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OCTOBER 2006
VOL. 22, NO. 10 • (pages 109-120)

What are your ethical obligations when it comes to alternative medicine?

Being honest about what you do — and don't — know is crucial

One of your patients is undergoing chemotherapy for cancer and is struggling with severe nausea. She tells you she wants to add acupuncture to her regimen of care; you have never been convinced that acupuncture provides benefits. What is your duty to the patient?

"The doctor at least needs to take the patient's questions seriously," says **Dónal P. O'Mathúna,** MA, PhD, lecturer in health care ethics at Dublin City University School of Nursing (Ireland) and a frequent author on complementary and alternative medicine (CAM). "I think the days are behind us when a doctor dismissed a patient who has questions about herbal remedies, hopefully."

But when the issue of CAM therapy is raised by a patient or in the literature that applies to that physician's practice, the normally clear duty of the physician to direct patients to treatments that are known to be effective and to advise them against those that are useless or harmful can suddenly appear not so clear. Finding scientific evidence of the benefits and contraindications of CAM therapies can be a challenge, but patients usually expect their physicians to know more than they do about the CAM treatments they've read about.

In some cases, it is not only preferable but essential that the physician be completely honest with the patient about his or her knowledge of the therapy being discussed, O'Mathúna says.

"This issue has to do with the area of evidence [that exists about CAM] and the relationship the physician has with his or her patients, in that a patient coming to the doctor is expecting the doctor to provide reliable, substantiatable advice," he explains. "I think the doctor then needs to communicate exactly where he or she is coming from when it comes to alternative therapies and needs to make clear if they don't know about it."

Often, there's a middle ground, O'Mathúna points out, where the physician might have some training in herbal remedies, but because

of the vast landscape of CAM and little research on many remedies, their effects, and side effects, does not feel well-versed on the subject.

"He or she can say, 'I have done some training in herbal remedies, but there's a whole host of other things I'm not sure about,' or that he or she is somewhat familiar with these things, and suggest that they talk about it," he continues. "Let the patient know just what [the physician] knows about it, without discouraging or encouraging at that point."

A report issued by the National Center for Complementary and Alternative Medicine (NCCAM), part of the National Institutes of Health, showed that in the United States in 2004, 36% of adults were using some form of CAM. When megavitamin therapy and prayer specifically for health reasons were included in the definition of CAM, that number rose to 62%. CAM, the report indicates, is more mainstream for Americans than many traditional practitioners realized.

CAM often used as complementary therapy

The NCCAM survey revealed that most people use CAM as a complement to, rather than an alternative to, conventional medicine. The results also showed:

- CAM use is greatest among women; people with higher educational levels; people who have been hospitalized within the past year; and former smokers.
- Prayer specifically for health reasons was the most commonly used CAM therapy.
- When prayer is included in the definition of CAM, mind/body medicine is the most commonly used domain (53%). When prayer is not included, biologically based therapies (22%) are more popular than mind/body medicine (17%).
- Most people who use CAM are self-treaters — only about 12% of respondents sought care from a licensed CAM practitioner.
- Americans are most likely to use CAM for back, neck, head, or joint aches, or other painful conditions; colds; anxiety or depression; gastrointestinal disorders; or sleeping problems.
- Those who use CAM said they did so because they hoped it would improve results when used in combination with traditional treatment (55%); because conventional medicine was not working (28%); their doctor recommended it (26%); or because conventional medicine was too expensive (13%).

Acknowledging the findings of the NCCAM, the American Medical Association (AMA) House of Delegates in June adopted a resolution encouraging physicians to increase their awareness of the benefits and risks associated with CAM. The AMA resolution calls for the incorporation of CAM in medical education, as well as continuing medical education curricula, covering its benefits, risks, and efficacy.

"This whole field is very broad, so patients can't always expect an answer of 'good' or 'bad,' because there is such a broad range of therapies," O'Mathúna points out. Some have side effects, some don't; some help one condition in one

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Medical Ethics Advisor**®, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $499. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. **Back issues**, when available, are $83 each. (GST registration number R128870672.)

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patient but not in another.

"I would think there is a responsibility among doctors to have some basic awareness of the most popular remedies and therapies for the specific conditions that they see. If a doctor is treating arthritis patients, then he or she should know the common herbal remedies or dietary supplements [popular for that condition]."

A physician whose patient is considering CAM should make it clear that he or she is open to dialogue about CAM, says O'Mathúna, not just to ensure the patient retains a sense of autonomy, but also because the doctor can learn much about why the patient is interested in CAM.

"They might be asking about herbal remedies because they can't afford traditional prescription medications," he suggests. "Or the doctor might find out that the patient is highly anxious about their treatment, and that's interfering with their general well-being."

Protect your patients, yourself

Physicians who practice allopathic medicine often know something about the most common CAM therapies used in their specialties — herbs and vitamins that aid in controlling side effects of chemotherapy, for example, or that are commonly used to ease joint pain in arthritic patients. If they don't, they should, says an expert on legal liability and CAM.

Michael Cohen, a Cambridge, MA-based attorney who specializes in medico-legal aspects of CAM, advises that physicians read up on alternative and complementary therapies that their patients might approach them about or that they might reasonably recommend.

"It is not difficult to search the Cochrane Collaboration, Medline, and other databases to find the literature," says Cohen, who has written and co-authored several papers on ethics, law, and CAM. "The best protection is to ensure that the patient is not harmed directly by the CAM therapy and not harmed indirectly by being diverted from a necessary conventional treatment."

One of the biggest problems, physicians say, is the lack of solid information that is available about CAM remedies, especially compared to the wealth of scientific information and clinical trial results available on traditional therapies.

"It puts the doctor in a very awkward situation," says O'Mathúna.

If a literature search shows that little to no information is known about a particular CAM remedy, that fact should be made clear to patients. If information is available, O'Mathúna says, the physician should take care to explain what kind of information it is — for example, if it is information derived from clinical trials, or more commonly, information that is anecdotal and testimonial.

If the patient insists on a therapy for which no evidence of benefit exists, or, even worse, if evidence of potential harm has been shown, Cohen advises physicians to inform the patient of potential risks and to have a thorough discussion in an attempt to dissuade the patient from a harmful therapy.

"In the end, the patient must make an autonomous choice," Cohen says. "Rather than abandon care, the physician who can no longer continue treating the patient in this situation should refer to a physician who can ably care for the patient."

In a 2002 *Annals of Internal Medicine* article[1], Cohen and his co-authors explored the dilemma of giving patients sound advice when information for making such advice can be sparse. While doctors should counsel patients in a way that respects the patients' values, the authors wrote, "Physicians should not violate their own values in the process of responding to a patient's needs or abandon the practice of evidence-based medicine in order to provide support for their patients' beliefs."

Informed consent becomes an area of uncertainty when CAM therapies are involved.

SOURCES/RESOURCES

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O'Mathúna points out that besides there often being little scientific evidence with which to inform the patient's decision, other factors, such as religion, also come into play.

Prayer and prayer-based therapies are among the remedies included in under the CAM umbrella. If a CAM therapy under consideration has a religious or spiritual component, O'Mathúna says some patients might not want to receive the therapy if the religious component differs from their own beliefs, and so that aspect of the remedy should be clearly disclosed.

Informed consent and CAM

Despite the dearth of clinical research into some alternative and complementary therapies, Cohen says, physicians can meet informed consent obligations by advising patients of CAM therapy for which there is information of safety and efficacy; clearly delineating known and potential risks; and explaining the benefits and risks of combining conventional and CAM therapy.

When the patient is a child whose parents are considering CAM, or if the child is being treated for a condition for which herbal or other alternative therapies are popular, the physician should exercise caution, O'Mathúna continues.

"There is almost no information available for pediatric patients, and as physicians know well, you don't just give pediatric patients lower doses of adult medications," he says. "In terms of herbal remedies, people's perception is that you just take less for a child, and for many of these [CAMs], we don't know how it will affect the less-developed system of a child. There has been very little research done with children."

Finally, questions about use of herbal, vitamin, and other alternative remedies should be part of any clinician's history-taking, experts recommend. CAMs that are benign on their own can have serious interactions when combined with other therapies; O'Mathúna points to cases of surgery patients who experienced unexplained bleeding that was traced back to use of supplements or herbal remedies.

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Making hospital-acquired infection rates transparent

Hospitals have an ethical obligation to release data

The push to make hospital infection rates more transparent is, on its face, an institutional and a patient safety issue. But there also is an ethics component, experts say, and health care has a duty to inform the public on hospital-acquired infections and to put that information in perspective so that it is not misleading.

At a March hearing before a U.S. House Committee on Energy and Commerce subcommittee, members of congress warned the Centers for Disease Control and Prevention (CDC) that cuts in federal funding could loom for hospitals that fail to get their infection rates under control. And more and more states are legislating that hospitals disclose their infection rates — a trend that one ethicist says should be greeted with a mixture of support and caution.

Hospitals do need to be transparent, says **Lauris C. Kaldjian**, MD, PhD, director of the University of Iowa Carver College of Medicine program in biomedical ethics and medical humanities. However, that transparency needs to render information that is useful to prospective patients, not simply numbers without context.

"How do patients calculate the importance [of the data on infection rates]?" he asks. "If one is going to refer to metrics, they should refer to ones that are the most useful."

Report infection rates same as medical errors?

Pennsylvania was the first state to adopt a law mandating reporting of infection rates, and the director of the Pennsylvania Health Care Cost Containment Council (PHC4) says the state's data show patients who acquire an infection while they are hospitalized are five times more likely to die than patients who avoid hospital-acquired infections.

Letting a community know that about its hospitals is very much an ethical issue, says PHC4's executive director, **Marc Volavka.**

"I am a strong believer in transparency," says Volavka, who likens reporting infection rates to being truthful in disclosing medical errors.

"In that context, from my perspective and [PHC4's] perspective, it is an ethical issue to some important degree," he suggests. "It is a component to what is right and ethical about letting patients know what is occurring in the hospital setting."

Kaldjian agrees that a community deserves transparency in infection reporting but says that is only part of the equation.

"This has been much discussed, back as far as [New York hospitals] reporting cardiothoracic surgery outcomes," he says. "Where do we draw a line between possible complications and medical error? That implies that [the event being disclosed] was preventable."

Because infections are one of the risks inherent in "puncturing, invading, and treating" a human body, Kaldjian points out, many infections are complications of necessary care and not the result of medical error or careless practices.

"These processes are necessary, but every time you invade the human body, you are creating a transit route," he says. "Through our best practices and standards of care, we try to limit the likelihood that bacteria will travel through those routes and cause infections that result in disease and illness, but we know that's a possibility."

Providing context for the numbers

That is the kind of contextual information that should accompany disclosure of infection rates, for the numbers to mean anything useful to patients, Kaldjian says. Only if a hospital had "all the money in the world and all the resources in the world" could it hope to limit iatrogenic infections, he suggests; but still, simply releasing numbers of cases without educating consumers might suggest that infection rates are completely controllable.

Another question is, how many cases are too many?

"Is there a rate of infection that is the gold standard?" Kaldjian asks. "That line has to be taken very seriously and addressed."

Other points to consider include how many categories of infection should be communicated to patients and how best to help patients calculate the importance of the information, Kaldjian adds.

For example, if the best brain surgeon on the West Coast is at a hospital with only average infection control rates, would patients deprive themselves of the stellar care that a surgeon could provide and opt instead for less-skilled care at a facility that has better infection control numbers?

"How do patients calculate the importance of the information?" Kaldjian asks. "If you are going to refer to metrics, you need to refer to the ones that are most useful."

Infection control — a new advertising tool

With transparency of hospital-acquired infection comes the inevitable ads claiming "best infection control rate in the region."

Kaldjian says the hospitals that choose to be most transparent in their disclosures could be "rewarded" by their transparency being used against them, with competitors using the information as a tool for their own gain.

"When I think about this issue, I think about two principles: transparency and justice," he explains. "In health care, we should not have anything to hide, and if we're inclined to hide things, then we need to question ourselves. And it's a matter of justice in that hospitals that are better about collecting and reporting their data should not be penalized for that."

Volavka says hospitals that are straightforward with their patient populations about infection rates are likely to find that transparency boosts patient confidence rather than undercutting it.

"The Veterans Administration has found this out, because it has been most prominent in taking

SOURCES/RESOURCES

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a different tack than others when it comes to medical error disclosure," he says. "What they have found is that patients want straightforward, honest answers, and that when that happens, they are not as likely to sue."

Volavka recounts being on a radio talk show recently. When he spoke about reporting infection rates, callers vented frustration about the lack of transparency, and those who had had first-hand experience with a hospital-acquired infection simply wanted straightforward answers and a demonstration of what the hospital was planning to do to prevent recurrences.

"I think the provider community, in broad terms, would be better served by being more transparent," he says. "But public reporting still has its skeptics. Our experience has been that public accountability brings focus on providers to improve, and the knowledge of public accountability has spurred the provider community to engage in quality improvement efforts."

Volavka agrees that, often, infections contracted in the hospital are the consequence of necessary procedures, but that simple and effective means of prevention can curb infection rates when rigorously observed.

Kaldjian has this to offer as a starting point for hospital administrators debating whether to support transparency in reporting infection rates:

"If an administrator needed medical care and leaned toward not receiving care from his or her own institution due to insider knowledge about infection or error rates, that would be a pretty straightforward test of whether or not that information should be disclosed to the public." ■

When patients ask you to hasten death, look closer

Most fears can be calmed with open discussion

For various reasons — pain, fear, or control — patients sometimes consider ending their lives; occasionally, they even ask their doctors for help. But ethicists say, before responding to the question as asked, physicians first should look at what might be going on behind the question.

First of all, nurses who care for the dying say intractable pain is not always the reason that requests for hastened death arise, according to one study.

According to hospice nurses whose experiences were reported in a 2003 *New England Journal of Medicine* article,[1] patients chose to stop eating and drinking for reasons that included being ready to die, the belief that continuing to live was pointless, and a sense of poor quality of life, as well as wanting to control the manner of death. Unbearable physical suffering did not appear to be an important reason for patients choosing suicide.

"I don't know the exact number, but I can tell you that requests for hastened death are not very common," says **Christina Puchalski,** MD, MS, founder and director of the George Washington Institute for Spirituality and Health (GWISH), and author of "A Time for Listening and Caring: Spirituality and the Care of the Chronically Ill and Dying."

"I find the request comes out of a deep fear of the unknown, and when patients find out that most of what they're fearful of can be handled, they don't have that fear anymore."

Honesty, clear answers douse fears

Puchalski, who says she would not feel comfortable participating in a physician-assisted suicide, says when people talk about patients wanting to hasten death, they sometimes are lumping in anecdotes of patients in terminal pain asking that their morphine levels be increased to a point of terminal sedation.

"That's not the same thing," she says.

But physicians should also counsel patients who ask for terminal sedation, Puchalski suggests, because they might not truly want to miss the time they have left — and she knows this from experience.

When her fiancé was dying of cancer more than a decade ago, he told her that he planned to

SOURCE

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stockpile medications (he, too, was a physician) so that he could end his life when he decided it was time.

"I was very upset about that, but it was out of my hands," she says now. "On the evening he died, I said, 'Eric, you can ask for morphine to help calm your breathing,' but he said no, that he wanted to be alert for this moment. So really, nobody knows how they'll feel about death until they get there."

There are things that physicians and nurses who work in hospice can do to help a patient who asks for a hastened death to have a clearer idea of what to expect.

"I explain what hospice is to begin with, to get to what the issues are and get to what they're fearful of," Puchalski says. "And usually, when I explain what hospice is, they don't have that fear anymore."

When patients are facing death, in addition to fearing death itself, they often are gripped with worries about their loved ones, questions about life after death, concerns that they will feel they are choking, suffocating, or in terrible pain, she adds.

"Dying is not easy, but being born is not easy, either," says Puchalski. "In our culture, there's a sense that if you can't participate fully in life anymore, to just put yourself out of your misery.

"But what is needed is a reframing, that dying is a natural part of life, and that dying is not a medical problem. It's a natural, sacred part of people's lives, a time of a lot of richness and for significant relationships."

When possible, the patient, physician, and family should have discussions about dying, hospice, and care options long before death is imminent. If assisted suicide is brought up, the physician should be as clear and specific as possible about what he or she is able to do for the patient, as well as any personal principles that apply.

Infrequently, physicians and patients find they cannot agree on key issues surrounding medicine's role in the process of dying. Even the idea of conscious sedation has a duality about it — the patient's pain is muted by unconsciousness, yet the patient does not die from the sedation (except in occasional cases); the patient is pain-free, but is unable to experience the "issues" involved in dying, Puchalski adds.

"We need to have more conversations with patients and talk with people about what's going on," she says. "There's a lot we can help people with. We can talk to them about their unfinished dreams, about what they want to finish.

"It's how you are living while you're dying that gives life meaning."

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Dealing with unpleasant patients? Be understanding

Suggestions for unpleasant encounters

Given enough experience and patience, a physician can become adept at dealing with patients who they find noncompliant or overly demanding. But how does a clinician deal with a patient he or she finds utterly intolerable to be around — someone who is abusive, insulting, or completely unlikable?

The first thing the doctor should do, experts agree, is nothing.

"Before you say anything, it is best to try to understand this person rather than simply react," suggests **John Banja**, PhD, assistant director for health sciences and clinical ethics at Atlanta-based Emory University's Center for Ethics.

Adhering to your role, experts say, rather than reacting to the unpleasant behavior or mannerism, is also important.

"[T]here are specified minimum behaviors that are required in treating every patient in every circumstance. They are the sorts of things that all health professionals do for every patient when acting as care providers," **Paul J. Reitemeier,** PhD, a member of the National Ethics Committee of the Veterans Health Administration (VHA), explained at a 2001 VHA ethics conference.

Even brief encounters unpleasant

Health care providers usually think patients are "difficult" when they refuse to comply with care recommendations, miss appointments, and are otherwise at odds with their physicians. However, there are those who might be compliant with care but who are verbally or physically

abusive, use vulgar or profane language, espouse beliefs morally repugnant to the physician; ignore personal hygiene, or have committed acts or crimes that lead the physician to have a deep, personal dislike of the person.

Developing a dislike for an uncooperative patient seen in a primary care setting or in the course of treating a chronic disease requires the physician to decide how he or she can best work, long term, with that patient, or, in the worst cases, how to arrange for the patient to transfer to another physician.

For a hospitalist or emergency medicine physician, however, encountering an unpleasant, abusive, or otherwise difficult patient means figuring out how best to deal with the patient knowing that this might be the only encounter with that person — in short, how to briefly tolerate an intolerable patient.

The first step, suggests hospital pastoral care director **Vincent Guss**, MDiv, is to try understanding who the patient is and what might be leading to the behavior.

"If a colleague on the health care team approached me in regard to a patient that person did not like based on their behavior or beliefs, I would suggest that this professional try to discern the interpersonal and intrapersonal dynamics with that [patient]," including cultural and personal elements that might be influencing how the patient is behaving and relating to the health care team, he says.

Then, Guss suggests, "exercise a level of empathy to whatever degree might be possible, balancing that approach with a dispassionate professional commitment to holistic care for the patient's total health and wholeness."

Guss and others readily concede that such understanding and dispassion won't always come easily when a patient is testing a doctor's limits.

Nancy Berlinger, PhD, MDiv, deputy director of The Hastings Center, advises that before addressing what the physician deems noncompliant or difficult behavior, he or she examine those labels.

"Watch out for that word 'noncompliant,'" she says. "As physician and medical anthropologist Arthur Kleinman says, this word implies moral hegemony: I'm right, you're wrong. The provider is the one who is allowed to use it — is it being used to conceal dislike, distrust, or broken-down communications? Is the provider willing to take the time to find out why a patient will not or cannot follow a treatment plan?"

Prompts for communication

Emory's Banja says that when the physician is able to set aside his or her personal feelings about the patient, information might surface that explains the behavior. He suggests asking the following questions to establish some empathy for the patient:

- "So, this must be very (difficult, sad, frustrating, etc.) for you."
- "You just said X. Tell me more about that."
- "So, what you're saying is that..."
- "Tell me what you've been told so far."
- "You are obviously very (angry, upset, etc.) — tell me what is happening with you right now."

"If you ask a 'why' question ('Tell me why you are so upset'), follow with a reframing statement, [such as] 'Oh, so you're saying that ...,' and, if appropriate, say, 'Well, no *wonder* you feel that way,'" Banja adds. "Expressing an observation like, 'Mr. Jones, I have a feeling that you are even (angrier/sadder/more depressed, etc.) than you are letting on' at the right moment can release a floodgate of tears, which is often quite cathartic."

Addressing how the patient must be feeling causes the patient to focus on — rather than feel

SOURCES

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- **Cynda Hylton Rushton,** PhD, RN, FAAN, clinical nurse specialist in ethics, Johns Hopkins Children's Center, Baltimore, MD.

— the emotion, Banja says, which can calm the patient because it replaces an emotional experience with an intellectual one.

The worst of the worst are still patients

David Schiedermayer, MD, a physician, author, and poet, draws on his experiences as a hospitalist when writing. In "Causing Pain," a poem published in 1996, he described how treating a man accused of rape and murder made him feel:

"So the challenge is
to place the last stitch
like I have many times before
with many apologies
and not enjoy the small pain it causes
in this particular patient."[1]

While not every physician encounters someone whose actions rise to the level of the patient Schiedermayer describes, most will find themselves treating patients whose behavior or demeanor makes it difficult to stay focused and objective.

Dealing with difficult patient situations is a skill that comes with experience, and Berlinger suggests drawing on coworkers who are good at it.

"Ally yourself with colleagues who are good at preventing or resolving conflicts," she advises. "Physicians can learn a lot from chaplains about how to talk with patients with different beliefs, how to use body language to de-stress a situation — start by uncrossing your arms — and so on."

But Berlinger points out that sometimes, a situation is beyond what a particular physician can or should endure.

Seek help when situation demands it

"You are not ethically obligated to accommodate behaviors and beliefs that are harmful to your patient, other patients, or providers, including yourself," she says. "When a situation goes beyond 'I don't like this patient or his/her beliefs' to 'I think his/her beliefs are putting this patient or others at risk,' it's time to call for an ethics consult."

Despite a clinician's best efforts and intentions, sometimes a patient/physician relationship, no matter how longstanding or brief, needs to end. Berlinger says handling such situations candidly and respectfully, even if the patient is neither, is called for.

When a patient is being "downright nasty," Banja advises telling him or her calmly and without anger, "I hope you will believe me when I say that I and the nurses want to help you. However, when you say things like XXXX, that makes it very hard for us to want to help you."

"Remember that lots of these difficult people are beyond fact and reason," he says. "For some of them, no technique, other than being as polite and as comforting as you can be, will work, and even then, their behavior might persist."

The ethically appropriate response in these cases, says Reitemeier, is "to keep the big picture in mind and become resourceful."

Drawing on intermediaries or hospital resources such as psychiatric or social work consultants can help the provider avoid a situation so deteriorated that the patient receives sub-par treatment.

Guss advises that using the entire multidisciplinary team can assist in getting the patient cared for in spite of his or her repellent behavior, as well as provide a sounding board for the physicians and nurses involved in direct care of the patient.

"Often, this process leads to the quality of compassion and greater empathy, with an increased ability to put oneself in the shoes of the patient," Guss adds.

Cynda Hylton Rushton, PhD, RN, FAAN, an associate professor of nursing who serves as program director for the Baltimore-based Harriet Lane Compassionate Care Program, says the feelings encountered by the physician or nurse might be as much about the clinician as about the patient.

"I would ask, 'What part of my own personal history does this patient/family ignite in me? Is my response to the behavior in proportion to the situation? What behaviors am I noticing in myself or other members of the team in response to this patient? What is the nature of the distress I am experiencing — it is disrespectful behavior, nonadherence, abusive behavior, moral distress?'" she suggests.

"You may not change the person or their behavior, but you certainly can adjust your own response to them. Often we see these types of situations being a huge emotional and spiritual drain on the team and the patient/family. Creating clear boundaries and putting in place an understanding about the norms of acceptable behavior are necessary, coupled with ongoing support for those who are interacting with the person regularly."

And while worst-case scenarios might make transfer of the patient a necessary consideration, abandonment is not an option, Rushton emphasizes.

"There are some — a small number — of cases where these efforts will not resolve the situation and there may be justification for transferring the patient elsewhere if a therapeutic alliance cannot be established," she concedes. "That said, we are not at liberty to abandon patients merely on the basis that we dislike certain behaviors or characteristics."

Reference

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Ethics stifling research? Some Britons say 'yes'

Delays in American trials over bad science

Some researchers in the UK have renewed debate over the limits placed on medical research by ethics regulations, saying ethical red tape is "stifling" advances in medicine. But ethicists in the United States say the argument is nothing new and that the review process for clinical trials protects both human subjects and research.

Clinical researchers at Britain's Leeds University wrote in the August issue of *British Medical Journal* that oppressive paperwork, restrictions barring approaching subjects who haven't previously opted in to being test subjects, and stifling rulings by ethics committees have deterred researchers and stopped trials before they even begin.

SOURCES

For more information:

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The United States does not have identical "opt in" requirements, but restrictions and delays, particularly when it comes to trial reviews by institutional review boards (IRBs), often draw criticism from researchers. But, research ethicists say clinical trials in general in this country are not often thwarted by ethical requirements or fears of risks to trial participants.

"I've never seen a protocol rejected by an IRB simply because it carried risk," says **Kenneth A. Richman,** PhD, associate professor of philosophy and health care ethics at Massachusetts College of Pharmacy and Health Sciences in Boston. "The main issue is whether the risk is worth it. Primarily, protocols are rejected when the science isn't good."

Slow process not due to ethical restrictions

Richman agrees that the review process for clinical trials can be extremely slow at times, but usually not on the grounds that the trial is ethically flawed.

"Sometimes it's a risk-benefit analysis," he explains. "Sometimes if it's referred or conditionally approved, the IRB looks for revisions to the [informed] consent form to make it clearer or more accurate; but even when I have reviewed protocols with an IRB that looks at clinical trials, the only reason for rejection is usually that the science isn't good.

"It's not just an ethical issue."

Richman says in his work with IRBs and clinical trials, he has not gotten the sense that the process has slowed recently.

"It is a case of there being hoops to go through, and that does slow things down, but that's just the research game," he says. "That's just the way it works."

Karen J. Maschke, PhD, associate for ethics and science policy for The Hastings Center in Garrison, NY, says the argument that ethics impedes research is not new.

"That exact same argument was made in the United States in the 1970s [when the] Tuskegee syphilis study [came to light]," she says, and again in New York in a study of chronic diseases among hospitalized patients at a Jewish hospital, when the trial subjects had not given consent to

CE/CME answers

13. C; 14. B; 15. D; 16. C.

be included in the study.

"In my experience, no one has pointed to any good, empirical evidence that research has been stifled by ethical requirements," she adds.

Some researchers have experienced delays because of the IRB review process, she concedes, "but that's an institutional issue with their own IRBs, not an ethical issue."

PolyHeme study drew attention in U.S.

Recently, a U.S. study examining the effectiveness and safety of a blood substitute, PolyHeme (Northfield Laboratories), drew fire for what some ethicists said was overstepping informed consent bounds.

The PolyHeme study, which is ongoing, compares use of the PolyHeme blood substitute to traditional saline in trauma patients who can unknowingly receive the experimental product because of a federal regulation that waives informed consent requirements for trauma or emergency patients under certain circumstances.

The oxygen-carrying PolyHeme fluid is intended for use in ambulances to prevent death before a patient can receive blood in an emergency room. However, the study allowed patients to continue receiving PolyHeme for up to 12 hours after arrival at the hospital. In an open letter published in the on-line version of *The American Journal of Bioethics* in early 2006, a panel of ethicists said while the use of PolyHeme is justifiable outside the hospital setting, patients should be given blood once they arrive at the hospital and are matched for donor blood.

"Studies like [the PolyHeme study] put pressure on the key fault lines in research ethics," Richman states. "We desperately want data on how to help trauma patients, but we also believe that patients should not be enrolled in studies without their explicit permission. Ethicists call this a conflict between beneficence and respect for persons."

While most research involves this conflict to some degree, Richman adds, "each study has to be examined in the context of available data and applicable guidelines, and people are concerned that scientists and review committees got it wrong in the case of the PolyHeme study."

Political pressures influence trials

More so than ethical restrictions, Richman says, the political climate in the United States is a bigger threat to clinical research.

"I'm more concerned about people turning away from research on stem cells and HIV due to the political climate," he says.

Prior to the mid 1970s, many drugs and pharmaceutical products were tested on prison inmates who were paid to participate in trials. Revelations of abuse at some prisons led to new regulations that said prisoners can participate only in trials that pose minimal risk, but an Institute of Medicine report presented in August recommends that trials with greater risks be conducted in prison populations if there are potential benefits to prisoners.

Ethicists are split over the potential benefits among prison populations, which suffer disproportionate rates of HIV and hepatitis C infections, and the risk posed when incarcerated, often functionally illiterate subjects are asked to consent to participate in trials.

"With the IOM report on prisoners, there are two responses to that," Richman suggests. "One is, 'Look at this report — it is broadening ethics oversight by suggesting that research on prisoners be reviewed by an ethics board'; and the other is, 'Oh no. They say it's OK to research on prisoners again.'"

In cases such as the PolyHeme trial, where anyone in one of the research locations could become a subject simply by being hit by a car or suffering other traumatic blood loss outside a hospital, Richman says the question of boundaries of consent become a bit fuzzy.

"The interesting [ethical] cases are the ones in between being clearly permissible and clearly impermissible," he adds. ■

COMING IN FUTURE MONTHS

- Using interpreters
- For-profit ethics committees
- When to call the lawyer
- Ethics and reproduction

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. ■

CE objectives

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. ■

CME Questions

13. According to the National Center for Complementary and Alternative Medicine in a report on complementary and alternative medicine, when megavitamin therapy and prayer were included in the definition of complementary and alternative medicine, what percentage of adults in the United States were using some form of the non-traditional medicine in 2004?
A. 15%
B. 36%
C. 62%
D. 88%

14. As yet, no state has passed legislation requiring the reporting of hospital-acquired infection data.
A. True
B. False

15. According to hospice nurses whose experiences were reported in a 2003 *New England Journal of Medicine* article, patients chose to stop eating and drinking for reasons that included:
A. being ready to die.
B. belief that continuing to live was pointless.
C. a sense of poor quality of life.
D. all of the above.

16. The PolyHeme trial of a blood substitute drew fire from ethicists because:
A. the approval process took too long.
B. the science behind the trial was flawed.
C. patients continued to receive the blood substitute even when blood was available.
D. none of the above.

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