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IN THIS ISSUE

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DECEMBER 2007
VOL. 23, NO. 12 • (pages 133-144)

Want to 'fire' your patient? Examine your motives, proceed cautiously

Philosophical differences need not mean end of the relationship

A patient deciding to change doctors is not an unusual occurrence; sometimes, the physician doesn't even learn the reason for the change. It's a much more highly charged situation when a physician decides he or she must end a professional relationship with a patient.

As patients and their families become more educated consumers, and the physician-patient relationship moves away from its paternalistic history, conflicts in the relationship arise more often. But with only a few basic guidelines to go by, physicians are forced to rely on careful, stepwise actions to make sure discharging patients from their care goes smoothly.

"Patients are not our customers; the relationship is much deeper than that," says **Neil Farber**, MD, clinical medical director and professor of medicine at University of California, San Diego, and member of the American College of Physicians Ethics, Professionalism, and Human Rights Committee. "We have an obligation to do good on the part of the patient, and that makes it a special relationship, so it's less likely we'd want to — or should — terminate that relationship."

That said, Farber concedes, "there are times when something intervenes."

Evaluate reasons for ending relationship

If something is interfering with a physician's ability to do what's in the patient's best interest, that's one reason to consider recommending that the patient find another provider. Conversely, if the patient is presenting an imminent harm to the physician, that is grounds for termination.

Other not-uncommon reasons for ending a doctor-patient relationship include noncompliance with medical advice, a misfit between patient expectations and what medicine can do, nonpayment of medical bills, verbal or physical threats or abuse against staff, harassment

or stalking the physician, repeated missing of appointments, and theft of prescription pads.

"If the interaction is such that the patient and physician are not talking effectively to one another, that would be grounds, but those should be extreme times," adds Farber, who is preparing to publish research on patient-physician conflicts.

Philosophical differences, however, should not be assumed to pose an insurmountable barrier to patient care, according to **Gene Rudd**, MD, an obstetrician/gynecologist who is senior vice president of the Bristol, TN-based Christian Medical and Dental Associations.

"People from different philosophical persuasions care for each other routinely, to the satisfaction of all," says Rudd. "When unusual situations arise, you want to positively interact with the patient."

That's not to say that the physician must abandon his or her beliefs or ethics when a patient's beliefs or ethics are at odds with the doctor's.

"If a patient asks me to do something that is morally objectionable, that's when I have a right not to do it," Rudd explains.

"I had a patient who came to my office, someone I had cared for for some time, and wanted an abortion," he recounts. "My dilemma was that in that particular town, there were two abortion clinics. Abortion clinic A was a butcher shop. Abortion clinic B did a technical job, and I knew she would be physically safe. My job was to let my patient know that.

"So I told her that I could not care for her in doing this, that she would have psychological trauma and spiritual trauma, but I didn't want her to have physical trauma as well. So I told her that while [her seeking] this procedure grieved me, and I could not do it, I would be here to care for her afterward if she needed me to."

Informing a physician on where his or her ethical boundaries are, when it comes to conflicts with patients, is not something that can be taught in medical school, Rudd contends.

"Ethical training doesn't make you ethical, anymore than sitting in your garage makes you a car," he says. "Your ethics are part of your character."

Practice 'preventive communication'

While some relationship-ending problems can't be foreseen, some can be — and therefore, can be avoided.

"Foremost, work on communication before it gets to be a problem," says Farber. "We train residents on communication techniques, and how to approach patients from a relationship-centered approach. When you're having a discussion with a patient, it's important to start from their perspective, and it's important for the patient to understand the physician's perspective."

Communication is one tool, Rudd says, but must be predicated by "respect, sensitivity, and permission."

"[Doctors] are trained to do that — we do that with every procedure," Rudd says. "Other qualities are competence, care, and compassion. Also, trust — the patient chooses to come to you, so there's implied trust already."

Further, the patient must provide accurate information and ask good questions, participate in decision-making, demonstrate willingness to com-

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media LLC, 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. Add $12.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions. For pricing information, call Tria Kreutzer at (404) 262-5482. **Back issues**, when available, are $83 each. (GST registration number R128870672.)

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ply with an agreed-upon plan; Rudd says when all these aspects of the physician-patient dynamic are satisfied, then communication can take place.

Just as patients provide their care providers with critical information by providing complete and accurate answers to a medical history, physicians can ward off problems by "letting patients know who you are and what you're about," Rudd continues.

"You can advertise, if you want to use that term, that you are an obstetrician, and that tells people that you deliver babies and you don't do heart surgery. But you can also train your staff to handle questions patients might ask before scheduling their first appointment — for example, you're an obstetrician who doesn't prescribe the abortion pill [RU-486], and you don't perform abortions. Or you are a general practitioner, and if someone asks if you'll put their elderly mother out of her misery, that you don't do physician-assisted suicide."

Though most patients don't, Rudd says it would be useful for patients to ask about a physician's position on ethical questions that are important to the patient before scheduling a first visit.

"If you're a patient, you shouldn't wait and see; you should ring up things important to you early, and if you're not in agreement, talk with the physician about how it might affect your care," Rudd adds.

What to do when the end has to come

While a patient who wants to end a relationship with a health care provider is not obligated to offer a reason — in fact, he or she can merely request their records be sent to a new provider with no cause given — a physician must guard against claims of ethical lapses and abandonment. Patients in medical crisis, those under acute care or who are in advanced stages of pregnancy or at high risk, are particularly tricky patients to discharge from care, and most physician insurers advise their clients against ending the relationship with those patients until their conditions are stable or their pregnancies or crises end.

But when the end must come, at least in the physician's view, there are some steps that are either required by law or are at least deemed appropriate:

• Talk to the patient. Don't send a letter or e-mail or leave a phone message unless you've spoken with the patient, either by phone or, preferably, in person. Farber suggests doing so in a non-threatening way, starting with asking the patient to gauge his or her understanding of the relationship; then, the physician should present his or her evaluation of the relationship, why it's not working, and suggest the patient seek care elsewhere. (An in-person conversation is not advisable if there is a threat of abuse to the physician or staff.)

• Follow up verbal conversation with a letter — preferably certified — summing up the decision to discharge. The letter should let the patient know he or she has 30 days to find another physician, and that during that time, the discharging physician will continue to care for the patient and will provide all medical records to the new physician.

"In terms of severing the relationship, all the patient has to do is not schedule another appointment; but legally, it's much more difficult and provocative for the physician," says Rudd. "It can create hard feelings, throw your past care into question, and incite gossip. But if you have a patient whose expectations you can't comply with, you have to recommend that they find another provider, and then give them time to do it."

Rudd blames the rise in patient-physician conflicts in part on the change inflicted by managed care.

"It used to be a covenant relationship, but the contractual elements of health care have changed it to a business relationship," he concludes. ■

SOURCES

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Guilt, fear after medical error can be bridged

Careful steps can yield solutions — and forgiveness

A medical error creates guilt, fear, and loneliness for both the caregiver and the patient and patient's family — feelings that can lead each side to withdraw unless efforts are taken by all parties

to develop solutions and foster forgiveness.

Much attention is given to prevention of errors and defusing potential for lawsuits, but **Tom Delbanco**, MD, and **Sigall K. Bell**, MD, both of Harvard Medical School, suggest that's only part of the solution.

"How can we characterize and address the human dimensions of medical error so that patients, families, and clinicians may reach some degree of closure and move toward forgiveness?" they ask in a recent commentary in the *New England Journal of Medicine*.[1]

Though there is a movement among health care providers nationwide to assume transparency when an error occurs — to acknowledge and disclose the error, and apologize for it — too often, fear keeps physicians and patients (or their families) from talking to each other.

According to Delbanco and Bell, while it has been well recognized that clinicians feel guilty after medical mistakes, family members often have similar or even stronger feelings of guilt. Further, patients and their families may also fear further harm, including retribution from health care providers, if they express their feelings.

Fear and guilt on the part of clinicians may further isolate patients, when fear of loss of reputation or license, or distress over the outcome of the mistake, cause them to avoid patients who have suffered harm, the authors say.

According to **John Banja**, PhD, assistant director for health sciences and ethics at the Emory University Center for Ethics in Atlanta, quickly creating a "transparent, empathetic conversation" after an error is realized is crucial to limiting the damage.

"We don't often think about how the patients may be traumatized into silence," says Banja. "And while patients or their families may be traumatized into silence while they're still in the hospital, once they get out of the hospital, that guilt and distrust and terror they felt while in the hospital might translate into anger, and that's when they go see a lawyer."

Truth, responsiveness key to dialogue

Family members of a patient hurt by a medical error sometimes will blame themselves — for not being present at the time, not monitoring care, not asking the right questions or anticipating the mistake, Delbanco and Bell suggest. Concurrently, physicians who are directly or peripherally involved in a medical mistake may assume the family will automatically be adversarial, and so distance themselves from them.

For both reasons, Banja says, honest and direct communication at the very earliest point following discovery of an error is important.

"There are two stages we're talking about here, and two sets of experiences," says Banja. "The first stage is simply the brute fact that this error occurred. The second stage occurs afterward, when the family or patient becomes more angered, more upset, and if no one is talking to them, they feel disbelief and a sense of injustice.

"If they sense that something went wrong and the health care team doesn't address it with a truthful, honest account of what happened, then you go to stage 2."

Some 30 states have adopted forms of so-called "I'm Sorry" laws, which permit health care providers to apologize for errors without the apology being used as an admission of guilt should litigation arise from the mistake.

But there remains some lack of clarity as to how much a physician can say when issuing an apology; medicolegal experts have said some of the laws allow providers to apologize, but don't protect them if they discuss specifically what they are apologizing for.

"Organizations need a policy that provides that you disclose a medical error in a truthful way," says Banja, who is a board member of the Sorry Works! Coalition, which advocates for disclosure, apology (when appropriate), and upfront compensation after adverse medical events occur.

Banja says keeping the patient or family in the loop as the error is investigated is important.

"That's what doesn't happen — there may be a lapse in time between when they're told an error happened and the conversation picks back up while the hospital investigates, and the family can feel dismissed during that time," he explains. "What doctors and hospitals have to do is really understand more keenly and empathetically what patients and families are experiencing during the time this is going on."

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One way of including families is to give them the name, phone number, and pager number of someone within the organization who they can reach anytime, night or day, with questions about their family member's care or about the investigation.

"Also, when a family says, 'We want names,' that's a contentious issue — do you protect the nurse who gave the wrong medication? Most of the time, there's more than one person involved in a medical error, so do you just come out and give the names?" Baja continues. "The family will find out sooner or later, so maybe the response should be, 'We can give you the name, but right now we are investigating what happened, and we don't know exactly what that persons' involvement is yet, but when we find out what happened, we'll tell you.'"

Possible to regain trust?

Delbanco and Bell say that doctors who frankly admit their mistakes and tell patients how they would safeguard against repeating the errors not only can avoid litigation, but also may be able to rebuild strong, long-lasting bonds with the patients and their families.

Saying "I'm sorry" and taking steps to prevent a recurrence of the error can reduce ill will. But is re-establishing trust after a medical error too much to ask? Banja says it strongly depends on the parties involved.

"Re-establishing trust [in the health care provider or hospital] depends on how narcissistic the family is," says Banja, who has written on physician narcissism, the need for physicians to protect their reputations as competent, authoritative, and even perfect — a need that conflicts with admission of error.[2] A "narcissistic" family might be one whose outrage at the personal harm that has come to them makes forgiveness and trust difficult, or impossible.

"I think that if I were the doctor and I was in error, in disclosing the error I might say, 'You might not want me to continue taking care of your mother, and please know that's a totally understandable decision.'"

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Hospice rotation proves beneficial to med students

Residents learn surprising things about dying

A third-year medical student sits with an end-stage lung cancer patient who is in hospice. The patient wants to talk, but not about pain or death or advance directives — he wants to know the student's plans for the future.

"I can't believe it," the student would tell his instructor later. "Here is this patient who's dying, and he's interested in knowing my plans for the future."

Such are the sometimes eye-opening lessons learned by Albany (NY) Medical College students who, for the past year, have been required to do a hospice rotation in their third year. The message, says **John Balint**, MD, professor emeritus at the medical college and founder of the medical ethics center at Albany Medical, is that an often repeated comment by physicians to dying patients — "there's nothing more I can do for you" — is one of the least true.

"The fact is, when a patient is dying is when you can sometimes do more for them than you could before," says Balint, who pushed for years to have a hospice rotation added to the requirements for Albany med students.

For medical students whose primary focus is acute medicine and healing, that's an important distinction, he adds.

Observing hospice care at work

Balint says once there were adequate hospice staff available for the rotation, the requirement was implemented in 2006. Every third-year student spends a week at hospice, almost exclusively with patients and staff in the home care field.

"They do home visits, sit in on a consultation

SOURCES

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visit where someone is being referred into the hospice program, and sit in on team meetings to see how the team contributes to the care of the patient," says Balint. "A week is too short a rotation to really learn about hospice, but it gives them an idea of what it can do."

Many students are surprised at the smiles on the faces of hospice patients.

"That's why we say that telling a patient [that there's no more that the health care team can do] is not true, because the students recognize that just being there and being interested in the patient does a lot," Balint says.

The value of just being there is an aspect of hospice medicine that surfaces frequently in the essays students are asked to submit at the conclusion of their rotation. Students are asked to write about the three most important things they learned, and why they chose the three that they write about.

"The essay is the major measure of whether we are achieving what we want to achieve, and that is that they understand what hospice is all about," says Balint.

Every student thus far (there are 140 third-year students) has written about the effectiveness of the team approach and the benefits it provides to hospice patients, Balint says. Two-thirds typically write about the differences between acute care, with the aim of healing, and hospice care and its goal of supportive care at the end of life.

"They often comment on spiritual healing and how interesting it is that patients who know they are dying can be smiling and cheerful," he adds.

Even though the rotation is short, its impact is palpable. Albany Medical College teaches a four-year course in clinical ethics that delves into palliative care, but until the rotation, students don't have any personal exposure to palliative care.

Albany Medical is thought to be the first medical college in the country that requires a formal hospice rotation, Balint says, and "it's turned out to be everything we hoped it would be." ■

Feds prioritize population to allocate scarce vaccine

Guidelines emphasize limiting spread

Since there have been pandemics and vaccines to fight them, ethicists have wrestled with the question of who should have priority when it comes to distributing vaccine. The federal government has released a draft in which it sets out how health authorities should allocate scarce doses of influenza vaccine in the event of a pandemic.

The interagency working group, made up of members representing all sectors of the federal government, sorted the population into four categories, and then ranked groups within those categories in order of priority. **(See "Pandemic vaccine prioritization list," p. 139.)**

The draft was prepared from the most current scientific information available, "balanced with the values of our society and the ethical issues involved in planning a phased approach to pandemic vaccination," according to the paper. (The draft guidelines are posted at www.pandemicflu.gov.)

Babies, soldiers top the list

Infants, pregnant women, doctors, and soldiers are among those in the top tier, or Level A, on the pandemic prioritization list. The four categories are Homeland and National Security, Health Care and Community Support Services, Critical Infrastructure, and General Population.

In the lowest-priority category — Level D under General Population — are healthy young adults and the elderly. Listing the elderly in the lowest-priority group and young children in higher-priority groups reflects the working group's conclusion that the most effective use of limited pools of vaccine is to target those who are most likely to spread the flu, not just those most likely to suffer the most — or die — from it.

The working group reports that strong consideration was given to the ethical issues involved in allocating limited supplies of vaccine.

"Vaccinating some people earlier than others to minimize health and societal impacts of a pandemic was considered ethically appropriate," the report explains.

Principles the group considered were:

- fairness and equity (recognizing that all persons have equal value, and providing equal opportunity for vaccination among all persons in a priority group);
- reciprocity, defined as protecting persons who assume increased risk of becoming infected because of their jobs;
- flexibility to assure that vaccine priorities are

Pandemic Vaccine Prioritization List

Homeland and National Security	Health Care and Community Support Services	Critical Infrastructure	General Population
A • Deployed and mission-critical personell	A • Public health personnel • Inpatient health care providers • Outpatient and home health care providers • Health care providers in long-term care facilities	A • Emergency Medical Services • Law enforcement • Fire services personnel • Manufacturers of pandemic vaccine, antiviral drugs, and other key pandemic response materials	A • Pregnant women • Infants and toddlers, 6-35 months old
B • Essential support and sustainment personnel • Intelligence services • Border protection personnel • National Guard (not included in level A) • Other domestic national security personnel	B • Community support services and emergency management personnel	B • Energy sector personnel (electricity and natural gas) • Communications personnel • Water sector personnel (potable/waste water) • Government personnel	B • Household contacts of infants under 6 months old • Children 3-18 years old with high-risk medical conditions • Children 3-18 years old without high-risk medical conditions
C • Remaining active duty military and essential support personnel	C • Other important health care personnel	C • Transportation sector personnel • Food and agriculture sector personnel • Banking and finance sector personnel • Pharmaceutical sector personnel • Chemical sector personnel • Oil sector personnel • Postal and shipping sector personnel • Other important government personnel	C • High-risk persons 19-64 years old • Persons 65 years and older D • Healthy adults, 19-64 years old, not included in other categories

Source: U.S. Department of Health and Human Services (pandemicflu.gov).

optimally tailored to the severity of the pandemic and the groups at greatest risk of severe infection and death.

A second ethical focus was the importance of developing guidance through an open and transparent process with multiple opportunities and avenues for input from the public and stakeholders, according to the working group's report. Meetings were held with local representatives in several areas of the country as the draft was prepared, and when finalized, the guidelines will be open to interpretation and adaptation by states.

Estimates are that the federal government will have stockpiled enough vaccine against the current strain of avian flu for 13 million people by the end of 2007, with a goal of stockpiling enough for 20 million people. Twenty million is the esti-

mated number of people in the top levels of the proposed prioritization list.

(Editor's note: Comments on the guidelines are being accepted by the Department of Health and Human Services through Dec. 28, 2007. Electronic responses are preferred and may be addressed to Panfluvaccine@hhs.gov. Written responses should be addressed to U.S. Department of Health and Human Services, Room 434E, 200 Independence Avenue, SW, Washington, DC 20201, Attention: Pandemic Influenza Vaccine Prioritization Guidance Comments.) ■

Med students don't know ethics of military medicine

Few can identify violations of Geneva Conventions

A survey of 5,000 U.S. medical students reveals that just over one-third understand the Geneva Conventions as they apply to military medical ethics; underlying that finding is the additional revelation that very few receive any medical school instruction in military medical ethics.

J. Wesley Boyd, MD, PhD, a psychiatry instructor and psychiatrist with Cambridge Health Alliance in Cambridge, MA, spearheaded a look into medical students' knowledge of military medical ethics after hearing reports that physicians were implicated in torture and abusive interrogations of jailed suspected terrorists.[1]

To start with, the Internet-based survey established that 94% of those medical students who responded had received less than one hour of instruction about military medical ethics. And only 3.5% knew that there exists a "doctor's draft" to ensure there are enough physicians in the military.

When it came to Geneva Conventions regarding the treatment of prisoners, 37% knew the conditions under which the Conventions apply, but fewer — 33.8% — knew that the Conventions require physicians to treat the sickest patients first, regardless of nationality.

As for medical students' understanding of a military physician's role in the mistreatment of prisoners, 37% said they did not know that the Geneva Conventions prohibit threatening or demeaning prisoners or depriving them of food or water, and nearly 34% said they did not know the conditions under which the Conventions would require them to disobey an unethical order.

For example, the survey posed the following hypothetical question:

"If a prisoner is refusing to answer questions about a recent battle or skirmish in which over 50 U.S. soldiers died, under the Geneva Conventions it is permissible to:

a) Deprive him of food or water for a period not to exceed 24 hours.

b) Expose prisoners to physical stresses such as heat, cold, and uncomfortable positions, as long as such exposure causes only minor tissue damage (i.e., medical intervention not required, and full healing takes place within 48 hours).

c) Threaten prisoners with physical violence, so long as such threats are not carried out.

d) All of the above.

e) None of the above.

The answer? "None of the above." Prisoners of war who refuse to answer questions may not be threatened, insulted, or exposed to harsh treatment, according to the Geneva Conventions.

Boyd writes that when asked about three hypothetical orders and whether they, as physicians, should obey any of them, the students fared no better. When asked if they should comply with an order to threaten a prisoner with psychotropic drugs that would not actually be given, to give a prisoner a shot of harmless saline solution that he had been led to believe is a lethal injection, or to actually kill a detainee with a genuine lethal injection, more than 25% said they would comply with the first two orders but not the third; 6% said they would comply with all three orders. The Geneva Conventions prohibit any of the actions.

Reference

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Foundations: Give ill access to experimental therapy

Supreme Court appeal sought over clinical trial access

Two foundations that seek to establish a constitutional right to experimental therapy for the

seriously ill will challenge a recent decision in a federal appeals court that favors the FDA's more cautious approach to access to experimental drugs.

The Fredericksburg, VA-based Abigail Alliance and the Washington, DC, Legal Foundation lost their bid in the U.S. Court of Appeals for the District of Columbia in late 2007 to give terminally ill patients access to therapies that have gone no further than Phase I clinical trials. The court said these patients do not have a constitutional right to the drugs.

Writing the majority opinion, Judge Thomas Griffin acknowledged that "[t]erminally ill patients desperately need curative treatments," but that their deaths could "be hastened by the use of a potentially toxic drug with no proven therapeutic benefit."

Griffin wrote for the 8-2 majority, which overturned a decision made by a three-judge panel from that court in May 2006, ruling that terminally ill patients do have such a constitutional right.

Judge Judith Rogers, writing the minority opinion, described the ruling as "startling." The decision, she said, left the right "to try to save one's life. . . out in the cold despite its textual anchor in the right to life."

The case is now headed for the Supreme Court, which may or may not grant a hearing.

While the decision is currently focused on anticarcinogenic drugs, the use of combination therapies to treat some cancers — such as nanoparticle delivery systems and adjuvant use of radiological equipment — and the prevalence of heart disease suggest that devices and diagnostics could become entangled should the Supreme Court rule in favor of the plaintiffs.

Abigail Alliance and the Washington Legal Foundation filed the case in 2003 in response to an incident involving Abigail Burroughs, who died of cancer of the head and neck in 2001 after attempting to persuade the FDA to allow her to try a pair of anticarcinogenics drugs. Burroughs' father established the Abigail Alliance after his daughter's death.

The FDA in 2006 published a notice in the *Federal Register* that proposed to amend regulations to expand access to investigational drugs. The notice points out that existing regulations permit such access so long as "there is no satisfactory alternative drug or other therapy available" and that the drug is under investigation in a clinical trial, that the trial is completed but the drug is not yet commercially available, or the sponsor is "actively pursuing marketing approval. . . with due diligence."

The proposed regulation would redefine unreasonable risk "in the context of the disease or condition to be treated," and would allow the use of Phase I clinical trials to serve as a pretext for access so long as preliminary evidence "suggests possible effectiveness" and failing any such clinical data, "the case for the potential benefit may be based on preclinical data or on the mechanism of action." ■

'Ashley treatment' doc's suicide not related to case

'History of depression' blamed for Gunther's death

The Seattle pediatric endocrinologist who spearheaded the growth attenuation treatment on a disabled 9-year-old girl known as "Ashley" died in an apparent suicide in late September. The family of **Daniel Gunther**, MD, who was 49, said they believe his death was not related to the controversy over the so-called "Ashley treatment," but rather was the result of a long struggle with depression.

Gunther was an endocrinologist at Children's Hospital and Regional Medical Center in Seattle when, in 2004, the parents of a then 6-year-old girl came seeking his help. Their daughter, who was and continues to be cared for by her parents at home, was diagnosed with static encephalopathy. Marked global developmental deficits caused her development to never progress beyond infancy. She cannot sit up, walk, or talk; she is fed via gastrostomy tube, and the specialists treating her say there will be no significant improvement in her cognitive and neurologic state.

When she started showing signs of puberty at age 6 (breast buds, pubic hair), her parents became concerned about the effects of growth and maturation on their ability to care for her and keep her comfortable. Lifting an immobile 7-year-old is difficult; maneuvering an immobile adult at home would prove very difficult. Fully developed breasts would interfere with Ashley's ability to comfortably wear the harness that allows her to sit up, and menses would make hygiene additionally difficult for her care-

givers and uncomfortable for Ashley, her parents said.

Gunther concurred, and together they approached Children's about performing three separate but concurrent treatments — a hysterectomy, hormonal growth attenuation, and surgical removal of her breast buds.

The course of treatment was approved by the hospital's 40-member ethics committee, and took place in 2004. The therapy came to wider public knowledge in 2006, when Gunther and his colleague, **Doug Diekema**, MD, MPH, of the Treuman Katz Center for Pediatric Bioethics at Children's Hospital, published their report on the procedures.

In mid-2007, Children's Hospital acknowledged that it broke Washington state law by permitting the hysterectomy portion of the treatment without a court order.

The parents of the child known as Ashley posted the following comment on their blog (www.ashleytreatment.spaces.live.com) following Gunther's death:

"We are deeply shocked and saddened to learn of the sudden death of Dr. Daniel Gunther. His tragic death is a tremendous loss to everyone, especially to other vulnerable kids like Ashley and their families, to whom he represented hope."

For more information on the treatment of the child known as Ashley, see *Medical Ethics Advisor* March 2007 ("Hysterectomy and growth attenuation: Therapy for disabled girl sparks debate," pp. 25-28) and July 2007 ("Hospital: Growth attenuation in disabled child illegal, not unethical," pp. 73-75). ■

Global HIV vaccine trials face ethical challenges

Enrollment in AIDS-stricken countries faces scrutiny

HIV vaccine trials likely will continue for a decade or longer, raising questions about ethical considerations of enrolling participants across the globe.

Since none of the studies so far have found a vaccine candidate that prevents HIV infection, one of the biggest ethical concerns is promoting inflated hope among trial subjects.

"There is the concern that despite having been told that this is research and the vaccine may not succeed in preventing HIV infection, participants will engage in risky behavior in the hope or belief that the vaccine will work," says **Ruth Macklin**, PhD, a member of the HIV Vaccine Advisory Committee at the World Health Organization, and a professor of Biomedical Ethics in the department of epidemiology and population health at Albert Einstein College of Medicine in the Bronx, New York.

"Evidence indicates, however, that participants in the trials have not actually engaged in 'behavioral disinhibition' — that is, engaging in behavior that is any more risky than when they are not in a trial," Macklin notes.

One reason HIV vaccine research is more ethically challenging is because HIV remains a stigmatizing condition, Macklin says.

"Phase III trials are almost always conducted on populations at high risk of becoming infected," she says. "Even though the participants are not infected when they enroll, if it becomes known that they are in a preventive vaccine trial, they might therefore be stigmatized."

The stigma factor isn't an issue for other types of vaccine trials, Macklin says.

There also has been the ethical challenge of pursuing the vaccine in the areas that need it most.

The HIV virus is different in various regions of the world, and any vaccine that is developed will need to be created specifically for the dominant virus present in the area where it will be given.

The challenge has been in starting vaccine trials in the resource-poor areas hardest hit by the pandemic, says **Pat Fast**, MD, PhD, executive director of medical affairs for the International AIDS Vaccine Initiative (IAVI) of New York.

"There wasn't enough emphasis being given to people who needed the vaccine the most, including the people in Africa and Asia," Fast says. "Less developed countries have fewer ways to protect themselves against HIV."

So organizations such as IAVI and the Bill and Melinda Gates Foundation have provided the funding and infrastructure necessary to initiate vaccine research in resource-poor countries.

CME answers

21. D; 22. A; 23. B; 24. D.

HIV vaccine research is very expensive, and it requires collaboration, Fast says.

For instance, the IAVI shares information with the U.S. Military HIV Vaccine Research Program and the Medical Research Council in the United Kingdom. The organization also receives Gates Foundation funding, as well as money from the United States and European governments, she adds.

"You have to go into these countries and spend time and make sure people have a sustainable operation that's not just dependent on one trial," Fast says. "You don't want to go in and set up the trial, and then when you leave and people go away, the facilities fall apart."

The goal is a long-term effort so that when the AIDS vaccine finally is discovered, the existing infrastructure can be used for other health care and research projects, she adds.

An ethical challenge related to HIV vaccine work is that the vaccine is likely to make participants test positive for HIV even when they are not really infected, Macklin says.

"If participants are in a setting where there is mandatory testing, such as in the military, it must be made clear to the testing authorities that although the participants have antibodies, they are not infected," Macklin says. "This is usually handled by providing a card to each participant, affirming that they are enrolled in HIV vaccine research."

Another ethical concern has involved worries that researchers might not counsel vaccine participants fully about practicing safe sex because of their desire to see if the vaccine succeeds in preventing infection, Macklin says.

"That is, if no one engages in risky behavior, there is no chance that anyone will be exposed to HIV and, therefore, no way of knowing whether the vaccine is efficacious," Macklin says. "However, there is no evidence that researchers are failing to counsel vaccine trial participants appropriately."

Vaccine trial investigators even distribute free condoms to encourage participants to have the safest possible sex, Macklin says.

"Both the informed consent process and the counseling are designed not only to provide full information to participants, but also, the vaccine trials have employed a test of understanding before potential participants can be enrolled," Macklin says. "By this method, researchers try to ensure that participants fully understand that the vaccine may not work, that they may test positive even if not infected, and that they are well-informed about the best method to prevent becoming HIV infected." ■

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. This issue signals the end of the semester. **The semester ends with this issue.** You must complete the evaluation form provided 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. ■

CME objectives

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

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COMING IN FUTURE MONTHS

- Who owns images of the dead?
- Spiritual history
- Alternative care at the end of life
- Do the right thing: ED on-call

CME Questions

21. Which of the following is/are considered grounds for ending the physician-patient relationship?
A. Physical or verbal assault on the physician or staff
B. Non-compliance with an agreed-upon plan of care
C. Nonpayment of bills
D. All of the above

22. A physician who feels compelled to discharge a patient from his or her care should take which of the following steps?
A. Discuss the reasons for the discharge in person, unless doing so would pose a risk to the physician or staff.
B. Inform the patient of the decision by mail, with no preceding verbal conversation.
C. Following notification of discharge but before the patient has found a new doctor, refuse to treat the patient, referring any acute care needs or emergency calls to the local hospital.
D. None of the above

23. Proposed federal guidelines for allocating scarce flu vaccines in the event of a pandemic list the elderly and healthy adults as among those with highest priority to receive vaccine.
A. True
B. False

24. If a prisoner is refusing to answer questions about a recent battle or skirmish in which over 50 U.S. soldiers died, under the Geneva Conventions it is permissible to:
A. Deprive him of food or water for a period not to exceed 24 hours, and threaten prisoners with physical violence so long as such threats are not carried out.
B. Expose prisoners to physical stresses, such as heat, cold, and uncomfortable positions, as long as such exposure causes only minor tissue damage (i.e., medical intervention not required, and full healing takes place within 48 hours).
D. All of the above
D. None of the above

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