research* 2011; in press. ■

Recycled pacemakers safe and effective

Many heart patients in India are too poor to afford pacemakers. However, a study [1] has found that removing pacemakers from deceased Americans, resterilizing the devices, and implanting them in Indian patients "is very safe and effective."

Gaurav Kulkarni, PhD, of Loyola University Medical Center, is a co-author of the study, published in the *American Journal of Cardiology*. Kulkarni helped conduct the research before coming to Loyola while he was a medical student in India.

Fifty-three poor patients in Mumbai received pacemakers that had been donated by the families of deceased Americans. Following operations to reimplant the devices, all Indian patients were alive and doing well, researchers reported.

The Indian patients had severe heart rhythm disorders called complete heart block and sick sinus syndrome. Typically, the slightest physical exertion would leave them gasping for breath and exhausted. Without pacemakers, they likely would have died within weeks or months. But in India, a pacemaker costs $2,200 to $6,600, which is well beyond the means of many patients.

The pacemaker donations began as a philanthropic project. Physicians later decided to make a formal study of the safety and effectiveness of the donated devices. At every step of the study, patients gave informed consent. After receiving the reused pacemakers, they were followed for an average of nearly two years. There were no infections or other significant complications and no device failures. All but two patients reported marked improvement in their symptoms.

Of four patients who were previously employed, all were able to return to their manual jobs. Twenty-seven women said their symptoms had improved enough so they could resume household chores. "Implantation of donated permanent pacemakers can not only save lives, but also improve quality of life of needy poor patients," researchers wrote.

Kulkarni added: "Without pacemakers, these patients would pretty much be forced to remain on confined rest, due to cardiac fatigue."

The Food and Drug Administration (FDA) prohibits reusing pacemakers in the United States. However, there is no prohibition against donating and reusing

pacemakers in other countries.

The authors conclude that reusing pacemakers could "alleviate the burden of symptomatic bradyarrhythmia (abnormally slow heart rate) in impoverished nations around the world."

REFERENCE

1. Bharat K, Patel S, Kulkarni G. Reuse of explanted permanent pacemakers donated by funeral homes. *Amer J Cardiology* 2011; published online Oct. 14, 2011. http://www.ajconline.org/article/S0002-9149(11)02752-4/abstract. ■

Recruiting minorities in clinical research

Research ethicists and others have long described the value of recruiting more minorities in clinical research (CR) trials, but the question is whether review boards have a role to play in advancing this goal.

Is it enough to ask investigators to work toward greater inclusion, or should boards take part in clinical research staff education and educating the greater community about the research enterprise and minority participation?

"We do believe there is a role for the [review boards] to simply monitor the inclusion of the women and minority component of the National Institutes of Health (NIH) guidelines," says **Stephen Thomas**, PhD, professor and founding director of the Maryland Center for Health Equity, and a professor of health services administration at the school of public health, University of Maryland in College Park, MD.

Review boards could ask researchers to outline their efforts to recruit minorities when they submit protocols, but it might be better to address recruitment inclusiveness from an institutional perspective, some experts say.

"I personally have a bias against using the regulatory arm — i.e., the IRB [Institutional Review Board] — in terms of telling investigators what to do," he adds. "The IRB has a role to play, but a greater role is needed from the institution."

Review boards can help a research institution with developing a more inclusive recruitment strategy by using their own data to assess the big picture. For example, the review boards can see what type of recruitment has taken place at hundreds or thousands of clinical trials, says **Sandra Crouse Quinn**, PhD, professor of family science and associate dean for public health initiatives in the School of Public Health at the University of Maryland.

"Review boards can have a sense of the big picture," Quinn adds. "Potentially, if they had the resources, they could serve a role at the institution of looking at how successful investigators are in recruiting diverse populations."

Review boards also are in a good position to note best practices and success stories in recruitment. "A good IRB staff could learn a lot from seeing what's submitted to them — what's successful and what's not," Quinn says.

At the University of Maryland, the board director joins other experts in working on a curriculum for educating researchers and minority communities about research participation, says **Mary A. Garza**, PhD, MPh, an assistant professor in the Department of Behavioral and Community Health at the University of Maryland School of Public Health and associate director for the Maryland Center for Health Equity. Also, review boards could expand to include more community members and make an effort to recruit members of minority communities, Garza suggests. "Review boards play a very strategic role, and this is their opportunity to make sure they can help the population," she adds.

For research institutions, the key to encouraging more minority participation in CR might be to separate regulatory authority from educational influence. The board could be helpful in the realm of educating the research community, but regulatory actions might be left to the government. "To add a regulatory function might be too much," Quinn says. "But they may have opportunities to spark dialogue because they have the big picture perspective."

Boards could hold brown bag lunches with investigators to highlight those who are successful at recruiting minorities and to encourage information sharing, she notes.

There is some benefit in putting regulatory teeth to any guidelines regarding minority inclusion in trials. For instance, the National Institute of Health (NIH) exercises some of that clout by giving research sites a lower score if they have fewer women and minorities in their trials, Thomas says. "We have been struggling in trying to determine where would be the best home for that responsibility [for minority inclusion]," he says. "So we think that current principal investigators and their research staff need formal training in recruitment and retention of racial and ethnic minorities in research."

Online bubble forms are insufficient. The training should be about more than tools and techniques, he

adds.

"It should truly be transformative training that also impacts attitudes and beliefs," Thomas says. "We don't want this area to carry all of the baggage of having the research board ask researchers to do one more thing, so we're trying to find an institutional, administrative home for who is responsible for ensuring researchers and research staff get appropriate training in minority recruitment and retention." ■

HHS secretary vetoes morning-after pill

The Department of Health and Human Services (HHS) has red lighted the morning-after pill for teens under 17, without a prescription.

Before the ruling, the Food and Drug Administration (FDA) was preparing to raise the age limit of individuals seeking emergency contraception, and allow it to be sold over the counter to anyone. But HHS secretary Kathleen Sebelius overruled the agency and said she was concerned that very young girls couldn't properly understand how to use it without guidance from an adult.

The Plan B One-Step pill can prevent pregnancy if taken soon after unprotected sex. Presently, only adults 17 and older can buy the "morning after" pill, if they show the pharmacist proof of age. ■

Abortion battle in full swing in D.C.

Pro-life advocate and Arizona representative Trent Franks (R-AZ) is chairing a House hearing to support the Prenatal NonDiscrimination Act (PreNDA). The measure would ban abortions performed on the basis of gender or race.

"It would simply say that you cannot discriminate against the unborn by subjecting them to an abortion based on their race or sex," Franks says in media reports.

Franks says that according to a finding by the Guttmacher Institute, the abortion rate for black women is almost five times that for white women. Franks also believes that sex-selection abortions are on the rise in the United States.

PreNDA contains civil penalties and jail time for those who violate the ban, but not the women who seek or obtain abortions. Franks has said publicly that he believes women who find themselves with an unintended pregnancy are victims who need help in the midst of a crisis, not punishment. However, physicians who perform abortions solely for sex- or race-selection purposes could face fines and penalties of up to five years in prison.

The bill has about 60 co-sponsors, but opponents don't believe the bill has a chance of being passed this term. ■

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.

COMING IN FUTURE MONTHS

■ Improve handling of medical errors from ethical framework

■ Ethical issues of palliative sedation

■ New recommendations for best approach to organ donation

■ Surrogates and reciprocal responsibilities

CME QUESTIONS

1. What factor did the Ninth U.S. Circuit Court of Appeals consider when it ruled that makes donating bone marrow a process nearly identical to giving blood plasma?
   A. The court differentiated between the classical technique of recovering bone marrow by aspirating it through a long needle from the hip and recovering stem cells by pheresis, which it likened to obtaining blood by donation.
   B. It stated that peripheral blood stem cells were a subpart of blood, and not of bone marrow, and hence not covered by National Organ Transplant Act (NOTA).
   C. Both A&B
   D. None of the above

2. True or False: According to Steven Z. Pantilat, MD, FAAHPM, SFHM, professor of clinical medicine and director of the Palliative Care Program and Palliative Care Leadership Center at the University of California, San Francisco, palliative care can be defined as care that is exclusively focused on improving quality of life for people with a serious illness such as heart failure, cancer, dementia, Alzheimer's disease, chronic lung disease, and chronic liver disease.
   A. True
   B. False

3. What is "presumed consent?"
   A. Notification, education, awareness, a central registry, program management, and legal protection for providers and oversight.
   B. An organ donor policy that would mandate that all American citizens are organ donors; however each citizen retains the right of free choice. They can opt out of the system at any time.
   C. When faced with a decision at the time of a tragic event, not consenting to donation of their loved one's organs or tissue because they don't know their loved one's choice.
   D. None of the above.

4. According to a study that appears in the Journal of Hospital Medicine, patients who talk to their physicians about end of life, live _____ as those who do not.
   A. Somewhat shorter than
   B. Much shorter than
   C. About the same as
   D. Much longer than