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Note: New CNE procedures. See p. 83 for details.

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As research of genetic testing grows, so do the pros and cons

Human Genome Project and beyond

While the possibility of using genetic information for evil, rather than good, sounds like something out of a science fiction movie, the likelihood of that happening is ever-present.

Mark A. Rothstein, JD, director at the Institute for Bioethics, Health Policy and Law, University of Louisville School of Medicine, Louisville, KY, says that although there are no specific studies to prove otherwise, it is likely that disclosures of genetic information in violation of the express provisions of Genetic Information Nondiscrimination Act [GINA] are common.

"For example, under GINA an employer is prohibited from acquiring the genetic information of an applicant or employee," he says.

Under the Americans with Disabilities Act [ADA], however, after a conditional offer of employment, the employer is lawfully permitted to require the individual to sign an authorization to disclose all of his or her medical information. Post-GINA, this disclosure applies to all medical information except genetic information. The problem is that for paper and electronic health records, it is extremely burdensome to separate genetic from non-genetic information, so the custodians of the records often send everything, says Rothstein.

The ethical and legal ramifications associated with genetic testing are now an integral part of genetic testing. *(For more information about Ethical, Legal, Social Issues, see article, p. 75)*. The matter of privacy and fair use of genetic information come into play. However, privacy is not the issue, says **Nancy M.P. King**, JD, professor, Department of Social Sciences and Health Policy Wake Forest University School of Medicine, co-director, Center for Bioethics, Health, and Society, Wake Forest University, both in Winston-Salem, NC. The issue is confidentiality, King says. "Since the only practical way that genetic information can be derived in the first place is by one person providing a biospecimen to another person so that the first person's genetic information can be obtained through analysis, the question should be whether genetic information can be kept confidential," King says.

Important questions can be asked of genetic testing and information. Can the information obtained remain confidential? Or could it be bought, sold, or leaked to employers, schools, insurance providers, direct marketers, banks, credit bureaus, law enforcement agencies, or quite frankly, to anyone who wanted that information. "There are federal laws protecting the confidentiality of medical information generally, HIPAA, and genetic information specifically, GINA," says King.

According to Rothstein, GINA only applies to individual and group health insurance. It does not prohibit genetic discrimination in life, disability, long-term care, or other types of insurance. Also, GINA only applies to people who are asymptomatic. "For example, under GINA, it would be unlawful for an individual health insurance company to deny coverage because a woman tested positive for one of the breast cancer mutations," Rothstein says. "But if a woman later developed breast cancer, then GINA would not protect her, and subject to state insurance law, the insurer could decline to renew the policy, charge substantially higher rates, etc."

EXECUTIVE SUMMARY

Even with the Genetic Information Nondiscrimination Act (GINA) applying to genetic testing and information dissemination, there is always a possibility that confidential information will be leaked.
- The ethical and legal ramifications associated with genetic testing are an integral part of the genetic testing.
- One significant question is, can the information obtained from genetic testing remain confidential?
- A concern among geneticists is the concept of "genetic exceptionalism," the question of whether genetic information should be treated any differently than other medical information.
- Even before HIPPA and GINA, there was very little evidence that genetic discrimination was taking place, but the fear of it kept many people from accessing genetic services.

What is 'genetic exceptionalism'?

A concern among geneticists is the concept of "genetic exceptionalism," the question of whether genetic information should be treated any differently than other medical information, says **Cecelia Bellcross**, PhD, MS, CGC, instructor/certified genetic counselor at Emory University School of Medicine in Atlanta.

Bellcross says, "When you have your cholesterol checked, nobody tells you that if it is high you could have problems with health/life/disability insurance. Is genetic information really different?"

During the Human Genome Project (HGP), concerns rose about what ramifications could ensue stemming from the availability of such large amounts of personal genetic information, in mostly unguarded and vulnerable data banks, as well as the potential discriminatory misuse of genetic information. The HGP was a study of genes and DNA that started in 1990. The goals of the project were to identify all the approximately

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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.**

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EDITORIAL QUESTIONS

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

20,000-25,000 genes in human DNA, determine the sequences of the 3 billion chemical base pairs that make up human DNA, store this information in databases, improve tools for data analysis, transfer related technologies to the private sector, and address the ELSIs that were sure to arise from the project. *(For more information on HGP, see article, below)* Rothstein says, "According to Congress, the main purpose of GINA is to allay the fears of individuals who want to avail themselves of genetic testing or other genetic services that they can do so without worrying about discrimination, [but] it is not clear whether this goal can be realized under GINA."

Bellcross says, "Even before HIPPA and GINA, there was very little evidence that genetic discrimination was taking place, but the fear of it kept many people from accessing genetic services. The best thing about these laws is they help to remove some fear."

SOURCES/RESOURCES

• **Cecelia A. Bellcross**, PhD, MS, CGC, Instructor/Certified Genetic Counselor, Emory University School of Medicine, Department of Human Genetics/Division of Medical Genetics, Atlanta. Email: cbellcr@emory.edu.
• **Nancy M.P. King**, JD, Professor, Department of Social Sciences and Health Policy Wake Forest University School of Medicine, Co-Director, Center for Bioethics, Health, and Society, Wake Forest University, both in Winston-Salem, NC. E-mail: nmpking@wfubmc.edu.
• **Mark A. Rothstein**, JD, Herbert F. Boehl Chair of Law & Medicine, Director, Institute for Bioethics, Health Policy and Law, University of Louisville School of Medicine, Louisville, KY. E-mail: mark.rothstein@louisville.edu.
E-mail: mark.rothstein@louisville.edu.

• **Human Genome Project Information.** Web: http://www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml.
• **National Human Genome Research Institute.** Web: http://www.genome.gov. ■

ELSI of HGP and other genetic testing

Ethical, legal, and social issues (ELSIs) recently have been raised concerning genetic testing following an incident last year at University of California, Berkeley.

"UC Berkeley sparked a controversy by proposing to do genetic testing on all incoming freshmen," says **Nancy M.P. King**, JD, professor in the Department of Social Sciences and Health Policy Wake Forest University School of Medicine, and co-director, Center for Bioethics, Health, and Society, Wake Forest University, both in Winston-Salem, NC.

The proposed testing was for several non-medically significant traits and would be used in a structured learning opportunity. The university first introduced plans to launch the voluntary program for incoming freshman that would test for three genes involved in the metabolization of alcohol and lactose. The project would be part of UC Berkeley's "On the Same Page Program," which attempts to engage new students in an intellectual exercise focused on a particular topic. UC Berkeley chose personalized medicine and had hoped to give students a small piece of their own genomic profile.

However, after conversations with the California Department of Public Health and other state health regulators, UC Berkeley was served with a directive asking it to halt the dissemination of genomic data to individual students because the genetic analysis would be delivered without the involvement of the students' doctors. As a result, the university will not release individual test results to students but instead will provide the results in aggregate form with the goal of engaging students in discussions about the ethical, legal, and social implications of personal genomics.

Human Genome Project ethics

When it comes to genetic testing, what might be considered new controversy to some is not new at all to those in the healthcare ethics field.

Because of the vast number of concerns and ethical issues that cropped up during the Human Genome Project (HGP), both coordinators of the study — the U.S. Department of Energy (DOE) and the National Institutes of Health (NIH) — committed about 3-5% of the yearly HGP budget to study the ELSIs associated with the availability of this new genetic information. HGP was a collaborative research program with a goal of complete mapping and understanding of all the genes of human beings.[1]

Part of that ELSI budget was earmarked for study into the potential effects of having such information readily available, and another part was set aside for educational materials about the ELSI for physicians, educators, students, clergy, and judges and other legal professionals. *(See resource listing, p. 76, for more information.)*

The overall mission of the HGP ELSI pro-

gram was to identify and address issues raised by genomic research that would affect individuals, families, and society as a whole. Analyses of the data continue, as do ELSIs associated with the study.

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- U.S. Department of Energy Office of Science, Office of Biological and Environmental Research, Human Genome Program. Human Genome Project Information. *DOE ELSI Program Emphasizes Education, Privacy – A Retrospective (1990-2000)*. Web: http://www.ornl.gov/sci/techresources/Human_Genome/resource/elsiprog.shtml. ■

Controversy brews from DTC testing

There are more than 1,000 genetic tests for human diseases and conditions on the market ranging from DNA-based identity testing to predisposition testing, even whole genome scanning. There is an increasing trend for genetic test companies to market and sell their genetic test products directly to consumers.

These direct-to-consumer (DTC) tests provide information that consumers weren't customarily privy to, without involving a physician in the process. As its name implies, the DTC genetic test is accessible directly to the consumer without the need of a healthcare professional to order the test or read the results.[1]

As expected, ethical issues have been raised because of these tests. Recently, the General Accounting Office (GAO) published the results of its investigation into DTC genetic testing companies and disclosed a great deal of variation in the results and their interpretation. *(To access the report, see Resource, p. 77.)* Regarding these DTC genetic testing companies, "the ethical, legal, and social issues [ELSI] implications include understanding the difference between screening and confirmatory testing; the differences between screening for traits, carrier status, susceptibility to common complex disorders, and single gene disorders; the difference between relative and absolute risk; genetic determinism and genetic essentialism; medicalization, commodification, and informed consent,"explains **Nancy M.P. King**, JD, professor, Department of Social Sciences and Health Policy Wake Forest University School of Medicine, and co-director, Center for Bioethics, Health, and Society, Wake Forest University, both in Winston-Salem, NC.

With all the ELSI involved with DTC tests, is more information always better? "Only if it's good information," King says. "DTC genetic testing does not yet produce good information."

Benefits of DTC testing are the accessibility of tests to consumers, promotion of proactive healthcare, and the privacy of genetic information. **Cecelia A. Bellcross**, PhD, MS, CGC, instructor/certified genetic counselor, Emory University School of Medicine, Department of Human Genetics/Division of Medical Genetics says, "If accompanied by appropriate genetic counseling and done in conjunction with consultation with one's local healthcare provider, [certain] DTC genetic testing can be helpful in some circumstances."

Risks of DTC testing include the lack of governmental regulation and the potential misinterpretation of genetic information.

Recently, there has been much debate about the legality of DTC genetic testing. DTC genetic testing has become more controversial as the number of available single gene tests has increased and particularly with the introduction of personal genome testing services, which provide risk assessment information for many diseases, traits, and conditions by genotyping thousands of gene loci in each individual. "[Some of] the tests offer no established clinical validity or utility," Bellcross says. "They test for a few variants that have been associated with particular diseases or traits; however, the ability of these tests to actually predict who will or will not get the disease in question is often no better than flipping a coin." The variety of genetic information tested for complicates the issue of whether these companies are providing information for recreational purposes only or whether they are also providing medical diagnostic information.

"In general [the tests] strike me as insufficiently informative to reasonably ground decision-making based on them," King says. "They seem to promote genetic essentialism, when there are many other factors of considerable significance to consider including family history, behavioral and lifestyle choices, and gene-environment interactions."

Bellcross agrees, "The SNPs [Single Nucleotide Polymorphisms] that have been found in association with most diseases only account for a fraction of the known heritability. So someone who is obese, and has three family members with diabetes could be falsely reassured about their risk based on a diabetes genomic profile, which doesn't account for these factors."

DTC genetic testing is considered highly controversial and in some cases unethical, due to great opposition from the scientific community. Opponents of DTC testing argue against the risks involved, especially the fact that the tests are unregulated by government, as well as the possibility of severe misreading of test results by a layperson, and not a licensed healthcare professional. Additionally, some advertising for DTC has been criticized as being exaggerated and inaccurate in the messaging regarding the connection between genetic information and disease risk.

"At least at present," King says, "there are many discrepancies and gaps in the information that DTC testing companies consider."

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Protecting participants in first-in-human trials

Review preclinical studies for treatments

The first-in-human clinical trials raise difficult ethical issues for researchers and review boards because of the uncertainty that accompanies them. Did the preclinical studies that preceded them provide enough information about effectiveness and risks and benefits to proceed with human volunteers?

Too often, positive expectations from those earlier tests do not end up translating well to results in human research, says **Jonathan Kimmelman**, PhD, an associate professor of biomedical ethics at McGill University in Montreal.

"I've studied areas like gene transfer, and there's an example of a field that's been characterized by this kind of boom-bust cycle where very promising preclinical trials come forward, they're rushed into human trials, and the agent turns out not to have the activity that everyone was expecting and hoping for from the preclinical studies," he says.

Kimmelman says review boards need to be able to look critically at proposed first-in-human trials, particularly in the area of balancing risks and benefits. "The vast majority of drugs that enter into human trials never survive to licensure," he says. "So there's a lot at stake in making good decisions at the point of initiating human studies. If you make a bad decision at that point, you end up exposing many patients to a drug that has an unfavorable risk-benefit balance, and you end up investing many resources into developing a drug that turns out not to be promising enough for licensure."

Review boards might mistakenly think that if the Food and Drug Administration (FDA) has approved the drug for human trials, it has adequately vetted its potential for efficacy, he says. "The FDA is mainly concerned about making sure that the investigators have a pretty good handle on the toxicity of the drug," Kimmelman says. "It's really up to review boards to be vetting first-in-human studies for clinical promise."

Preclinical studies key

The key to evaluating first-in-human trials is having reliable information about prior non-human studies, Kimmelman says.

In an article in the journal *PLoS Medicine*, Kimmelman and his colleague, Alex John London of Carnegie Mellon University, argue that predictions about the potential of an investigational drug are too often based on prior studies that might have problems themselves (such as lack of randomization in an animal study, for example) or that might not be comparable to the proposed human study under review.[1]

Sorting this issue out can be difficult for review boards, due to the complexity of early phase trials. "These are not garden-variety clinical trials," Kimmelman says. "They involve a very high level of expertise, not just in the clinical realm, but also in understanding the preclinical realm. One of the challenges of reviewing early phase studies is that it can be very difficult for review boards to have

Issues concerning informed consent

Casting a bigger net for first-in-human trials

When there's a lack of strong data on a new experimental agent for first-in-human studies, researchers should cast the net wider by providing information to review boards about other drugs that work in the same way or that have other important similarities to the study drug, says **Jonathan Kimmelman**, PhD, associate professor of biomedical ethics at McGill University in Montreal.

Those other relevant studies shouldn't just influence the evaluation of a review board; they should be included in the informed consent in a trial going forward, Kimmelman says. Because first-in-human studies deal with such unknown quantities, informed consent must give participants any information possible that can aid in a decision.

"To simply say, 'We don't know how well this drug is going to perform,' you're telling a patient that there's somewhere between a 0 and 100% chance that the drug is going to have the clinical activity that's predicted in preclinical studies," Kimmelman says. "That basically has no informational content at all. What we're saying is if there is a record of similar interventions going forward, and not succeeding in clinical trials, patients should be told that."

Review boards should consider carefully the type of subject who is to be enrolled in a first-in-human trial, he says. One approach taken in many studies is to limit enrollment to patients for whom there has been no effective treatment to that point.

"If you enroll patients who have advanced disease, they have less to lose if there is no clinical activity or if there turn out to be risks that were unanticipated," Kimmelman says.

On the other hand, a person whose illness is well managed by existing treatments has greater potential for his or her quality of life to be harmed by participating in a first-in-human trial. "You want to have a good justification for enrolling patients who have other treatment options," Kimmelman says. "You want to be able to say that your new agent is competitive with those other treatment options, and in order to do that, you need to be able to make reliable predictions about the clinical activity of your drug. If you apply the procedures that we recommend and you conclude that effects that you saw in animals are unlikely to generalize to human beings, then I think you should be very cautious about enrolling patients who have other treatment options." ■

qualified personnel to review those studies."

Review boards should be ready to seek out the necessary expertise to deal with a particular study, he says. Also, they should look, wherever possible, to outside resources such as the National Institutes of Health's (NIH's) Recombinant DNA Advisory Committee, which reviews human gene transfer research. "In certain areas, such as areas of gene transfer, centralized oversight really provides an opportunity for experts to weigh in on the quality of preclinical studies," Kimmelman says.

Review boards also should hold investigators and sponsors accountable for ensuring that all relevant studies have been included.

"There is some pretty solid evidence that not all preclinical data get published," Kimmelman says. "And it's not entirely clear what proportion of preclinical data actually end up getting shared with review boards. If you're a review board member, you want to be sure that you're not just looking at the most positive outcomes from the preclinical studies; you want to make sure that you're looking at all the preclinical studies."

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Organ transplants for inmates

Ethical questions and concerns are being raised in cities and towns all over the United States as a number of prison inmates seem to be receiving better and/or reduced rate healthcare for otherwise costly medical procedures.

The situation begs the question, for people who break the law, in addition to losing their freedom, what other rights do they lose, or for that mat-

ter, gain? Inmates probably would have less of an opportunity to receive a life-saving organ transplant or other expensive healthcare if they weren't in a state or federal penitentiary.

Senators and taxpayers alike are demanding that these questions of ethics be addressed by lawmakers so that taxpayers are not bearing the burden of costly inmate medical care. In the news recently was convicted rapist Kenneth Pike, an inmate at Coxsackie Correctional Institution in upstate New York, who was set to receive a heart transplant. That transplant ultimately could have cost taxpayers upward of $800,000. The United Network for Organ Sharing (UNOS), the organization that determines who receives transplants, does not recognize any "categories," which means an incarcerated individual has the same chances of receiving a transplant as say, a CEO or a Hollywood celebrity, because no matter what the individuals status in life, it doesn't change where they are on the transplant list.

"The U.S. Supreme Court has determined that withholding medical treatment from those who are incarcerated is cruel and unusual punishment, because prisoners are not allowed to seek healthcare for themselves. The court did not say which treatments are obligated, which could be withheld, or whether prisoners ought to be listed for transplants," according to **Richard Demme**, MD, FACP, associate professor of Medicine and Humanities, chair of the Ethics Committee, University of Rochester (NY) Medical Center, Strong Memorial Hospital.

As an ethicist, Demme agrees with the Supreme Court ruling. "It became clear early on in the history of transplantation that criteria of 'social worth' should not be a significant consideration in the allocation of organs," he says.

Questions raised by members of the upstate New York town of Rochester broached many ethical questions: Should an imprisoned rapist be in line for a transplanted organ that could otherwise go to someone leading an honest, productive life? Who makes that call? What about people committed to state mental institutions or under state care for disabilities?

"It is simply not ethically defensible for a politician or celebrity to have a greater chance to receive an organ than an electrician, teacher, or homemaker. But there is a difference between 'social worth' and the rights of and obligations to those who have been found to have caused significant harm to the community," says Demme.

Many people in the town and others came to the forefront with these concerns about Pike and his bid to receive a heart transplant. Demme says, "Transplantation is a unique field in medicine, in its requirement for community support. If the community does not donate organs, there can be no transplantation. The community donates a tremendous amount of financial support to transplantation by funding research and Medicare funding of transplants."

Community involvement in the transplant process can make or break a patient's bid to be a recipient. "A prisoner is someone who has been convicted of causing harm to a community. It is possible that if a prisoner receives a transplant, another community member who did not receive the organ could die," Demme says.

Strong Memorial Hospital, part of the University of Rochester Medical Center, was involved in the firestorm from the community because it was the hospital that would perform the surgery for Pike, but fortunately, not in a negative way. "I don't believe the hospital was negatively impacted in the short-term as a result of recent media coverage in our area. We provided media with a general statement that explained our ethical responsibility to evaluate all patients equally for transplant, with no bias related to whom they are or where they reside, how much money they make, or what insurance they carry," Demme says. *(To view the Strong Memorial Hospital media statement in its entirety, see box above.)* "What cannot be determined are the long-term effects on local rates of organ donation if there is concern by members of a community about the choice of specific organ recipients."

After townspeople raised concerns, NY state

Media Statement

As a provider of healthcare to a large and diverse population, we have an ethical responsibility to treat everyone who comes to us in need of care. Strong Memorial Hospital doctors, nurses and staff members are committed to providing that care without discrimination. We believe in and follow the organ allocation policies and guidelines of the federally regulated OPTN/United Network for Organ Sharing, which ensure equal consideration for transplantation and access to donated organs.

SOURCE: Strong Memorial Hospital, Rochester, NY. ■

Sen. Mike Nozzolio called for a Senate hearing to address the issue of inmate healthcare and outrage around the state of New York. Pike has since withdrawn his name from the transplant list. "It could be argued that a prisoner should not be eligible for transplantation until after he has completed serving his sentence," Demme says. "It also is certainly true that some prisoners have been wrongly convicted."

As hardly an 'all's well that ends well' situation for Pike and his family, this case has certainly heightened the role of the community, healthcare institutions, and lawmakers when it comes to healthcare bias, and this case is not an isolated incident.

"In general, the role of hospitals should be to try to extend lives and to provide medical services, not to limit or forbid treatments," says Demme.

SOURCE/RESOURCE:

• **Richard Demme**, MD FACP, Associate Professor of Medicine and Humanities, Chair, Ethics Committee, University of Rochester Medical Center, Rochester, NY. E-mail: richard_demme@urmc.rochester.edu.

• **The United Network for Organ Sharing.** Web: http://www.unos.org. ■

Ethics in the news: Catholic hospitals

Recently Catholic hospitals have received a large amount of media coverage in the news and on the Internet stemming from certain decisions concerning healthcare and ethics. One case in particular occurred earlier this year when the amniotic sac of a pregnant woman in Manchester, NH, tore, and she was in the midst of experiencing a miscarriage.

Reportedly, she was rushed to her local hospital, which had recently merged with a Catholic hospital. Because the doctor still could detect a fetal heartbeat, due to directives of the Catholic Church, he was unable to perform a uterine evacuation that would help complete the miscarriage.

Stories like this one are not remote incidents. According to **Barry Lynn**, executive director of Americans United for Separation of Church and State, based in Washington, DC, issues like this one occur more when hospitals merge. "When a Catholic hospital joins with a non-Catholic hospital, the latter is almost always required to accept the church's directives," Lynn says. *(For more information on directives, see box below.)*

Because of the directives of the Catholic Church, healthcare providers at Catholic-affiliated facilities are not allowed to perform procedures that the Catholic Church deems "intrinsically immoral, such as abortion, and direct sterilization," says Lynn. Also included in that list are birth control, ectopic pregnancies, embryonic stem cell research, in-vitro fertilization, sterilizations, and more.

Susan McCarthy, clinical ethics director, Ministry Health Care, Milwaukee, WI, begs to disagree with those reports. "There is no directive requiring the absence of fetal heart tones prior to medical intervention," McCarthy says. She points out that the operative Ethical and Religious Directive in cases where the fetus has not reached viability is no. 47: "Operations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn

Vatican to update Catholic hospital guide

Vatican officials believe that controversies over bioethical standards at U.S. Catholic hospitals show the need for greater Catholic education for healthcare workers.

According to reports coming out of the Vatican, church leaders said a new set of biomedical guidelines will be published later this year, as well as a separate document on AIDS prevention.

According to **Bishop Jose L. Redrado**, the secretary of the Pontifical Council for Health Care Ministry, in the updated guide, the language should be clear and explain what the church says, where the frontiers are, and where there is a risk of crossing the line. Health care ethics guidelines for Catholics were updated before in a 1995 document, The Charter for Health Care Workers, but it has not been updated since. A great many things have changed since 1995, including a significant surge in abortion rates around the world, as well as the rapid development of destructive embryo research and artificial reproduction technologies. ■

child is viable, even if they will result in the death of the unborn child," McCarthy quotes.

In some cases, directives can provide a good model for holistic healthcare, according to **J. Vincent Guss Jr.**, DMin, BCC, medical ethics director, Kaiser Permanente West Los Angeles Medical Center. "For example," says Guss, "directive 46 provides that 'compassionate physical, psychological, moral, and spiritual care [should be] given to those who have suffered from the trauma of an abortion.'"

Guss points out, however, that some directives can be viewed as negative, or provide an effect viewed negatively, such as directive 45: the directly intended termination of pregnancy before viability or the directly intended destruction of a viable fetus is never permitted. Lynn says, "[The directives] reduce healthcare options for people in the community and force non-Catholics to accept church directives that they may not agree with."

The hospital in this particular case in New Hampshire decided against providing treatment, but as Guss points out, ethics committees are not entities that are equipped or chartered to mandate or forbid clinical treatments. "Rather," Guss says, "they exist to provide a forum and moral climate of discussion and exploration of a range of possible treatments that can be ethically justified." Guss says that the committees attempt to rationally apply bioethical principles to clinical situations and give voice to the expression of values to all of the stakeholders in clinical cases. "They serve patients, families, clinicians, and the community in a consultative and educational role as a resource to decision-makers," he says.

What's next for separation?

Although no one knows the future of the separation of church and state, Guss predicts that the status as it pertains to healthcare will remain the same: very little separation.

"Religious institutions receive public funds," Guss says. Governmental bodies highly regulate them. "To say there is a true separation is spurious," Guss says.

Lynn believes that the face of American religion is changing, so true separation might be possible. "Americans remain a spiritual people, but many are finding a religious home outside of the traditional dogma of established houses of worship and are adopting a 'do-it-yourself' spirituality," he says. "This means people will be less likely to automatically defer to and blindly accept church teachings, especially those that relate to personal decisions, like those connected to healthcare."

McCarthy says, "as the provisions of the Affordable Care Act are implemented, we hope to see more affordable and more accessible care for all, regardless of the sponsorship — Catholic or otherwise — of the healthcare facilities chosen by patients. I don't anticipate any conflicts to arise regarding the separation of church and state."

With each incident such as the New Hampshire woman, lessons can be learned.

Guss says, "Ethics consultants have the responsibility to help decision-makers, i.e. clinicians and the patient/family/surrogate, to weigh the risks and benefits of any healthcare decision. If the life and/or long-term health of a patient is threatened by a decision not to give the medical treatment required in an emergency because of the care provider's moral conscience, that care provider should seek to help the patient find another provider who is willing to provide the necessary treatment in a timely and safe way."

McCarthy mimics the sentiment by Guss, "We are proud of our Catholic heritage and of the care we provide, regardless of ability to pay."

SOURCES

• **Barry W. Lynn**, JD, Executive Director of Americans United for Separation of Church and State, Washington, DC. E-mail: americansunited@au.org.
• **Susan McCarthy**, MA, Clinical Ethics Director, Ministry Health Care, Theology and Ethics Committee, Board of the Catholic Health Association of America, Milwaukee, WI. E-mail: susan.McCarthy@ministryhealth.org.
• **J. Vincent Guss, Jr.**, DMin, BCC, Medical Ethics Director, Kaiser Permanente West Los Angeles Medical Center. E-mail: vincent.j.guss@kp.org. ■

Health professionals report CME bias

The commercial funding of continuing medical education (CME) and the potential for bias is of great concern for a significant number of healthcare practitioners and researchers, many of whom admit to being unwilling to pay higher fees to

eliminate or offset commercial funding, according to a report in the Archives of Internal Medicine, *(*Arch Intern Med *2011;171:840-846)*.

Organizations including the Institute of Medicine, the American Association of Medical Colleges, and the American Medical Association, have indicated wanting further decreases in the role that pharmaceutical and medical device manufacturer's play in directing CME.

From January through June 2009, a group led by **Jeffrey A. Tabas**, MD, from the University of California, San Francisco surveyed attendees at CME courses delivered by the International AIDS Society — USA (IAS-USA), a nonprofit organization. In total, 770 attendees (a 57% response rate) completed the 22-item survey, which concentrated on beliefs about commercial funding and the possibility for bias, willingness to offset the cost of commercial support, knowledge about the costs of producing CME programs, and demographic information.

Participants included physicians, nurses, nurse practitioners, physician assistants, and persons with PhDs or other academic degrees. "Our two main outcome variables were dichotomized as follows: one, agreed or strongly agreed that raising the registration fees is an effective way to decrease commercial support versus not, and two, agreed or strongly agreed that commercial support for live CME should be eliminated versus not," the authors of the survey explained in Archives of Internal Medicine.

Eighty-eight percent of responders reported that commercial support of a CME activity introduced the potential for bias. This perception of bias also was directed toward CME faculty who receive support from industry.

In general, participants who suspected industry bias in CME were more likely to favor reducing or abolishing such funding. But the majority of the group would opt against raising registration fees or offering fewer topics or speakers, among other measures. ■

Specific programs enhance hospice care

Study confirms hospice not necessarily targets rich

Developing a business model or marketing strategy that includes services focused on specific patient populations does not necessarily mean that a hospice is targeting higher revenue patients, as implied in a study recently published in the *Journal of the American Medical Association (JAMA)*,[1] but it often represents a response to a community need, says **Carole Fisher**, president and chief executive officer of Nathan Adelson Hospice, a not-for-profit hospice in Las Vegas. "One way to improve care is by addressing specific patient needs," Fisher says.

Although hospices accept all appropriate patients according to Medicare's Conditions of Participation, some hospices are developing disease-specific programs to provide more focused care for some conditions. "We developed a program to address the needs of patients with pulmonary diseases such as chronic obstructive pulmonary disease [COPD]," says Fisher. "COPD patients are an underserved population in our area, and offering services that are specific to their needs was the right thing to do."

Mark M. Murray, president and chief executive officer of The Center for Hospice Care, a not-for-profit hospice in Mishawaka, IN says, "My hospice has specific programs for Alzheimer's, congestive heart failure, and COPD," These conditions are non-cancer diagnoses for which it is more difficult to predict length of service and which typically result in longer lengths of service, Murray says. "It is a good business model that results in our hospice providing service to a variety of patients who benefit from hospice care," he adds.

Murray was surprised that the *JAMA* article used the care of dementia patients as an indicator that for-profit hospices were selecting patients who required less expensive care. "Dementia-related deaths increased by 46% from 2000 to 2006, which means this is a population that hospices should be serving in increasing numbers," he says.

The key to providing good hospice care is to look at the needs of your community, Murray suggests. "This study did not look at local needs that drive the programs you develop or the patients you serve," he adds. "We developed our COPD program because a high percentage of our community members smoke and develop lung diseases," he explains.

Programs that provide care to patients in nursing homes are also important, regardless of the hospice's tax status, says **Joan M. Teno**, MD, MS, professor of community health and medicine at the Warren Alpert School of Medicine of Brown University, Providence, RI, and associate medical director for Home and Hospice Care of Rhode Island, a not-for-profit hospice in Providence.

Hospices and nursing homes can work together to provide the best care possible at the end of life, she says.

"Not only can hospice staff and volunteers provide the hospice services directly to nursing home patients, but they can also serve as consultants and educators to support the nursing home staff," says Teno. "The nursing home will have patients who don't qualify for hospice care but may need palliative care, and a partnership with a hospice can benefit those patients as well," she says. For all areas of healthcare to provide the best care possible, it is necessary to look for innovative ways to partner with each other, she suggests.

While hospice originally was focused on care of cancer patients, the increase in the number of non-cancer diagnoses has changed the needs of hospice patients, says Fisher. She adds, "At one time, hospices tried to be everything to everybody, but now we see patients with a wide range of diseases that increase the need to offer some disease-specific programs."

REFERENCE

1. Wachterman MW, Marcantonio ER, Davis RB, et al. Association of hospice agency profit status with patient diagnosis, location of care, and length of stay. *JAMA* 2011; 305:472-479. ■

Hospice cap deficits = managing case mix

A good balancing act reduces the risk

Balancing your case-mix to avoid hospice cap deficits doesn't mean discharging patients or admitting patients who don't meet hospice criteria, warns **Kyle Terry**, MBA, consultant and principal at Hospice CAP Consultants in Owasso, OK.

"Although a balance of short- and long-term patients is the best strategy to minimize your risk of receiving a repayment demand letter from Centers for Medicare and Medicaid Services (CMS) based upon the hospice cap, it is important to follow admission criteria guidelines issued by CMS," he says.

After the hospice manager has evaluated the cap deficit risk, the manager should look at the types of patients your hospital typically admits and also the referral sources, Terry suggests. "Then, look at where the marketers are going," he says. "Generally, oncologists will refer shorter term patients and family practitioners will refer longer term patients, many of whom may be in nursing homes," he explains. To ensure a balanced case-mix, make sure your marketers are visiting all types of referral sources, he adds.

The hospital manager should monitor admissions on a monthly basis with a focus on how the patient mix affects cap deficit or surplus, says Terry. By watching on a monthly basis, the hospital manager will have an opportunity to make changes and redirect marketers in a timely manner, according to Terry.

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

- ehealth: Personally accessing health records via the Internet
- Informed consent and re-consent
- Transitions in end-of-life care
- Improving communication in palliative care

Tricks such as not filing a claim with CMS until after the start of a new fiscal year won't work, warns Terry. "The calculations are not based upon the date the claim is received. They are based upon the dates on which services were provided," he says.

Staff members, not just marketers, should be included in discussions about the need for a variety of patients, says Terry. "Staff members are sources of referrals also because their friends and families are likely to choose the hospice because they know someone who works there," he says. "I was always very open with my staff about the reality of the hospice cap and how we could work together to avoid repayment demands." ■

CME QUESTIONS

1. What is the federal law that specifically protects the confidentiality of genetic information?
   A. Health Insurance Portability and Accountability Act (HIPAA)
   B. Genetic Information Nondiscrimination Act (GINA)
   C. Ethical, Legal and Social Issues (ELSI)
   D. All of the above

2. According to Cecelia Bellcross, PhD, MS, CGC, instructor/certified genetic counselor, Emory University School of Medicine, what is the concept of "genetic exceptionalism"?
   A. The question of whether genetic information should be treated any differently than other medical information.
   B. The question of whether healthcare information should be treated differently than other medical information.
   C. Tremendous strides will continue to be made in using genomic technology to improve human health.
   D. All of the above

3. What are the benefits of direct-to-consumer testing?
   A. The widely accessibility of tests to consumers
   B. Promotion of proactive genetic counseling
   C. Privacy of genetic information
   D. All of the above

4. Why did the U.S. Supreme Court determine that withholding medical treatment from those who are incarcerated as being cruel and unusual punishment, according to Richard Demme, MD, FACP, associate professor of medicine and humanities, chair, Ethics Committee, University of Rochester Medical Center?
   A. Because prisoners would have to pay for the healthcare themselves.
   B. Because prisoners are placed at the end of the UNOS list for transplants.
   C. Because prisoners are not allowed to seek healthcare for themselves.
   D. All of the above.