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Medical tourism: Ethical pitfalls of seeking health care overseas

Care provided in 'settings of exploitation'

A patient on a transplant waiting list learns she can quickly and less expensively obtain the organ she needs — in Thailand. Another person plans to go to Brazil for affordable plastic surgery. While both are legal, is either ethical? And should their American physicians encourage or discourage the practice of "medical tourism?"

Medical tourism, or traveling outside one's own country to obtain health care procedures, is not new. Some experts say it began hundreds of years ago, when wealthy Romans traveled to Germany and other countries to seek healing waters at spas; the modern version of medical tourism saw its first real boom when would-be parents in Europe began traveling to Italy and Belgium to obtain in-vitro fertilization and other assisted reproduction therapies that were either difficult or impossible to obtain in their home countries.

As health care has advanced and borders have opened in more and more countries, some developing nations have realized a huge profit to be made by funding hospitals and attracting international patients willing to pay for care.

Nathan Cortez, JD, assistant professor of law at Southern Methodist University in Dallas, has written on the subject of medical tourism, and says one of the great unknowns is how extensive the trend is. Reliable data on the number of American citizens traveling outside the country for medical care are not always easy to find, he points out.

Article reports on medical tourism

His forthcoming article in the *Indiana Law Journal*[1] states that in 2003, an estimated 350,000 patients from various countries traveled to Cuba, India, Jordan, Malaysia, Singapore, and Thailand for medical care. In 2006, more than 55,000 Americans visited Bumrungrad Hospital in Bangkok for medical care. The Confederation of Indian

Industry says that medical tourism in India alone is a $300 million business and could grow to $2 billion by 2012.

While it is legal for Americans to travel overseas for medical care, medical and legal experts say the ethics of the medical tourism phenomenon are murkier.

Traveling for transplants decried

Among the most desperate medical tourists are those in need of lifesaving organ transplants. That category of medical travel, according to transplant ethicists, is the least ethically defensible.

The Richmond, VA-based United Network for Organ Sharing (UNOS), which regulates and monitors organ donations and transplants in the United States, and the UNOS Ethics Committee recently restated the organization's condemnation of transplant tourism.

"It is the position of the Ethics Committee that participation in such a practice cannot be defended on ethical or current empirical grounds," the committee stated, with UNOS President **Sue McDiarmid**, MD, adding, "[W]e cannot condone a practice that fundamentally violates human rights and exploits human vulnerability."

Michael Shapiro, MD, FACS, chief of organ transplantation at Hackensack University Medical Center and a member of the UNOS ethics panel, says from an ethical point of view, "the biggest of the issues with transplant tourism is that, almost always, the tourism takes place in a setting of exploitation."

"We heard at the last UNOS ethics meeting [in September] that maybe the country of Columbia legitimately has an excess of deceased organ donors, and people are going there and getting on a [waiting] list, just as we allow foreigners to come to the United States and get on our deceased donor list," Shapiro says.

"But most transplant tourism to other countries is for living donors, and in those cases, the donors are almost without exception desperately poor; are never paid the market rate — if you can determine a market rate — for the organs; and are not getting first-world medical care either at the time of the donation or after their donations; and are probably not getting a true informed consent."

The UNOS Ethics Committee, in its statement to the UNOS board in September, said, "Transplant tourism typically operates in countries where the rule of law is absent, or incompletely enforced. The practice of transplant tourism, by design, manifestly undermines the ethical principle of non-malfeasance."

At a meeting of the World Health Organization on travel tourism in early 2007, attendees were told that in some villages in Pakistan, as many as half of the residents have only one kidney because they have sold the other as a transplant for a wealthy person, often from another country.

Until living donors receive the treatment and disclosure that we expect under American transplant rules, Shapiro says, "it's reasonable for us in the United States — and for the whole world community — to say, 'This is not an ethical practice.'"

So what do U.S. doctors say to patients who are badly in need of transplants and want to

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Accreditation agency keeps an eye on medical tourism

Safe travel practices protect patients, boost industry

Call it health care travel or medical tourism, international travel by people seeking medical procedures and therapies is big business, with estimates commonly in the neighborhood of $20 billion per year.

Such a booming enterprise encourages opportunity — and invites confusion and abuse, says the founder of a service that works to accredit overseas medical providers and provide potential travelers with accurate information.

Los Angeles-based nonprofit HealthCare Tourism International, launched in early 2006, aims to establish, improve, and maintain the reputation and safety of the health care tourism industry, according to co-CEO **Neilish Patel**.

"We want to help ensure safe tourism practices, and part of what that entails is a nonclinical accreditation system, with which we hope to improve the industry," says Patel. "It is complementary to what the Joint Commission International [JCI, the international accreditation arm of The Joint Commission] is doing with clinical accreditation."

When HealthCare Tourism International was creating its nonclinical accreditation system, Patel and co-CEO **Elliot Mendelsohn** dovetailed their agency's protocols with those of JCI.

"We address the components of health care travel that aren't addressed by JCI, which are often the nonclinical aspects of travel," Patel adds. Some of those aspects border on the clinical, however.

A patient who travels to India for surgery, for example, will have a recovery period after discharge from the hospital but before he or she can safely make the return trip home. HealthCare Tourism International accredits hotels that are equipped and staffed to house recovering patients — for example, staff members are trained in CPR and there is ready access to physicians if emergencies arise.

JCI has been accrediting hospitals worldwide since 1999. Accreditation standards for overseas providers are based on international consensus standards and set uniform, achievable expectations for structures, processes, and outcomes for hospitals. The accreditation process is designed to accommodate specific legal, religious, and cultural factors within a country.

Accreditation boosts credibility

HealthCare Tourism International also accredits agencies that book travel for patients.

"I think the typical service provider that applies for accreditation is the dot com that sets up to become a medical travel agent," Patel says. "They set up web sites and attract patients, and become travel agents — they put together the tickets, the housing, the transfers.

"Some of these travel agencies are springing up overnight, and they're trying to gain credibility and want to gain accreditation. We have a backlog of those companies wanting to apply for accreditation."

Accreditation protocols for providers and institutions offering medical care for international travelers also address ethical concerns that can arise with a growing, largely unregulated activity.

"With a booming industry, you find corruption, and our protocols aim to reduce that, to reduce things like kickbacks from physicians to medical travel agents who might be promoting the physicians without disclosing the relationship," says Patel. "We seek to minimize conflicts of interest, and we're finding that the health care tourism industry is being heavily regulated by other countries' ministries of tourism, not their ministries of health. That shows that, at least for now, it's more about the tourism than about the health care in some cases."

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travel overseas to get them?

"Certainly our recommendation is to dissuade people from doing it, and to point out that donors are being exploited. Frankly, some recipients respond to that, and some don't," says Shapiro. "I understand that. If my daughter needed a heart and couldn't get one, I might be less concerned about the ethical implications and more concerned about her life. But I don't think health professionals should recommend that their patients do that."

An even more likely scenario — and one that Shapiro himself has faced — is when a transplant surgeon's patient shows up in the emergency

department "with a huge gaping, infected wound" following an overseas transplant.

"What do you do when they go to Pakistan for an organ, and then show up in your ER saying, 'Here, take care of me?'" he asks. "Then you're stuck. We're physicians, and we're obligated to care for them in the emergency setting.

"That doesn't mean, however, that once the emergency is over you can't say, 'What you did was despicable, and I think you need to find another transplant professional.' Until they find another doctor, though, you're stuck with caring for them."

Shapiro says he doesn't see lots of patients who've traveled overseas for transplants, but there's a "steady trickle" of them. He expects that travelers to the worst offender, China — which was charged by international health bodies with essentially executing prisoners when matching donors were needed — will continue to be minimal, at least as long as pressure is on by the international community and the upcoming Olympic games keeps a spotlight on the country.

Some cases of transplant tourism are less ethically questionable, he says. In the case of foreign-born Americans with relatives in other countries, it is sometimes easier to travel to those countries to obtain matching transplants from relatives than to bring the relatives to the United States in the post-9/11 atmosphere.

Reasons for travel vary

Cortez says a physician's response to a patient who wants to travel overseas for medical care is probably determined by the facts of the case.

"Why is the patient going overseas? Is it a life-threatening problem that no one in the United States will pay for? Did they lose insurance coverage and are paying out of pocket?" Cortez asks. "Another thing to consider is the procedure itself. Is it something widely performed and medically acceptable, or is it a treatment that is banned by law or regulation or considered unethical in the United States?"

Cost, health care economists have written, is a driving force behind most medical tourism. Cortez writes that world health experts estimate a $10,000 knee replacement in the United States can be had for $1,500 in Hungary or India; a coronary artery bypass graft that costs $35,000 in the United States costs less than $9,000 in India or Thailand.

Another ethical consideration is patient autonomy: Does a patient's right to pursue a procedure in a place where it is not banned make it acceptable?

"The counter-argument is that we might not want patients leaving the United State to get morally or ethically questionable treatments in other countries, because the concern is that countries are offering more and more really dangerous, morally questionable procedures to attract patients — a 'race to the bottom,'" he suggests.

On the other hand, patients in the United States are finding that procedures that they can't afford here — joint surgery, neurological surgery, cosmetic surgery — can be affordably done overseas in hospitals that meet or exceed U.S. hospital standards, says Cortez.

"It's tricky for a U.S. physician if a patient asks if he or she should go overseas because you don't know if the hospital is reputable, with a U.S.-trained and accredited staff, or if it's a less reputable facility," he continues. "From a physician's perspective, he or she would be concerned that the patient is going overseas without fully appreciating the risks or the recovery period or aftercare." **(See "Accreditation agency keeping an eye on medical tourism," p. 123, for more on U.S. accreditation of foreign health care providers.)**

"If a patient asks for [his or her doctor's] opinion, it's really a crapshoot. From a lawyer's perspective, I would urge the patient to do his or her homework, but I would be hesitant to endorse a physician or facility unless I had specific knowledge of their quality."

If a physician is concerned that a patient's decision to travel overseas for care will result in complications that the doctor will then have to take care of when the patient returns, "the physician

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would probably be justified in trying to terminate the doctor-patient relationship," Cortez suggests.

Another developing layer to medical tourism is determining what recourse patients have if something goes wrong. Other countries' malpractice and liability courses are not like those in the United States, and can take years to navigate if there is, in fact, any recourse.

"Can you sue a foreign health care provider in a U.S. court? Can you sue the medical tourism brokers? Can you sue your doctor if he or she recommended a foreign provider?" says Cortez, adding that all are potential risks for traveling patients.

Neilish Patel, co-CEO of HealthCare Tourism International, a California-based nonprofit that accredits foreign health care providers and some travel brokers, says physicians in the United States are slow to warm to the idea of patients traveling abroad for care.

"Globalization in health care has hit so recently, and a lot of older, more traditional physicians and dentists believe patients should stay in local areas, and that health care should be a relationship-building modality," says Patel.

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Doctors at executions: The debate continues

16 states have executions on hold

In recent months, 16 of the 38 states that have the death penalty have put executions on hold, primarily over objections raised regarding the lethal injection method. At the center of the storm in several states are physicians caught between legislatures that require they be present at executions and ethical boundaries that demand they play no part in capital punishment.

"I think the problem is that once you start having medical people — physicians or nurses — directing the killing of a person, you start blurring the lines of what a medical provider should be doing," says **Jeffrey Uppington**, MBBS, professor of anesthesiology and vice chair of the department of anesthesiology and pain medicine at UC Davis Health System in Sacramento.

Generally regarded as unethical

Uppington, who serves as a spokesman for the American Society of Anesthesiology (ASA), says most state and national medical associations adhere to policies that mirror the ones set forth by the ASA and American Medical Association (AMA), both of which flatly reject the participation of physicians in the execution process.

According to the AMA, the only death penalty-related actions ethically acceptable for its member physicians are testifying as to mental competence at trial; certifying death after the condemned person has been declared dead by another; witnessing an execution in an unprofessional capacity; witnessing the execution at the request of the condemned, again in an unprofessional capacity; and relieving the acute suffering of a condemned person awaiting execution, including providing tranquilizers at the condemned's request.

Many states have built physician participation or attendance into their laws governing the death penalty, and the refusal of individual physicians and state medical boards to comply have led to some states having to temporarily halt executions. The North Carolina Superior Court recently ruled that that state's medical board overstepped its authority in threatening sanctions against physicians who participate in executions there.

The judge in the North Carolina case ruled that executions are not medical procedures, and therefore, the medical board has no say in the debate over whether executions are cruel and unusual.

"Although the current effort by the medical board to prohibit physician participation in executions may well be viewed as humane and noble, such a decision rests entirely with (elected officials)," the court's ruling stated. "As of this date, the legislature has taken no such action."

"Some states have medicalized executions, even having them take place in prisons' medical wings,

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to further sterilize the procedures," says Uppington.

Physicians, he says, have an ethical duty to avoid participation in executions. It wasn't long ago, he points out, that physicians participated in government-ordered procedures during the Nazi rule of Germany, and even more recently in the Tuskeegee venereal disease experiments; those memories linger in the minds of the public and of physicians.

Easing suffering or inflicting death?

In a 2006 article in the *New England Journal of Medicine*, a rarely heard voice was included — that of a Georgia physician, Carlo Musso, who agreed to be named and quoted as a physician who participates in lethal injections in his state.[1]

Musso related that he believes execution under statutory death penalty laws "is an end-of-life issue," and that his duty as a physician is to care for the condemned as a patient, in a humane way, to alleviate suffering and pain at the time of death.

However, Uppington takes exception to that opinion.

"The view that we are minimizing suffering is ethically flawed, because you shouldn't be there at all," he says. "You are assisting in the death of a person. That's not the role of a physician."

In the September 2007 issue of *Mayo Clinic Proceedings*, author **David Waisel**, MD, an anesthesiologist at Children's Hospital Boston, writes that the problems associated with lethal injection — pain, for example — are the reasons that the AMA should reassess its stand and allow doctors to participate so that the condemned have more humane deaths.[2]

But countering that commentary is an editorial in the same issue of the journal by **William Lanier**, MD, and **Keith Berge**, MD, anesthesiologists at Mayo Clinic, who say Hippocratic principles prohibit doctors from assisting in executions, and that the "theoretical good" of easing the process is outweighed by the harm of "causing the death of a person under a physician's care."[3]

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'Reasonable suspicion' in suspected child abuse cases

Ethicist seeks to quantify a non-specific concept

Health care providers are among groups ethically and legally obligated to report suspected child abuse. But does the wording of child abuse reporting laws create an ethical quandary for doctors who must decide for themselves the definitions of terms such as "reasonable suspicion" and "belief?"

"As clinicians, we live with the uncertainty of the diagnoses we make," explains **Benjamin H. Levi**, MD, PhD, FAAP, a philosopher and associate professor of humanities and pediatrics at Penn State University. "What's challenging is that unlike in clinical medicine, where there are accepted standards, guidelines, and evidence-based medicine, what my research — and that of others — has shown is that there is no standard for what the term 'reasonable suspicion' means."

That leaves it up to the individual who is mandated to report suspected abuse to decide for himself or herself what the standard is.

"I think it proves a heavy burden on people trying to figure out what they are supposed to do," Levi continues. "It asks us to use a screening test where we don't know the sensitivity or specificity of that test, and as a result, it does a poor job generating true positives when we report."

Levi has led several studies into clinicians' attitudes toward mandatory reporting and their interpretations of "reasonable suspicion" and "reasonable belief," and his findings may best be summed up by the conclusion drawn in one of the reports:

"Our data show significant variability in how pediatricians interpret reasonable suspicion, with a range of responses so broad as to question the assumption that the threshold for mandated reporting is understood, interpreted, or applied in a coherent and consistent manner" or "that any general consensus exists."[1]

Belief vs. known fact

Lawmakers nationwide generally have worded statutes on mandatory child abuse reporting vaguely, to encourage reporting of suspicions. Use of terms such as "suspicion" and "belief" rather than "knowledge" or "known fact" is a

protective measure that allows reporting of suspected child abuse without the presence of verified proof.

Some states require "belief," as in "I believe this child is being abused," while others use the term "suspicion," allowing the somewhat less-certain threshold of "I suspect this child is being abused."

Levi says that there is a problem with relying on "belief," in that "it involves holding an idea to be true, whereas in the context of mandated reporting, one is seldom sure that abuse occurred, but instead concerned that it might have."

All statutory thresholds on child abuse reporting fall under the legal umbrella of reasonable suspicion, Levi explains, and mandated reporters are told that they must report any time they reasonably suspect a child is being abused.

But what does "reasonable suspicion" mean? Levi maintains that it means something different to everyone, and there is too little definition given to allow a consistent application of the term.

For some, it can mean a fleeting notion that abuse might have occurred; to others, it may mean there is a significant indication that abuse has taken place.

For example, Levi's survey of more than 2,000 pediatricians found that 15% of respondents said that abuse would need to be better than 75% likely to qualify as reasonable suspicion; but a quarter of respondents set the threshold at a 60-70% likelihood, and another quarter set it at 40-50%. More than one-third (35%) set the threshold as low as 10-35% probability.[1]

"Classically, the idea of a belief is the holding of an idea to be true," he explains. "This, I think, is confusing for those states where the threshold for statutory language reporting is framed in terms of belief, because it sends a mixed message. On one hand, you supposed to believe what's true, and on the other hand, you're supposed to have a low bar for suspicion to report [potential abuse]."

The ethical dilemma that results is whether to suspend the notion of whether abuse is believed and report a suspicion of abuse — thereby perhaps making a report that proves to be unfounded, or to hold out for signs that lead one to believe abuse has occurred, and thereby perhaps not reporting suspicions that later prove to be true.

"Given the burden to families that investigations pose, it gives rise to injustice in terms of what our reporting does to families," he says, in addition to overburdening already taxed investigative and social services resources. On the other hand, under-reporting leads to the feared result of missing true abuse cases.

Adding to the problem, Levi says, is that there are so many groups of mandated reporters in the United States — as many as 70 million people — and all, from bus drivers to day care providers to doctors to teachers, are expected to be able to reach some sort of consensus on what the terms "reasonable suspicion" and "reasonable belief mean."

Despite the size of the group, Levi believes consensus is possible.

Quantifying suspicion

"I think you can create a consensus, and I think estimated probability is the way to go," he suggests. "People prefer to receive information about probability numerically."

For example, if police officers are told to ticket drivers who are going "too fast," without any speed limit to use as a basis, tickets would be issued for a broad range of speeds.

"If the law or policy set a numerical threshold, maybe 50% probability or 35% probability — and that's something that there would have to be agreement reached on — then reporters would be able to look at that number and decide whether their suspicion reaches that level of probability," he adds.

Critics of Levi's proposal say many people don't understand probability, but he disagrees.

"If people are told, 'There's a 75% chance of rain,' rather than, 'There's a likelihood of rain,' most would take umbrellas with them, because they understand the probability," he suggests.

Even if statutes were revised to include probabilities, Levi is quick to point out that reporters will not be able to always agree. But given a ballpark number to work with, "you'll get better agreement — not perfect, but better," he says.

Both practically and conceptually, significant problems arise from the current lack of direction on reporting, Levi says, including inconsistent

SOURCE

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reporting of possible abuse, unequal protection of children, inequitable treatment of parents, and inefficient use of child protection service resources.

"We owe it to people to be able to define that. I would argue it could violate due process, and it's bad for kids," he says.

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Vulnerable patients not at greater risk with legal PAS

Data in Oregon, Netherlands show no 'slippery slope'

It's a slippery slope say those who oppose legalizing physician-assisted suicide (PAS): Legalizing PAS will create disproportionate death rates among groups such as the elderly, uninsured, mentally ill, and poor. But a team of international ethicists say data don't support that concern.

A study of PAS in Oregon and the Netherlands showed that legalizing PAS did not result in a disproportionate number of deaths among the elderly, poor, women, minorities, uninsured, minors, chronically ill, less educated, or psychiatric patients, says **Margaret Battin**, PhD, a University of Utah bioethicist and professor of philosophy and internal medicine.

"Fears about the impact on vulnerable people have dominated debate about physician-assisted suicide," says Battin. "We find no evidence to support those fears where this practice already is legal."

The study found that of 10 patient groups studied, only AIDS patients used PAS at elevated rates.[1]

Is the slope slippery?

Battin and her colleagues sought to establish whether there is merit to the "slippery slope" argument, which has raised concern even among proponents of legalized PAS.

"Would these patients be pressured, manipulated, or forced to request or accept physician-assisted dying by overburdened family members, callous physicians, or institutions concerned about their own profits?" the researchers ask.

The researchers focused on two places where physicians can legally help patients end their lives: Oregon and the Netherlands.

Oregon is the only state in the United States where PAS is legal. The Death with Dignity Act was approved by voters in 1994 and 1997, and upheld by the U.S. Supreme Court in 2006. In the nine years following enactment of the law, 456 patients obtained lethal prescriptions from physicians, and 292 actually used the drugs to end their lives, accounting for 0.15% of all deaths in the state during that period.

The Netherlands enacted a law in 2002 allowing doctors to prescribe medication for suicide or to perform "voluntary active euthanasia," in which the physician, rather than the patient, administers life-ending medication. Unlike Oregon's law, the Dutch PAS law does not require that the patient be diagnosed with a terminal illness, but must be facing "intolerable suffering." Battin and her colleagues found that of 136,000 deaths annually in the Netherlands, about 1.7% are by voluntary active euthanasia, 0.1% by PAS, and 0.4% are what researchers called "extralegal" because they involve patients who did not make a request to die at the time of their deaths, but either made requests before losing competence or were deemed by surrogates to be "suffering intolerably."

The researchers noted that in both Oregon and the Netherlands, people who received a doctor's help in dying averaged 70 years old, and 80% were cancer patients.

Underprivileged not the majority

The researchers divided their findings into three categories:

- Direct evidence that elderly people, women, and the uninsured do not die in disproportionate numbers where PAS is legal, but AIDS patients do. (The insurance data apply only to Oregon; all

SOURCE

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citizens of the Netherlands are insured.)

• Direct and inferred evidence that PAS does not kill disproportionate numbers of people who are poor, uneducated, racial and ethnic minorities, minors, or people with chronic physical or mental disabilities or chronic but not terminal illnesses.

• Inferred and sometimes contested evidence that shows people with psychiatric illness — including depression and Alzheimer's disease — are not likely to die in lopsided numbers.

"Those who received physician-assisted dying … appeared to enjoy comparative social, economic, educational, professional, and other privileges," the researchers write.

Of AIDS patients who died in Oregon in the nine years following the passage of the Death with Dignity Act, six died with the assistance of physicians, 2% of all PAS deaths during that time. But AIDS patients were 30 times more likely to take advantage of the PAS law than non-AIDS patients who died of chronic respiratory disorders, Battin reports.

"We've known for a long time from studies elsewhere that rates of assisted dying outside the law were much higher in people with AIDS," particularly in areas with large, supportive gay communities such as San Francisco, Battin says. "It's not a surprise to find high rates where physician-assisted dying is legal.

"We found no evidence to justify the grave and important concern often expressed about the potential for abuse."

The report on the study is available on-line at http://press.psprings.co.uk/jme/october/591_me22335.pdf.

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Should Bibles be available in all patients' rooms?

Minister leaves hospital after objecting

A chaplain who recently resigned from her post at Peninsula Regional Medical Center in Salisbury, MD, said her resignation was requested by the hospital after she tried to end a policy permitting The Gideons missionary organization to deliver Bibles to all hospital patients.

Kay Myers, PhD, a Presbyterian minister who headed the hospital's chaplaincy program, told the *Salisbury Daily Times* that she was concerned not only with keeping the chaplaincy non-sectarian (the Bibles contained only the New Testament), but also feared that allowing The Gideons access to patients violated privacy regulations set out by the Health Insurance Portability and Accountability Act (HIPAA).

Myers told local media that she objected to one religion — in this case, Christianity — receiving preferential treatment over other religions. When she proposed removing Bibles from rooms and making all religious texts available upon request, she was asked for her resignation, Myers says.

A spokesman for Peninsula Regional Medical Center said the hospital does not comment on personnel issues.

J. Vincent Guss Jr., MDiv, a pastoral care and bioethics consultant in Alexandria, VA, and advocacy commissioner for the Association of Professional Chaplains, says he agrees in principle with Myers that all faith groups should be treated with parity, and that making one religion's sacred text readily available could be interpreted as promoting one faith over another.

"However, I believe that one can be too legalistic in implementation of that general principle, especially if other religions' sacred texts are also available upon request, as they should be," says Guss.

He adds that "there are other, more important ethical concerns where the spiritual dimensions of health care are not being adequately addressed by hospitals and health care practices for people of all — or no — faith groups."

Guss recounts that at a hospital where he directed the pastoral care program until recently, he initiated a program where Gideons-provided Bibles would be placed in patients' rooms, but he told The Gideons that the hospital would only accept Bibles that included both Old and New Testaments, thus including texts sacred to both Jews and Christians.

"It would be impractical to try to stock each patient's nightstand with every sacred text of every religion. Having Bibles readily available, especially when provided by an outside group as a gift instead of the secular hospital itself and when there is a note attached indicating other

religions' sacred texts are available through the hospital chaplain, can add to the healing environment hospitals should create." ■

Research, ethics need close collaboration

Ethics need not be a barrier to research, ethicist says

Research ethics is seen as a nuisance at best, an impediment to progress at worst, says a Cornell University medical ethicist, who adds that a closer collaboration between researchers and ethicists might lead to a change in that perception.

"While clinical ethics has become a central and welcome component of the health care landscape, many still view research ethics as a nuisance to investigators and an obstacle to science," says **Inmaculada de Melo-Martin**, PhD, MS, associate professor of public health in the division of medical ethics at New York's Weill Cornell Medical College.

De Melo-Martin says hospitals and medical centers can foster a culture of ethics in their research programs by insisting on collaboration between researchers and ethicists from the early stages of research. In a recently published paper,[1] she describes the establishment of Weill Cornell's research ethics consultation service.

Going beyond IRBs

Institutional review boards (IRBs) are the public face of research ethics, but de Melo-Martin says IRBs and other similar oversight mechanisms that protect human research subjects take a "regulatory approach" that, while necessary, does not delve deeply into ethical analysis. Relying on this regulatory approach alone underemphasizes the ethical concerns that accompany medical research and create a false sense that merely following regulations is enough to achieve ethically responsible research.

"As recent public debates about conflicts of interest, exploitation of human subjects, and scientific fraud remind us, ethical problems arise within research contexts," she points out.

On the other hand, a research ethics consultation service that can identify ethical problems and issues while a research study is still in development and continue throughout the research process can help researchers understand and work out potential ethical quandaries.

"It is becoming increasingly clear that collaborations between investigators and research ethicists are as essential as those between physicians

CME Questions

17. Which of the following could be considered an ethical response by a physician whose patient is considering travel overseas to receive an organ transplant?
A. An explanation of the exploitation of third-world organ donors.
B. A caution on the risks of operative and post-operative complications at an unfamiliar facility.
C. Notice that the physician's ethical concerns require him to end the doctor-patient relationship with that person.
D. All of the above

18. The American Medical Association bars any physician involvement with a condemned prisoner, including relieving the acute suffering of a person awaiting execution by providing tranquilizers.
A. True
B. False

19. Levi et al, in studies of pediatricians' attitudes toward mandated reporting of child abuse, conclude that mandated reporters have difficulty reaching consensus on:
A. what child abuse is.
B. who abusers are.
C. what constitutes reasonable suspicion.
D. what steps to take when abuse is suspected.

20. In a recent University of Utah-led study of the "slippery slope" effect of legalized physician-assisted suicide, which vulnerable population group was the only one that demonstrated an increased death rate from suicide?
A. AIDS patients
B. mentally handicapped
C. elderly
D. chronically ill

CME answers

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

SOURCE

For more information, contact:

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and clinical ethicists," according to **Joseph J. Fins**, MD, FACP, chief of Weill Cornell's Division of Medical Ethics and director of the Weill Cornell Research Ethics Consultation Service. "Promoting research integrity needs to go beyond regulation — it has to be integrated into the fabric of scientific research."

Institutions that encourage collaboration between ethicists and researchers can promote an environment "that encourages critical reflection on all aspects of research," Fins adds.

The Weill Cornell Research Ethics Consultation Service is composed of faculty in the division of medical ethics, and represents the college's attempt to create a non-regulatory approach to research ethics. Similar to ethics consultations in the clinical setting, research ethics consults are non-confrontational and non-punitive, de Melo-Martin explains.

The service is provided free of charge to Weill Cornell individual investigators and research teams prior to submission of research protocols to their IRB and throughout the course of the studies. This service does not duplicate IRB efforts, de Melo-Martin says, but complements them.

Researchers request research ethics consultations through the college's Institute for Clinical Research (ICR), which assists investigators in the development, negotiation, and completion of the contract process for all clinical trials. The research ethics consultation is now a formal part of the process of the ICR.

More details about the services offered and contact information is available on the ICR web site at www.med.cornell.edu/icr/resources_and_services/bioethics.html, and at the Medical Ethics Division web site, www.med.cornell.edu/public.health/ethics/index.html.

Reference

1. de Melo-Martin I, Palmer LI, Fins JJ. Developing a research ethics consultation service to foster responsive and responsible clinical research. *Acad Med* 2007;82:900-904. ■

CME instructions

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

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

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

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

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- Spiritual assessments and outcomes
- First for-profit med school opens in '08
- Ending a doctor-patient relationship
- Allowing families to witness trauma care

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