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AHC Media

# Kaiser Permanente changes landscape for hospital ethics

While most people know Kaiser Permanente is a managed care organization, what many might not know is that it encompasses eight states, and the southern California region of Kaiser instituted a distinctive bioethics program that is unlike any other.

"Our program is distinctive because we have a dedicated clinical staff ethicist at each of our medical centers, with a very well-defined structure that provides support to the individual bioethicist. This enables the bioethicists to leverage their expertise in facilitating bioethics consultations and serving as co-chairs of their medical center bioethics committee," says **Paula Goodman-Crews**, MSW, LCSW, co-director of the Kaiser Permanente Southern California Bioethics Program.

At the medical center committee level, positioning within the hospital structure enables the medical center's institutional bioethics committee to develop working relationships with many stakeholder groups such as quality management, risk, nursing and physician leadership, and compliance. "Not only do we have leadership from each of these areas participating in the bioethics committee meetings, but our bioethicists are 'at the table' and contribute to several multidisciplinary committees involving several departments and disciplines," says Goodman-Crews.

Southern California Regional Bioethics Committee provides policy, education, and consultation based on collaboration at multiple hospital centers. It is not government-financed and not academic-based. This bioethics program has paid full-time staff. Decisions are evaluated by multiple metrics and are overseen by multiple individuals and all preconceived outcomes are documented.

**Malcolm Shaner**, MD, co-director of the Kaiser Permanente Southern

## EXECUTIVE SUMMARY

The southern California region of Kaiser Permanente has a distinctive bioethics program named Southern California Regional Bioethics Committee that provides policy, education, and consultation based on collaboration at multiple hospitals. The program has paid full-time ethic staff and is not government-financed or academic-based. All decisions are evaluated by multiple metrics.

- The entire ethical process at multiple hospitals is overseen by multiple individuals.
- All preconceived outcomes are thoroughly documented in chart notes.

California Bioethics Program, Los Angeles, says, "The program began in 2008 with the hiring of our clinical ethicists and was given official 'birth' in June 2010 with our first report to the Kaiser Permanente Southern California Quality Committee."

The special program for bioethics was prompted from a leadership perspective in the Southern California region, says **Patti Harvey**, RN, MPH, CPHQ, vice president of quality and risk management, Kaiser Foundation Hospitals and Health Plan Southern California, Pasadena. "There was keen interest in developing a clinical/medical bioethics program that would support our care providers and our patients in their decision-making processes," Harvey says. The value of clinical ethicist support is important in creating an integrated patient care experience, she adds. "The ability to have a clinical ethicist at the bedside as a part of the care delivery team provides an environment conducive to thoughtful discussions that can lead to more agreement and understanding about the patient's care," Harvey says.

Shaner says, "Since about 1986, we built a 'moral community' holding quarterly meetings of the chairs of the Committees on Bioethics across the Southern California service areas, which now number 13. We exchanged visions of a program in bioethics and considered carefully models for such a program." In 2008, leaders of the Kaiser Foundation Hospital and Health Plan and the Southern California Permanente Medical Group provided them the resources that would allow the carefully thought-out plans to move forward, according to Shaner.

Goodman-Crews adds, "We leveraged an established regional ethics committee and, with our internal experts, we began to design, build, and implement a clinical/medical ethics program within each of our medical centers. From the early years, our best practices propelled us to expand the program. For example, the medical bioethics director position that was developed in San Diego became a model for replication across the region." Within the program, they grew the number of clinical ethicists incrementally over three years according to Goodman-Crews.

One special aspect of this regional bioethics program is the variety of disciplines represented in the clinical ethicist group itself. **Vincent Guss**, DMin, BCC, medical ethics director, Kaiser Permanente West Los Angeles Medical Center, Los Angeles, says, "Although each of us has had extensive clinical training and experience in bioethics as a discipline, most of us began in another healthcare discipline including medicine, nursing, social work, philosophy, law, laboratory science, theology, and pastoral care."

## A needed program in a changing setting

The evolving medical landscape provides a field where the diverse values of a pluralistic society play out, Shaner says.

"These familiar themes are expressed in a myriad of circumstances but can be sketched along the lines of different answers to deep questions and incomplete agreement over the best means to promote

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the good of an individual patient and optimal ways to improve the health of our society," he adds. "Our Kaiser Permanente Medical Care Program in Southern California feels that in keeping with our integrated approach to medicine, we require an approach to these often-emotional clinical situations based on an examination of deep, foundational questions. We see a need to adopt a considered approach that results from ongoing, responsible reflection that respects the needs of our patients, our medical professionals, and our society."

The program works a great deal differently than other medical centers. Shaner says, "Our program is piloted in the Southern California Region of Kaiser Permanente. Kaiser Permanente is unique because it is both a health plan and a provider." Specifically, the framework includes the capitated, not-for-profit Kaiser Foundation Hospitals and Health Plan and the medical partnership, Southern California Permanente Medical Group, serving some 3.5 million members. "This structure distinguishes us from most medical groups in private practice. In addition, while we have educational programs and we are affiliated with teaching programs, we are not an academic institution. We are not funded by the United States government, as are the Veterans Administration Medical Centers.

"We have a medical program integrated tightly among the health plan, hospitals, and medical group," says Shaner. Decreased fragmentation might be one key to achieving the goals of the pilot program in bioethics within the Southern California Region, he adds.

### Looking ahead to the future

The ethicists involved with Southern California Regional Bioethics Committee are prepared to face the considerable challenges in the future including the continuing and changing metrics, and work toward continuous improvement for clinical ethicists, medical centers, and the program as a whole. The committee develops standards of ethical practice across the region by developing policy, identifying ethics quality improvement opportunities, self-education, and professional education. The results are shared across the region.

Harvey says, "From a leadership perspective, the value of our clinical ethicist program is just beginning to take off. With our increased membership and the growing importance of bringing our member's voices to the forefront, our bioethicists help us shape our decisions, programs, and strategies to ensure that we are responsive and supportive of our caregivers and our members."

Guss adds, "There is a strong sense of solidarity, mutual accountability, respect, and collegiality among the ethicists who meet each month to address regional bioethics issues we all face. There is mutual support and guidance for each other when addressing complex cases and situations in each of the ethicist's own medical center."

### SOURCES/ RESOURCE

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Bioethicists from around the nation will learn more about Kaiser Permanente Southern California Regional Bioethics Committee, how it developed, its current mission, and its vision for the future on Oct. 15, 2011, when the ethicists from this regional program will provide a presentation at the annual conference of the American Society of Bioethics and Humanities (ASBH) at the Hyatt Regency Minneapolis (MN). For more information, see http://www.asbh.org. ■

# Disaster preparedness for mentally impaired

Planning for disaster response generally has overlooked the special needs of people who suffer from pre-existing and serious mental conditions, say bioethicists at Johns Hopkins University in Baltimore, MD. Survivors already diagnosed with schizophrenia, dementia, addictions, and bipolar disorder are vulnerable long before a disaster strikes, they point out.

More attention should be devoted to triaging and managing those already identified as having mental disorders, faculty from the Johns Hopkins Berman Institute of Bioethics, Baltimore, MD, say in a commentary appearing in a recent issue of the journal *Biosecurity and Bioterrorism*.[1] This group must be given just as much consideration during the planning stage as is given those who will have

physical injuries and more obvious anxiety-related reactions, such as post-traumatic stress disorder (PTSD).

"Disasters limit the availability of resources, and these groups are especially vulnerable because they cannot advocate for themselves," says **Peter Rabins**, MD, MPH, Richman family professor for Alzheimer's and related diseases at the Johns Hopkins University School of Medicine, Baltimore, MD. "But little attention has been given to the ethical challenges that arise when resources are limited, to the importance of identifying these ethical issues ahead of time, and for establishing mechanisms to address these moral dilemmas."

In the article, Rabins and **Nancy Kass**, ScD, the Berman Institute's deputy director for public health, say that many of the mentally ill are dependent on caretakers and aren't fully capable of making sound decisions on their own. Emergency planners are ethically obligated to ensure that immediate and adequate mental health services are provided alongside more traditional triage, the authors say. Rabins says, "Disaster-response managers and those on the front line are well aware that survivors may succumb to PTSD and other mental disorders." "But sudden devastation also puts people with both lifelong and acquired intellectual disabilities in grave danger as well."

Whether a disaster is natural, as in an earthquake, or is caused by man, as in war, the ethical obligation to treat those with mental disabilities in the aftermath is just as important as aiding those with flesh wounds, Rabins says. One study the authors cite found that 22% of Hurricane Katrina survivors who had pre-existing mental disorders faced limited or terminated treatment after the disaster.

Beyond patients with dementia and others who are mentally impaired, the authors say that this vulnerable group includes those who suffer from chronic pain and might be dependent on opiates, as well as substance abusers who receive treatment in the form of powerful sedatives classified as benzodiazepines. Withdrawal can be life-threatening, the authors note.

The authors acknowledge that drug and alcohol addicts often are seen as unworthy of focused attention during a state of emergency, with scarce resources, because their condition is widely perceived as "self-inflicted." But distinguishing between conditions that individuals have or don't have control over "is neither practical nor ethically justifiable, and in emergencies becomes wholly impractical," the authors assert.

### Ethical challenges

The authors also recommend that planners focus on ethical challenges likely to arise when assisting the mentally disabled during and after a disaster. These challenges might be partially addressed by adopting a "crisis standard of care" consistent with guidelines from the Institute of Medicine, they say.

Special attention should be given to assisted-living and long-term care facilities that house many residents with significant cognitive impairment, such as dementia. If these people are forced to evacuate, they might not fully comprehend the crisis and might be at risk for extreme emotional distress. Hence, disaster-preparedness training for first-responders should include information about how to interact with such individuals in a way that respects their dignity, the authors say.

More broadly, criteria for priority setting and the allocation of scarce resources can be based on objective factors, such as the likelihood of response to intervention, the prevention of chronic health problems, and the impact on public safety, the authors explain.

REFERENCE

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# Community engagement-mental health research

Applying community engagement to mental health research can help researchers design studies that incorporate the priorities of people with mental illness and arrive at the best strategies for working with them. However, review boards can hinder this type of research by seeing the population as too vulnerable to fully participate and by requiring "paternalizing" protections not just for participants, but for peer evaluators who assist in the study, says a researcher who has specialized in community-engaged mental health research for more than 20 years.

"[Review boards] may over-reach on protection of vulnerable populations that want to participate in

research," says **Jean Campbell**, PhD, a research associate professor with the Missouri Institute of Mental Health in St. Louis. "They assume [peer evaluators] are part of the patient population, as opposed to the research population."

The push for community engagement in research in general has intensified in recent years, out of a sense of respect to the communities being studied, but also because it can help strengthen studies and aid in recruitment, says **James DuBois**, PhD, DSc, director of the Center for Research Ethics and Integrity at the Albert Gnaegi Center for Healthcare Ethics at St. Louis University.[1]

DuBois, who specializes in mental health research ethics, says that as he speaks with mental health consumers, he is struck by how their priorities about research differ from those of investigators. For example, he says research tends to focus on efficacy of drugs, with less attention given to side effects that can be so disturbing to patients that they discontinue taking the medications.

In the area of mental health research ethics, DuBois says, the vast majority of studies funded by the National Institutes of Health (NIH) focus on decision-making capacity. "I think it's good research, I think it's an important topic," he says. "Studies clearly show that you can have a diagnosis of bipolar disorder or schizophrenia and frequently retain decision-making capacity. So in one sense, you could say it's de-stigmatizing. But I know some mental health consumers who say that the very fact that this is the topic they keep studying is stigmatizing, because it reinforces the idea that they don't have decisional capacity."

### Treating evaluators as vulnerable

DuBois says that while review boards are most concerned with decisional capacity and undue influence, mental health consumers tend focus more on a study's benefits, whether payment for participation fairly compensates subjects, and whether subjects face the possibility of being randomized to placebo or being asked to undergo a washout period.

Because of these differences, it's important to include people with mental illness at the earliest stages of research projects, DuBois says. But building in this type of involvement can raise challenges that don't come into play when dealing with other communities. Because of concerns about confidentiality, it might be as difficult to recruit mental health consumers to join an advisory board or to act as a peer evaluator as it is to recruit subjects.

Campbell says she sometimes must deal with gatekeepers just to put up posters in a community mental health center looking for workers. "I'd have to go through case managers who would try to evaluate whether people were well enough to do this work." And review boards might put extra restrictions on how they can participate on the research team. "There is some assumption that the peer evaluators aren't going to maintain confidentiality as well, even if we show them the training that they're given," Campbell says. Review boards worry that participating might "endanger their mental health — the peer evaluators' mental health," she says. "These things aren't true, but they are the type of things that a [review board] would question."

As one example, Campbell says, a research project that wants to post pictures of its staff, including peer evaluators, on a web site might prompt concerns that the confidentiality of the peer evaluators is being breached, even if the evaluators give permission for the use of the photos. "[The review board is] concerned that you're violating their confidentiality as a patient, which doesn't make sense," she says.

REFERENCE

1. DuBois JM, Bailey-Burch B, Bustillos D, et al. Ethical issues in mental health research: The case for community engagement. *Curr Opin Psychiatry* 2011; 24:208-214. ■

# Organ trafficking – truth or urban myth?

All over the world, illegal organ trafficking is being reported. Most people have probably heard the urban myths of many out-of-country vacationers who wake up in a bathtub full of ice and their kidneys removed.

Whether any of these morose incidents have ever been confirmed is not clear. What has been confirmed are the incidents in which individuals are being accused of paying for organs that they received from third world countries. China, Pakistan, Sri Lanka, Egypt, India, and the Philippines have all been identified as countries where there is a trade in living organs.

There are a few theories that can be investigated as to why the practice of medical tourism is suddenly so prevalent. "For recipient hopefuls, it is surely the high demand and the scarcity of available healthy organs," says **David E. Taylor**, BCCC, pastoral care coordinator, co-chair Bioethics Committee, Texas Health Presbyterian – Wilson N.

## EXECUTIVE SUMMARY

Third world countries are a breeding ground for individuals paying for illegal organs. There are a few theories that can be investigated as to why the practice of medical tourism is suddenly so prevalent.

- China, Pakistan, Sri Lanka, Egypt, India, and the Philippines have been identified as countries where there is a trade in living organs.
- Organ trafficking is obviously illegal, but there are other negatives.
- This issue came before the ethics committee in 2009 at Mount Sinai Hospital in New York City.

Jones Medical Center (WNJ), Sherman, TX. "When you couple that with the disposable wealth of so many in the United States, we have the perfect conditions to produce a thriving black market."

Medical tourism easily can be blamed on high demand of organs, lack of availability of those organs, as well as affluence of society, according to **Emmit Essin**, MD, chairman of medical staff credentials committee, physician advisor for case management department, co-chair of the Bioethics Committee, Texas Health Presbyterian – Wilson N. Jones Medical Center (WNJ), Sherman.

Besides obviously being illegal, there are other major negatives and ethical issues that arise when it comes to organ trafficking. "Immediately I would think of several areas of exploitation of the donors who too often are the very poorest of their societies," says Taylor. "The average price paid for a kidney is about $1,030, of which the market price is $100K and up."

Essin adds that one of the biggest concerns is the danger of inadequate contrast of match.

According to Taylor, ethics committees have the responsibility of educating the physicians and staff concerning the practice of organ trafficking. Ethics committees also have a responsibility to "be a touchstone to maintain high ethical standards in the matter of illegal donor practices," says Taylor.

Under 1984 federal law, it is illegal for anyone to knowingly buy or sell organs for transplant. The Organ Donation and Recovery Improvement Act was signed by former President George W. Bush. It states that while it is illegal to sell or pay for organs, the act authorizes the federal government to reimburse living donors for expenses and to offer project grants aimed at increasing donations and improving organ preservation and compatibility.

This issue came before the ethics committee in 2009 at Mount Sinai Hospital, New York City, when it was discovered that Levy Izhak Rosenbaum of Brooklyn, NY, was found guilty of trafficking human organs, after a sting by an undercover FBI agent. Currently in the news is an American diplomat that is investigating whether Kosovo's prime minister, Hashim Thaci,was involved in trafficking organs from murdered Serb prisoners. In a Council of Europe report, a Swiss member of the European Parliament alleged that the Kosovo Liberation Army ran detention camps where civilian prisoners were killed and their organs sold on the black market.

WNJ Medical Center participates in organ transplantation with Southwest Transplant Alliance of Dallas. "Their standards of identification of eligible donors and our policies in determining 'brain death' and more recently 'DCD' [donation after cardiac death] would well identify any illegal activity," says Taylor.

### SOURCES

For more information contact:


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- **David E. Taylor**, BCCC, Pastoral Care Coordinator, Co-Chair Bioethics Committee, Texas Health Presbyterian – Wilson N. Jones Medical Center. E-mail: dtaylor@WNJ.org. ■


# Muslim beliefs shape healthcare attitudes

The perceived role of God in illness and recovery is a primary influence upon the healthcare beliefs and behaviors of American Muslims, a recent study has discovered. Outreach and education efforts by the healthcare community can help address Muslim concerns and improve healthcare quality in this rapidly growing population, the report recommends.

The traditional Ramadan fasting is but one of many facets of the Islamic faith that might influence a patient's health behaviors. But few studies have comprehensively examined how religious beliefs and cultural attitudes across the different sub-communities within the American Muslim community shape a Muslim patient's experience.

"The idea was to talk about the healthcare values of American Muslim patients and the challenges they face inside the healthcare system," said **Aasim Padela**, MD, MS, assistant professor of medicine and director of the Initiative on Islam and Medicine at the University of Chicago. "The findings can guide us as we move forward on accommodating these patients

and others."

For the report, "Meeting the Healthcare Needs of American Muslims," researchers interviewed people who share Islamic faith from a variety of ethnic backgrounds to gauge how their faith influences behaviors and the cultural obstacles they face within the healthcare environment.

Muslims are one of the fastest-growing minorities in the United States, with an estimated 7 million Americans identifying as Muslim and more than 2,000 active mosques in the country according to the Council on American-Islamic Relations. Muslims also are the most diverse religious group in the United States, with contingents of Arab origin, of South Asian (predominantly Indian and Pakistani) origin, and African-Americans.

To assess the common healthcare values of this diverse religious community, Padela and colleagues conducted several focus groups in southeastern Michigan, home to one of the largest Muslim-American communities in the United States. More than 100 men and women participated in 13 focus groups organized through mosques chosen to represent each of the community's ethnic backgrounds. "We looked at American Muslims as a conglomerate and asked what was common," Padela said. "We wanted to talk to each of these three large groups, which we know comprise the majority of American Muslims, and look at what's similar in terms of healthcare challenges and beliefs. What we found as similar is something we can attribute to their faith."

One significant area of overlap was in the assignment of responsibility to God for health, disease, and healing. Illnesses ranging from influenza to cancer are attributed by many Muslim-Americans to the influence of God, with some describing illness as "a disease of fate." The authors wrote, "Most participants perceived illness through a religious lens as predestined, a trial from God by which one's sins are removed, an opportunity for spiritual reward, a reminder to improve one's health, and sometimes a sign of personal failure to follow Islam's tenets."

These views were accompanied by a holistic view of healing involving a combination of spiritual and medical agents. The healthcare role of imams, the spiritual leaders of the Muslim community, frequently was discussed. "God also says to take care of your body, and that means you have to go to people in this world," Padela said. "Doctors are a part of that, but only a part. Imams play a big role in healing, in the sense that they help you understand disease and illness."

Though imams are often consulted by patients for advice during illness, Muslim chaplains are a rarity in the American healthcare system. Improving communication between hospitals and community imams would help Muslim patients address spiritual concerns during times of serious illness and educate imams on how to counsel their patients on medical issues, Padela said. Other recommendations in the report for healthcare institutions included cultural sensitivity training for staff, providing halal food and prayer space for Muslim inpatients, and building partnerships with mosques to create health awareness campaigns targeting the community.

"In this community in Michigan, Muslims aren't a new group, they've been there for a long time," Padela said. "There is an undercurrent of 'we've been there and asked for these things, but the onus is always on us. They don't meet with us.' If hospitals go to the community and have that mutual learning process, it will help the community and help the patients at the bedside."

### RESOURCE

The free report, "Meeting the Healthcare Needs of American Muslims," can be found at http://ispu.org/GetReports/35/2110/Publications.aspx. ■

# HHS regs enhanced for human research

The Department of Health and Human Services (HHS) announced that the federal government is contemplating various ways of enhancing the regulations overseeing research on human subjects.

Before making changes to the regulations, which have been in place since 1991and are often referred to as the Common Rule, the government is seeking the public's input on an array of issues related to the ethics, safety, and oversight of human research. The changes under consideration can be found in an Advance Notice of Proposed Rulemaking (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, published in the July 25 "Federal Register." *(For information on how to access this notice, see Resource, p. 116.)* The proposed changes are designed to strengthen protections for human research subjects.

"The adoption of the Common Rule two decades ago was a landmark event to ensure ethical practices and the safety of those individuals who participate in research," said **Howard K. Koh**, MD,

MPH, HHS assistant secretary for health. "This regulatory review effort is primarily about enhancing protections for human subjects. The changes under consideration offer the promise of updating and enhancing those protections to keep pace with current challenges."

The current regulations governing human subject research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Expansion of human subject research into many new scientific disciplines and venues and an increase in multi-site studies have highlighted ambiguities in the current rules and have led to questions about whether the regulatory framework is effectively keeping up with the needs of researchers and research subjects.

Revisions to the regulations are being considered because HHS believes these changes will strengthen protections for research subjects in several important ways. Comment is sought on the following:

- Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.
- Using a single Institutional Review Board review for all domestic sites of multi-site studies.
- Updating the forms and processes used for informed consent.
- Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.
- Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.
- Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies.
- Providing uniform guidance on federal regulations.

The public's input on these matters will be critically important to the government's efforts to ensure that regulations keep up with today's changing research environment, HHS officials say. The input will be considered by HHS as it develops new proposed rules, which also will be made public for comment.

## RESOURCE

To view "Advance Notice of Proposed Rulemaking (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," published in 76 *Fed Reg* 44,512 (July 26, 2011), visit http://1.usa.gov/qBjdyd. ■

# High schoolers learn about protections

*Gaining experience with review boards*

As high school students get exposed to more sophisticated science and health programs, some are also having their first encounters with human subjects protection issues.

In science fair projects, in special science and health schools, and through outreach programs from research institutions, they're doing social and behavioral studies and being taken on to help established scientists with medical research.

While the number is not necessarily large, observers say aspiring investigators are interacting with review boards.

**Rebecca Dahl**, PhD, CIP, manager of the human subjects protection program at Children's Hospital, Los Angeles, was approached about allowing a high school student who was participating in a summer research program to be added to a protocol. "They wanted to have the student assist them," Dahl says. "And people were wondering what to do and how to go about the proper process."

Dahl says that she would be cautious about what type of assistance a high school student would be able to provide. "I would have to determine if what the student is doing is really at the level of knowledge and understanding so that they can perform things where they can feel successful," she says.

Those tasks might include interaction with subjects, such as handing out surveys or answering simple questions, as long as they were closely supervised by an investigator. And Dahl says they would require the same type of training required of older research staff." But remember, most of these kids, although they're screened very carefully to even be involved in the summer programs, they're not screened for research knowledge, and they don't get that, necessarily, in the high schools."

## High school research ethics

At some specialty high schools, however, human research ethics is part of the curriculum.

**Judith Scheppler**, PhD, is coordinator of student inquiry and research for the Illinois Mathematics and Science Academy (IMSA) in Aurora, IL.

Scheppler's students conduct their own research projects, as well as working off-site with established researchers at area institutions such as the University of Chicago, Northwestern University, and Fermilab.

The school requires that students working off-site be written into investigators' review boards proposals and that the school receive a copy of the outside review boards approval letter. "We don't want our kids to be used in the wrong way to do data collection," Schepplersays. "And we also use it as an educational tool for our students. By getting that [approval], we hope that they understand that you can't just go out and do research with human subjects without oversight."

IMSA also has its own review board, chaired by Scheppler, in part to deal with student-generated research It also fields requests from adult investigators wishing to recruit IMSA students for studies. Although the school does not handle federally funded research, Scheppler says the board's policies require that it follow federal guidelines.

"If your students are doing research, one can make the case that they are doing it as an educational endeavor and, therefore, they don't actually need review board approval," Scheppler says. "But for a number of students, it really becomes a gray area. I will have some of my students present at places such as the Illinois Gifted Conference. At that point, they are subject to review board guidelines, because they are participating in a public venue, contributing to generalizable knowledge."

Scheppler says that about five years ago, the school added a core course for sophomores called "Methods of Scientific Inquiry," part of which deals with human subjects protection issues.

When students submit research proposals, they must provide an ethical overview of their research, and, if it involves humans, must detail how they plan to handle such questions as voluntary participation, confidentiality, and informed consent.

Some of Scheppler's students have conducted observational research in classrooms at other schools and have quizzed students to gauge the effectiveness of different teaching styles. "We're really not going to do anything that's more than minimal risk, because our students just aren't skilled enough to take on anything more than that," she says. "And we're dealing with, at least on the campus, non-biomedical research."

However, she says students have studied topics such as teasing, where there was some concern about psychological risk. "What we do is make sure they're working with one of the counselors when they do those surveys, so the counselors are aware if any student becomes stressed because of the nature of the questions," Scheppler says. ■

# Test can determine fetal sex at 7 weeks

According to a recent study in *The Journal of the American Medical Association* (JAMA),[1] a simple blood test can determine a baby's sex as early as seven weeks into pregnancy is highly accurate if used correctly. Experts say this blood test is likely to lead to more widespread use by parents concerned about gender-linked diseases, those who are merely curious, and people considering the more ethically controversial step of selecting the sex of their children.

The test, which analyzes fetal DNA found in the pregnant woman's blood, can determine the sex of the fetus weeks earlier than other options, such as ultrasound, and is noninvasive, unlike amniocentesis and other procedures that carry small risks of miscarriage.

The tests have been available to consumers in drugstore chains and online for a few years, but their use has been limited, partly because their accuracy was unclear. One company, which guaranteed 99.9% accuracy as early as five weeks into pregnancy, filed for bankruptcy after a lawsuit by scores of women whose tests showed the opposite sex of the baby they ended up having.

European doctors routinely use the tests to help expectant parents whose offspring are at risk for rare gender-linked disorders to determine whether they need invasive and costly genetic testing. For example, Duchenne muscular dystrophy affects boys, but if the fetus is not the at-risk sex, such tests are unnecessary. But doctors in the United States generally have not prescribed the tests because they are unregulated and medical labs are not federally certified to use them.

That issue and other aspects of the pregnancy landscape could change as a result of the new study. The study analyzed large amounts of research on fetal DNA tests — 57 studies involving about 6,500 pregnancies — and found that carefully conducted tests could determine sex with accuracy of 95% at 7 weeks to 99% at 20 weeks.

One potential ethical issue is that women might abort fetuses of an undesired sex. Several companies do not sell tests in China or India, where boys are prized over girls and fetuses found to be female have been aborted. While sex selection is

not considered a widespread objective in the United States, companies say that occasionally customers expressed that interest and have been denied the test. A recent study of third pregnancies in the journal *Prenatal Diagnosis*[2] found that in some Asian-American groups, more boys than girls are born in ratios that are "strongly suggesting prenatal sex selection," the authors said.

At least one company, Consumer Genetics, which sells the Pink or Blue test, requires customers to sign a waiver saying they are not using the test for that purpose. "We don't want this technology to be used as a method of gender selection," said the company's executive vice president, **Terry Carmichael**. Sex-determination tests are part of a new frontier of fetal DNA testing, which can be used to determine paternity and blood type and is being used to develop early screening tests for genetic diseases such as Down syndrome.

The tests are not regulated by the Food and Drug Administration because they are not used for medical purposes, a spokeswoman said, but the agency is investigating the explosion of home genetic tests such as these and genome-sequencing kits. A typical blood test like Pink or Blue, for example, costs $25 for the kit. Lab fees and shipping costs, which vary, bring the total expense to $265 to $330.

REFERENCES

1. Devaney SA, Palomaki GE, Scott JA, et al. Noninvasive fetal sex determination using cell-free fetal DNA: A systematic review and meta-analysis. *JAMA* 2011; 306:627-636.
2. Egan JFX, Campbell WA, Chapman A, et al. Distortions of sex ratios at birth in the United States; evidence for prenatal gender selection. *Prenatal Diagnosis* 2011; 31:560-565. ■

# Conference analyzes ethics in research

When you have blood taken for a test or have tissue removed for a biopsy, it might be used for medical research. While there are clear benefits to such research, medical and healthcare professionals need to be aware of cultural and confidentiality concerns on the part of patients.

Members of the Creighton University (Omaha, NE) faculty and others presented on those topics as part of "The Use of Human Tissue and Public Trust: The Chasm Between Science and Ethics," a conference sponsored by Creighton's Center for Health Policy and Ethics (CHPE) and the Department of Health and Human Services Office of Research Integrity.

The conference was designed to expand awareness about the importance of weighing the benefits of knowledge derived from tissue research against such issues as cultural traditions and beliefs; exploring the concept of trust among patients, especially from the perspectives of populations vulnerable to exploitation or marginalization; and identifying gaps in communication and understanding between the science community and the public regarding the use of human tissue.

The event was designed for physicians, physician assistants, nurses, healthcare educators, public health professionals, medical students, and members of the public.

CHPE professor **John R. Stone**, MD, PhD, gave a presentation on "Ethical Issues — Trust and Trustworthiness, Dispelling Myths." Stone has often focused on social justice in his work, particularly health inequalities that affect minority populations.

Other Creighton faculty members involved in the conference included CHPE director **Amy Haddad**, PhD, Mabel L. Criss Endowed Chair in the Health Sciences, who was the primary organizer of the conference, and **Donald Frey**, MD, vice president for health sciences.

The Center for Healthcare Policy and Ethics is home of Creighton's master's of science in healthcare ethics, which is offered entirely online. The interdisciplinary program educates students who must deal with bioethics as part of their duties (such as physicians, nurses, public health workers, attorneys, and chaplains) on the various issues and factors involved in the field, giving them greater ability to explain, justify, and analyze ethical decisions in healthcare. ■

# Palliative care group comments on ethics

*Marketing addressed in statement*

The National Hospice and Palliative Care Organization (NHPCO) issued a position statement and commentary, "Hospice and Palliative Care: Ethical Marketing Practices," that guides providers to the use of sound, ethical practices that enhance the perception of hospice in the

community.

NHPCO's position statement focuses on six key components:

**• Access to care.**

NHPCO recommends that hospices regularly review potential barriers to access and implement education and marketing efforts that help remove these barriers for individuals or groups.

**• Competition.**

Although competition can be a healthy, positive incentive for all providers to provide high quality service, NHPCO warns providers to avoid making promises of service that cannot be fulfilled. The position statement says, "Hospices must accurately represent the capacity and services of their organization in all marketing, outreach, and education."

**• Hospice and palliative care organizations as referral sources.**

The selection of business partners or referral sources such as durable medical equipment, pharmaceutical, and homecare services that provide services to hospice patients must be made with care, suggests NHPCO. "....organizations [should] have clearly stated policies for contracting with and making referrals to other community providers."

**• Customer service excellence and boundaries.**

NHPCO recommends that excellent customer service is attained by providing the highest level of clinical care "within the parameters that constitute clinically appropriate hospice and palliative care services which are compliant with all applicable federal and state regulations." Hospice and palliative care organizations, therefore, "assume responsibility for ethical decision-making and behavior related to the provision of hospice care."

**• New trends in marketing and communication.**

The growth in technology and the use of social media have increased the need for all organizations to review and enhance policies regarding the use of these new media for communication with the general public and with patients. NHPCO encourages the development and implementation of policies that especially pay attention the privacy rules set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.

**• Traditional media marketing.**

The use of traditional media such as print or radio also requires a careful examination of policies to ensure that the organization's efforts "promote the ethical and responsible use of patient/family testimonials in media outreach, respecting confidentiality, privacy and the physical and emotional well-being of those being served."

**RESOURCE**

To access the complete, free copy of the position statement, go to www.nhpco.org, click on "Professional Resources," then click "Communications and Publications," then "NHPCO Position Statements and Ethical Positions." ■

## 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

■ When advance directives are not honored

■ The risks and benefits of reconsent

■ Transitions in end-of-life care

■ Ethics in clinical research

# CME QUESTIONS

1. According to the authors of a disaster planning commentary that appears in the journal *Biosecurity and Bioterrorism*, planners should focus on ethical challenges likely to arise when assisting the mentally disabled during and after a disaster, that are consistent with guidelines from _____.
   A. The Institute of Medicine
   B. American Medical Association
   C. Biosecurity and Bioterrorism
   D. None of the above

2. According to David Taylor, BCCC, pastoral care coordinator, co-chair Bioethics Committee, Texas Health Presbyterian – Wilson N. Jones Medical Center (WNJ), Sherman, TX, what can organ trafficking can be blamed on?
   A. High demand of organs
   B. Lack of availability of organs
   C. Affluence of society
   D. All of the above

3. True or False: The Organ Donation and Recovery Improvement Act that was signed by former President George W. Bush states that while it is illegal to sell or pay for organs, the federal government can reimburse living donors for expenses and offer project grants aimed at increasing donations and improving organ preservation and compatibility.
   A. True
   B. False

4. What is one potential ethical issue of determining fetal sex as early as 7 weeks using the new test of fetal DNA?
   A. Carries a risk of miscarriage.
   B. The accuracy of the test is unclear.
   C. Women might abort fetuses of an undesired sex.
   D. None of the above