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## Crossing new frontier: Paving the way to make face transplantation reality

*Much is unknown about outcomes for subjects*

Even before doctors in France performed a thus-far successful transplant of a partial face in November 2005, experts in the United States had the expertise and knowledge to transplant a face. What they have lacked is the right person to receive the graft.

**Katrina Bramstedt**, PhD, faculty bioethicist and director, research subject advocate program at the Cleveland Clinic, knows the first American face transplant could take place at her institution tomorrow. Or it could be a year or more away. Her job is to screen potential participants for what is still very much an experimental procedure. And she hopes that just because partial face transplants have been performed in France and, more recently, in China, the public doesn't assume that the procedure has become standard.

"From my perspective, a lot of things get done quicker in Europe, and that includes things like drug studies, than they do here," says Bramstedt. "That simply reflects the regulatory atmosphere, and hopefully [partial transplants in other countries] are not making people think it's a procedure that is ready to do in all cases."

### ***Clinic received approval in 2004***

In November 2004, the Cleveland Clinic became the first medical center in the United States to be approved by its institutional review board (IRB) to perform a full face transplant. But the time since has been spent screening potential candidates for the procedure and addressing how to go about finding a donor.

Doctors in France transplanted a chin, lips, and nose onto a woman who'd been bitten by her dog while unconscious from taking an overdose of sleeping pills. In April 2006, surgeons in China grafted a nose, cheeks, and upper lip onto a man who was mauled by a bear several years ago. The Cleveland Clinic team is seeking someone who needs a full face transplant, and has created a procedure it hopes will permit the team to successfully transplant the entire face, ears, and scalp of a

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brain dead donor onto someone whose trauma or disfigurement has left them with no other option.

Surgeons say it will be some time — perhaps years — before it is known whether the partial transplants in France and China are successful. Skin grafts are more susceptible to rejection than many organ or other tissue transplants and carry a life-threatening — and life-altering — risk. In the event that a face transplant was rejected, Bramstedt points out, the results would be impossible to hide, and the patient could be left in worse condition that he or she was in before.

On the upside, Cleveland Clinic surgeons hope that transplanting an entire face carries benefits, allowing nerves and circulatory vessels to remain

intact, compared to partial face transplants that have partial nerves and blood vessels.

If the transplant is successful, it comes with a price. Many ethicists opposed to the idea of face transplants ask if it is appropriate to take a healthy person who is grossly disfigured and turn him or her into someone with an improved appearance but who is rendered chronically ill by the toxic regimen of immunosuppressants that must be taken for life.

Such opposition has led the United Kingdom's Royal College of Surgeons to place a moratorium on the procedure pending further discussion of the risks and ethical issues involved. The 2004 Working Party Report from the Royal College of Surgeons concluded that there were too many unanswered questions regarding facial transplantation to warrant clinical trials at the present time; and that position has not, as yet, been rescinded. The American Society of Plastic Surgeons and American Society of Reconstructive Microsurgery jointly have created a list of guiding principles for surgeons contemplating performing face transplant research. (See table, p. 76.)

### ***Right subject hard to find***

Bramstedt says the perfect candidate for the surgery would have exhausted all other options.

There is, unfortunately, no shortage of people whose disfigurements are extensive enough that a new face would seem a godsend.

"It is amazing what can happen in car and truck accidents; the disfigurement is almost unbelievable," she says.

It is her job to find someone whose life has been ruined by their disfigurement, but yet is psychologically fit enough to recognize the risks and not be blinded by the very uncertain chance of a benefit.

A facial disfigurement is different from any other condition that causes a person to consider a transplant.

"The face is a social organ. Your whole concept of a first impression comes from what you see when you view a person, and you don't have the same reaction when you see someone with a disfigured hand," Bramstedt says.

Assessing a potential subject for a face transplant is different from assessing a potential organ recipient.

"The outcomes are measured differently," Bramstedt continues. "If the labs are off when you have a kidney transplant, you might not notice

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### **Editorial Questions**

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## Noted neurologist, Schiavo consultant, MEA advisor, Ron Cranford, dead at 65

**R**onald E. Cranford, MD, recognized that the case of Terri Schiavo, the brain-injured Florida woman whose family fought over terminating her life support, was the culmination of his career, much of which was spent studying and educating people on the vegetative state and medical futility.

"There are enormous changes in the area of medical futility, and hundreds of families out there who can't accept the reality of medical futility," Cranford, a *Medical Ethics Advisor* editorial board member, told *MEA* last year. "There's nothing wrong with that, because the idea of futility runs against the grain with patients and families. So it's a good thing to work on."

Cranford died May 31 in Minnesota after a two-year battle with cancer. After his diagnosis, he shunned chemotherapy, preferring to go on teaching and lecturing about the vegetative state.

Vilified as "Dr. Death" by many who disagreed with

his support of Michael Schiavo's fight to carry out what he said was his wife's wish to not be kept alive artificially, Cranford was not a proponent of euthanasia or physician-assisted suicide. He steadfastly maintained he was an advocate for the rights of the patient, and in the Schiavo case, he felt she was irreparably brain damaged, in a persistent vegetative state, and that her husband had the right to ask that artificial nutrition and hydration be removed.

His diagnosis of Schiavo's condition was confirmed upon her autopsy.

Cranford was a neurologist at Hennepin County Medical Center and a professor at the University of Minnesota. He served on various ethics committees and was a prolific author on the subjects of the right to die and medical ethics.

He is survived by his wife Candy, two daughters, and a son. ■

that, but if your nose is off-center, you'll notice."

Mental health issues become very important when evaluating a potential subject, as body image is a critical factor for the person before and after surgery.

"How have they been affected by their disfigurement? Are they shunned? What kind of support system do they have?" Bramstedt asks.

"This is still very much an experimental procedure. We don't know how it will work; so it's a huge step, and we have to be sure, as much as we can, that the candidate realizes what they are trading in and what the risks are related to the outcome."

The subject's expectations of how he or she will look afterward are explored in detail, with Bramstedt interested in how realistic or unrealistic those expectations are. "Do they misunderstand that this research is standard therapy and we do it all the time?"

One drawback to the worldwide media attention — and reported movie and book advances — surrounding the French woman who received a partial face transplant in 2005 is that Bramstedt occasionally encounters candidates who are interested in the media exposure that would come to the first American transplant recipient.

"If people are interested in being the first, that raises a lot of red flags on their motivation and

goals," she says.

Ethicists say candidates for face transplants must understand that they are participating in research for the benefit of science, like participants in clinical trials, and are not receiving traditional medical care.

"I have had discussions with people who are trying to get into the studies for health care; but this is research. We're trying to learn about plastic surgery," Bramstedt says.

### **Donor faces: New frontier in transplantation**

Receiving tissue transplants from deceased donors often has emotional and psychological repercussions for both the recipient and the donor families, though the procedures are common enough that they rarely gain attention outside the immediate circle of friends and family involved.

Face transplants, like the still-new hand transplant, carry additional baggage, experts agree.

Because the face is so closely tied to a person's idea of self, the recipient may have concerns that he or she will look like the donor; the donor's family may either hope or fear that their loved one's face will be recognizable on the recipient.

Researchers say the outcome is likely to be something in between.

“We educate [potential subjects] that their facial structure now will determine how they would look afterward,” says Bramstedt. “They won’t look like the donor.”

Bramstedt explains that while it is not considered unethical to take tissues or organs from a consenting donor, some people question whether it is ethical to take a face.

“We talk with research subjects about how they feel about it — about how they would feel about receiving so much tissue, and tissue from the face,” she says.

For example, some hand transplant recipients refuse to look at or touch their new appendage. The same could be true of face transplant recipients, Bramstedt says.

“We want the person [receiving the graft] to look at that face, and be able to emotionally do it,” she points out.

Doctors are also concerned that the recipient understands the heavy responsibility that comes with the procedure. In addition to the lifelong commitment to taking immunosuppressants to help ward off rejection, the recipient would have other lifestyle changes to consider.

Experts everywhere — including the physicians who worked on the woman in France — were dismayed when the first face transplant patient resumed smoking before she even left the hospital, threatening the oxygen supply to the graft. Bramstedt says it’s no different than making sure a potential liver recipient, whose own liver was damaged by alcohol abuse, abstains from drinking when he or she has a new liver.

Delving into a potential candidate’s lifestyle and mental health are crucial not only for the success of the operation, but also to help increase the chances the patient will survive. Researchers are aware that if early attempts at the procedure fail,

## SOURCES/RESOURCES

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- **American Society of Plastic Surgeons**, 444 East Algonquin Road, Arlington Heights, IL 60005. Web site: [www.plasticsurgery.org](http://www.plasticsurgery.org).

## Guiding Principles for Face Transplant Surgeons

The American Society of Plastic Surgeons and American Society of Reconstructive Microsurgery urge surgeons who are considering participating in facial transplant surgery to consider certain principles, including:

- Facial transplantation should be utilized only for patients with severe facial deformities who cannot be helped through traditional reconstructive surgical measures, in institutions with institutional review boards familiar with the intricacies of new procedures and protocols, and only when there are appropriate resources and institutional commitment to the project;
- The team should include the disciplines of plastic surgery, immunology/transplant, medical ethics, psychology, infectious disease, oncology, medico-legal, physical therapy, pharmacology, and patient advocacy;
- A complete risk/benefit ratio must be considered for each patient on a case-by-case basis;
- To facilitate informed consent, the patient should be provided with the most complete information available on the risks and must demonstrate a thorough understanding of those risks;
- The physician should regard facial transplantation as experimental and it should be subjected to the evaluation of an independent research ethics committee, and results must be peer-reviewed. ■

*Source:* American Society of Plastic Surgeons and American Society of Reconstructive Microsurgery.

and the results are that recipients die or are even more disfigured than before, support for further attempts would plummet.

Seeking donors for partial or full face transplant is another unexplored area. U.S. tissue and organ transplant protocols do not address taking donors’ faces. Families and potential donors who might have no problem with donating corneas, organs, and other tissues that would not noticeably disfigure a corpse know that removal of the face would inevitably result in a disfigured body and require a closed casket.

Some experts are concerned that potential organ donors might fear that if they sign an organ donor card, they will be automatically donating their faces upon death, and that those fears might cause people to avoid signing donor cards or to tear up donor cards they already have.

The United Network for Organ Sharing, which administers the nation's only organ procurement and transplant network, has no specific provisions for matching facial tissue donors and recipients. The McLean, VA-based American Association of Tissue Banks, the accrediting body for tissue banks in the United States, does not specifically address donation of facial tissues in its universal donor card, but does include space for donors to specify limitations or special wishes, which could be used to specifically donate or opt out of donating facial tissues.

Bramstedt points out that key to the debate over the risks and rewards of this research is that it "is not lifesaving surgery."

"If you need a liver, you need a liver to live," she says. "This is not surgery to preserve life or health."

The Chicago-based American Society for Reconstructive Microsurgery (ASRM) agrees. In its position paper on the ethics of facial transplantation, ASRM urges that "the ethics of inflicting an untried, and potentially fatal or deforming, remedy for the purposes of advancing science must be carefully weighed against the Hippocratic credo of doing no harm."

"The ethics of facial transplantation go beyond the life and death issues common to most transplants and engage other topics that heretofore have not influenced medical decision processes," the ASRM paper continues. "In the final analysis, however, ethics must be regarded as a means for discussing the issues of facial transplantation and not, necessarily, for resolving them." ■

## When minors choose risky, alternative therapies

*Virginia teen foregoes chemo for herbal remedy*

**A**braham Cherrix is a 15-year-old boy with Hodgkin's disease. He's also an Internet-savvy free thinker who doesn't want to do another round of chemotherapy and radiation; what he wants to do is go to Mexico for a controversial herbal treatment he hopes will cure him.

He has the support of his parents, but to his doctors, hospital, and the Commonwealth of Virginia, he is risking his life and his parents are helping; this case of a patient seeking alternative therapy has ended up in court, with not only Cherrix's health but also his parents' continued

custody in question.

For cases of minors or their parents resisting standard care in favor of alternative remedies, ending up in court should be a very last resort, says **Douglas Diekema**, MD, MPH, interim director of the Treuman Katz Center for Pediatric Bioethics at Children's Hospital in Seattle.

When he is called to consult with a doctor whose patient or patient's family is making a treatment decision the doctor feels is not in the patient's best interest, Diekema tries to help find ways for the discourse to continue, so that both sides don't end up digging their heels in and wind up in court. The key, he says, is in both sides maintaining respect for each other.

"And going to the state is inherently disrespectful," he says. "Talking about each option is the respectful approach, and that builds trust, and trust is frequently the most important part of the relationship between doctor and patient."

### ***Who should decide care, and when?***

Cherrix was diagnosed in 2005 with Hodgkin's lymphoma after he found a suspicious lump in his neck. He underwent three months of chemotherapy at Children's Hospital of the King's Daughters (CHKD) in Norfolk, VA, treatment that he says made him deathly sick.

"It poisoned me," he says. "It was the worst I ever felt in my life."

When follow-up tests in early 2006 showed cancer was still present, doctors at Children's recommended another round of chemotherapy. Cherrix, who had begun researching alternative therapies when he was first diagnosed, said no.

He and his father, who helped his son do research, had settled on a treatment called the Hoxsley method, offered by a clinic in Tijuana that is based on an organic diet and herbal supplements, some of which are ingested and some of which are applied topically. Someone — Cherrix and his family are not certain who — reported his case to child abuse investigators in the county where he lives, and the Department of Social Services asked a court to order Cherrix to continue conventional treatment.

A judge ordered tests to see if the cancer had progressed, filed a temporary order saying the Cherrixes had neglected or refused to provide necessary treatment for their son, and placed Cherrix in joint custody of his parents and social services. Cherrix is permitted to continue living at home. He went to the hospital as ordered in May,

but refused to have the diagnostic work done.

According to an expert on medical ethics in Virginia, Cherrix may be charting new territory.

“Virginia does not have a mature minor statute [which in some states recognizes older minors’ right to consent to or refuse medical treatment], so there is no staged ability for adolescents to gain more and more authority over their own health care,” says **Michael Gillette**, MD, a professor at the University of Virginia School of Medicine and president of Bioethical Services of Virginia, a bioethics consulting firm.

Minors in Virginia cannot give consent to or refuse medical care unless they are emancipated — either by being in the military, being married or being declared emancipated by a court.

Diekema says he believes patients are better served if treatment decisions can be made jointly by the patients (or their surrogates) and their physicians.

“The standard we usually use with parents in deciding when to consider state intervention is if their decision places the child at significant risk of substantial harm, above and beyond what [harm] they’d face if they pursued the path the physician chose,” says Diekema. In Cherrix’s case, regardless of what his physicians think, he firmly believes that chemotherapy is worse for his body than the herbal remedy he began taking in the spring during a visit to the clinic in Mexico.

Cancer patients are perhaps the most likely patients to seek alternative cures, particularly after an unsuccessful experience with traditional therapy. That’s because the disease is so serious and the side effects of conventional treatment are so uncomfortable.

“In oncology, the point at which the parents start looking for alternative therapies is when standard therapy is not successful the first time around,” according to Diekema. “And I don’t think it’s unreasonable for a parent to pursue [alternative therapy], so long as it doesn’t put the child at risk anymore than, say, a Phase 1 clinical trial.”

### ***Consent to an X-ray — but just one***

Back in court in June for a hearing to determine his competence to make his own health care decisions, Cherrix and his parents received no decision on custody and no decision on competence. But they did win one of their battles — the judge agreed to let Cherrix’s parents take him back to Mexico later in the month, provided he let the hospital in Norfolk take an X-ray of the tumors in his neck and chest.

“The judge said that if I would get a CAT scan from CHKD, that he would allow me to go to Mexico for my medicine and to see my doctor,” Cherrix told *Medical Ethics Advisor* after the hearing. “I agreed to one snapshot [X-ray], and one snapshot only. I really just want to get to my other doctor in Mexico; so it seemed fair enough.”

He says he does not want the multiple radiation exposures that a CAT scan would entail.

The judge also said he would welcome medical evaluations from the Mexican clinic to take into account as he decides whether Cherrix should determine his own care.

After two months on the Hoxsley program, Cherrix believes he is getting better.

“I feel more alive, and can tell an incredible difference,” he says. “I feel better than I did before I was told I had cancer.”

### ***Difficult decisions involving children***

Cherrix’s case is unusual in many ways, including his desire to entirely exclude conventional medicine. Doctors say that usually patients want to incorporate an alternative therapy in a way that complements — or, in the case of cancer patients, eases — the effects of standard treatments, such as using aromatherapy and herbs or roots like ginger to help calm the nausea that accompanies chemotherapy.

Diekema says that in some cases, such as a child newly diagnosed with leukemia who has perhaps a 90% chance of recovery with treatment, the decision to pursue conventional treatment is fairly obvious.

“But maybe you have a child with a much poorer outcome for survival, then that’s different,” he says. “If the odds are less in favor of the child and treatment has a fair amount of toxicity — when you add that into the equation, and if the child agrees with the parents — it makes the case stronger for not pursuing state interventions.”

Gillette says that while there are situations that demand forcibly overruling parents’ or minors’ decisions to veer from conventional therapy, as well as times to agree to those decisions or to part company, such decisions often don’t come easily.

“The most difficult cases are when patients force us to within a hair’s-breadth of the standards of care,” he says. “It’s easy when they go way beyond the boundaries or when their request is well within the boundaries of the standards of care.”

In a few states, the doctrine of the “mature minor” exists in statute, allowing courts and physi-

## Understanding Resistance to Treatment

When a patient resists treatment or intervention, ethicists with the Veterans Health Administration recommend physicians consider the following:

- Why is the patient resisting this intervention?
- Is the intervention causing physical discomfort or psychological distress?
- Are there ways to modify the intervention to minimize the patient's discomfort or distress?
- Is it essential to provide this intervention to achieve important goals of care, or, given the discomfort or distress it causes, could it be postponed or foregone entirely?
- Might the patient's resistance in fact be an expression of his or her authentic wishes?
- Might the patient have the capacity to make an informed decision about this particular intervention?
- Should we re-evaluate our assessment of the patient's overall decision-making capacity? ■

Source: National Center for Ethics in Health Care, Veterans Health Administration.

cians to take into account the age and situation of the minor, in context with the decisions being made, to determine if he or she is capable of making those decisions alone. Typical wording of the statute states that any unemancipated minor of sufficient intelligence to understand and appreciate the consequences of proposed surgical or medical treatment or procedures may offer consent on his or her own behalf.

The mature minor doctrine has been consistently applied in cases in which the minor is 16 years or older and understands the medical procedure he or she faces or requests — but primar-

ily only when the procedure is not serious. Application of the doctrine in more serious circumstances has seen mixed outcomes

### *Try to understand motivation for decision*

Diekema says that even when there is little chance the physician will agree with the decision to reject traditional care, he or she should make an effort, repeatedly if necessary, to understand why the patient or the patient's parents want to make that decision.

"We should try to understand what's driving their desire to pursue something else," Diekema says. "Perhaps, if they suffered greatly during a previous round of treatment, a decision could be made for better symptom control. Maybe the drug that caused the symptoms in the first cycle won't be used the second time."

The doctor's No. 1 obligation, Diekema says, should be to work with the patient, respect his or her concerns, address them honestly, and try every way possible to strike a compromise that satisfies the medical, ethical, and autonomy questions that swirl around these situations. (See table to the left for other suggestions.)

If the patient or the parents are laboring under misconceptions about conventional treatment or the alternative therapies they are considering, Diekema says the physician is obligated to try to provide clarity. In the case of alternative therapies, the Internet provides endless sources of information, some of which are not particularly balanced, he points out.

"Maybe you can provide the patient some alternative sites to look at, but overwhelmingly, the most ethical approach is to take the time and try to work with the family," he says. "Many families will come around, and that's one of the advantages to taking a respectful approach, is that it builds trust."

Even if the physician is doubtful that the alternative therapy will help, if it is something that does not interfere with or complicate the conventional treatment, he or she should suggest an "in addition to" rather than an "instead of" course.

"I have taken care of a patient who was taking St. John's Wort, which was interacting with her chemo, resulting in arrhythmia, and the end result was the child spent a week in the hospital being monitored," related Diekema. "But if the family asks for something that doesn't interact in a negative way, then we should do that even if it doesn't fit exactly into standard medical therapy."

### SOURCES

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Cherrix, however, is insistent that the chemotherapy regimen did him more harm than good, and that a second go-round would be even worse.

"I am capable of making decisions for myself," he says.

Diekema says there are times that the physician is faced with a mature adolescent who perhaps should be allowed to chart his or her own course.

"Another variable is how strongly does the adolescent feel about it? If you're faced with a 16- or 17-year-old who really doesn't want to do this, if it's a second relapse and they're looking at, say, a second bone marrow transplant — we'd let an adult make that decision [to forego treatment], and not necessarily think they were making a terrible choice," says Diekema. "So there can be strong cases to make for accepting an adolescent's choice."

Echoing Gillette's comments, Diekema says that if the odds are less clear cut, the decision becomes more difficult.

"If it's not a relapse and you have an 80% chance for a cure, you really want to make that treatment happen, but how far are you going to go to do that? I have asked doctors who are in this position, 'Are you going use physical force to hold a 17-year-old down to administer chemo?'" he says. "The answer is universally 'no,' so there is a line they won't cross. How can you treat cancer if you don't have a somewhat compliant patient?"

"That is just another argument for using the dialogue approach, and showing some respect. Sometimes with adolescents there is a desire for some control, especially when they are facing a disease like cancer, and they are pushing their limits to see how much control they can have. The best way to resolve that is to let the adolescent know that ultimately, it is their choice."

*(In future issues, Medical Ethics Advisor will update readers on the outcome of Abraham Cherrix's treatment.)* ■

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## Cedars-Sinai's traveling Torah brings blessings

*Portable holy document a first in U.S. hospital*

A gravely ill Sephardic Jew came to Cedars-Sinai Medical Center in Los Angeles from his home in Israel, hoping to find a successful treatment for his terminal cancer. The treatment did not yield the results he had hoped, but chaplain Rabbi Levi Meier visited his room with something more comforting than medicine.

A gift from a hospital volunteer has made Cedars-Sinai the only Jewish hospital in the country to have in its chapel an easily portable Torah, the most sacred document of the Jewish faith. The small, lightweight Torah can be taken to patients' rooms, and Meier says it has made more of an impact on his patients than anything else he's done for them in his 28 years as a hospital chaplain.

Handwritten in Hebrew, the Torah typically is a bulky scroll always kept safely in an Ark in a synagogue. To touch or even kiss the Torah as it is carried into the synagogue for services is considered a blessing; to be able to hold a copy of the Torah in a hospital bed is, for most Jews, unthinkable.

### **Torah brings peace, comfort**

"The day I brought [the ill Israeli patient] the Torah, it was just a regular day, not any holiday, but as soon as he saw me with it, he said, 'You know, Rabbi Meier, today is not an ordinary day. Today is my Simchas Torah,'" Meier recounts.

Simchas Torah is a celebration of the Torah, and falls on the last day of the Jewish harvest festival Sukkos. On that day, Jews in synagogue complete the yearlong cycle of reading the Torah, and begin the cycle again. Because the Torah is considered a document not only of the Jewish faith but also of the Jewish people, its importance is deep and far-reaching. For this reason, being able to hold and spend time with the Torah when they are ill or suffering is tremendously beneficial to Cedars-Sinai patients.

"He was telling me that even though he would not live to see another Simchas Torah [which is celebrated in the fall], bringing the Torah to him in the hospital brought him a sense of healing, and that his life was taking on a sense of completion," Meier says.

Patients weep, laugh, sing, and pray when

holding the Torah, Meier says, and inevitably, they are heartened, cheered, and calmed.

Meier tells of an elderly rabbi who was admitted to the medical center for hip surgery. When Meier brought the Torah to his room, the patient began reciting a psalm.

"He started reciting. . . and his voice just completely broke, and he said the rest of the psalm in complete tears," Meier recounts. "That's what I find amazing about the effects of this [Torah]; I think that King David wrote that psalm from his depths, and that's how the rabbi recited it."

### ***Idea came from chaplaincy volunteer***

Meier says the idea for the portable Torah came from a volunteer who was with Meier when he made a visit to a patient while carrying the chapel's large, heavy, bulky Torah. Despite its unwieldy size, the Torah restored the patient's spirits. The volunteer, Sandy Gordon, had the idea to locate a smaller version of the Torah and place it in the chapel in honor of her parents.

Meier says two rabbis in Jerusalem located a scribe in Israel who could do the meticulous job of hand writing the scroll. The rabbis delivered it to Meier in January, who placed it alongside the full-size Torah in the hospital chapel's Ark.

The beneficial effects of having a Torah easily accessible to patients are not only in comforting patients nearing the end of their lives. Meier says patients recuperating from surgery and experiencing pain have found relief from their pain simply by touching the scroll.

"I took it yesterday to a man, and just as I brought it to him he was being discharged on a gurney to a rehabilitation facility," Meier says. "He told me he was scared to leave, so I put the Torah on the gurney with him and said we will take it all the way down to the ambulance. I later got a call from rehab, and they told me that because of that, he feels that connection is still there."

The traveling Torah has gotten lots of attention from other institutions and the media, Meier says, and he hopes the idea catches on.

"If there is one thing I would like to see, it is this: There are 33 Jewish hospitals in the United States, and ours is the first to have a traveling Torah," he says. "I would like to see others adopt the same thing, because it has changed my whole pastoral counseling and care, like nothing ever has before."

"This has taken what is an ordinary visit and

made it so special, so spiritual. It gives patients a connection; if they're lonely, when they hold the Torah they don't feel so lonely."

*(For more information on Cedars-Sinai Medical Center's traveling Torah, contact Rabbi Levi Meier by e-mail at [meier@cshs.org](mailto:meier@cshs.org).) ■*

## **A prescription is worthless if a patient can't afford it**

*Make sure patients can afford meds, or get assistance*

**K**nowing that you have hit on the ideal medication for your patient's condition is a satisfying feeling. But if you fail to ask one important question before handing him the prescription — "Can you afford this medicine?" — your careful thought may have been wasted.

"A physician has an obligation to get patients the medication they need; but they [also] need to be aware if the patient can't afford the medications the physician is prescribing," says **Richard J. Sagall, MD**.

Sagall is a family practice and occupational medicine physician and consultant in Philadelphia who has spent several years building a Web-based, nonprofit resource, NeedyMeds.com, to help match patients with assistance in getting medications and care they might not be able to afford.

Inquiring about a patient's ability to afford prescribed medications is a question many doctors fail to ask, Sagall says.

"Doctors who don't deal with this issue by asking if the patient can afford to buy the medicine are wasting their patients' time and their own," he asserts.

Some doctors might not think of asking; others might just forget. It might be an obvious question to ask a patient you know is uninsured, Sagall says, but sometimes it's easy to assume that a patient with insurance can afford the copay his or her plan requires, when the truth is that the patient cannot afford even a \$10 or \$20 charge.

### ***Patients' conditions go untreated***

While some drug plans provide generic or inexpensive prescription drugs at no cost or for a nominal fee, some "upper tier" or newer drugs

can result in a hefty copay not affordable for some low- or fixed-income patients.

A Department of Veterans Affairs study published in 2004 showed that two-thirds of the 660 chronically ill older adults studied never told their doctors ahead of time that they planned to underuse their medications due to cost concerns, and 35% never told their doctors at all.

"If we don't ask, our patients usually won't tell," Sagall points out. "This is such an important thing, and a lot of physicians don't consider it. Not because they don't care, but because there is so much else to consider [during a patient encounter] that it is not high on their list of priorities."

According to a study funded by the National Institute on Aging, part of the National Institutes of Health, middle age and older Americans with heart disease who cut back on their prescribed medications because of cost were 50% more likely to suffer heart attacks, strokes or angina than those who did not report cost-related medication underuse. The authors, physicians with the Veterans Affairs Ann Arbor Healthcare System, also found that older patients who restricted medications due to cost concerns had increased rates of depression.

Sagall suggests physicians look at all available options before prescribing medications their patients have trouble affording. Among other alternatives:

- Non-medicinal treatments, such as weight loss, smoking cessation, and exercise can help, but only so much, Sagall concedes.
- Generics can cost up to 90% less than the brand-name drugs, but are not available for every condition.
- Old standbys — older drugs, rather than the

## SOURCE/REFERENCES

For more information

- **Richard J. Sagall**, MD, president, NeedyMeds.com, P.O. Box 63716, Philadelphia, PA 19147. E-mail rich@needymeds.com
- Piette JD, Heisler M, Wagner TH. Cost-related medication underuse: Do patients with chronic illnesses tell their doctors? *Arch Intern Med* 2004; 164:1,749-1,755.
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latest drugs on the market — may be more affordable. However, they may not always be the best choice for certain patients.

Sagall also advises physicians to familiarize themselves with how much the drugs they prescribe cost.

"And while you might have a favorite drug that you really like, in terms of its effects, you have to consider whether the difference in benefits justifies what might be a higher price," he adds.

## PAPs, other assistance available

There are resources available to patients who need help purchasing needed medications, but most may not be aware of the programs, and if they are, they need a physician's help in qualifying.

Patient assistance programs, or PAPs, are programs offered by pharmaceutical companies to low-income individuals and families. They typically require a doctor's consent and proof of income and insurance (or lack thereof).

Sagall developed NeedyMeds.com almost 10 years ago along with a home health social worker who had created a database of assistance programs for clients who could not afford their medications. Sagall said the list became a Web site, which has grown exponentially.

"For almost every condition, there are medications available through patient assistance programs," says Sagall. NeedyMeds.com identifies more than 350 companies or programs, as well as 200 state-funded programs, offering nearly 2,700 drugs and dosages.

The Pharmaceutical Research and Manufacturers of America, an association of pharmaceutical companies, reports that its member companies distributed free of charge more than \$4 billion worth of medications through PAPs in 2004.

NeedyMeds.com has expanded to provide information not only on PAPs, but also on disease- or condition-specific resources (e.g., cancer, Parkinson's disease, amputations), paperwork and application assistance services, and govern-

## CE/CME answers

1. D; 2. B; 3. B; 4. A.

ment-sponsored assistance programs.

"We have designed it so that with four clicks of the computer [mouse], you should be able to find what you are looking for," he says. Despite its ease of use, Sagall points out, patients may need their physicians' help in first finding the program, and then taking advantage of PAPs or other programs that can assist them. NeedyMeds also offers brochures that physicians can order for their offices or download and print out for patients.

"Our philosophy is that if we can teach people how to get help, they can continue to get it on their own," he says. ■

## Gene therapy trials: Parents in UK say include CF kids

Clinical trials involving gene therapy are considered to be of great enough real and potential risk that they are not attempted in children before they have been conducted with adults. But a survey conducted by doctors at Britain's second-largest hospital specializing in cystic fibrosis treatment indicates parents are inclined to favor clinical trials for their children.

Cystic fibrosis is a life-limiting illness with high morbidity, with a median life expectancy of just more than 24 years. Gene therapy is considered a promising potential treatment for genetic diseases like cystic fibrosis, and results, experts say, might be better and more easily measured in children than in adults.

In the *Journal of Medical Ethics*, researchers question which is more ethically sound — to subject children to experimental genetic therapy that has not been tested in adults, or to deny children access to therapy from which they might gain even greater clinical benefits than adult patients would.

One difference, the authors say, is that the goal in the treatment of cystic fibrosis is to get to it as

early a possible; therefore, the benefits of gene therapy in early childhood could be substantial.

The authors of the study, based at Great Ormond Street Hospital and the Institute of Child Health in London, presented a questionnaire to the parents of children with cystic fibrosis treated at their unit. They asked parents whether, considering the potential risks and benefits of gene therapy for cystic fibrosis, they would be in favor of their children receiving the trial therapy.

Overall, 82% of the parents considered gene therapy to be the most important area of research in cystic fibrosis, and of those, 56% hoped it would result in a cure, 31% sought alleviation of symptoms, and 10% said they hoped for both.

Almost all — 99% — of the parents surveyed said they felt it was ethically sound for children to be given the opportunity to participate in gene therapy trial, provided appropriate safeguards were in place. Slightly fewer parents (91%) said they would consider consenting to their own children participating in clinical trials of gene therapy.

The authors suggest their study findings might help in the design of future clinical trials, but warn that children with cystic fibrosis and their parents should be protected from unnecessary harm.

The authors point out that their study was based on a small sample, and the questionnaire did not explicitly describe all possible risks of gene therapy.

Cystic fibrosis is caused by a single defective gene on chromosome 7, resulting in the defective production of a protein that regulates cellular ion transport. Researchers say gene therapy, the insertion of a normal gene into deficient host cells, is a potential treatment or cure for diseases caused by single-gene defects.

The researchers' findings are found in: Jaffe A, Prasad SA, Larcher V, et. al. Gene therapy for children with cystic fibrosis — Who has the right to choose? *J Med Ethics* 2006; 32:361-364. ■

### COMING IN FUTURE MONTHS

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■ Elderly patients with no support system

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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 certificate of completion. When your evaluation is received, a certificate 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

1. Among the challenges facing research teams planning to perform the first face transplant in the United States is/are:
  - A. establishing the mental health and stability of potential subjects;
  - B. ensuring that informed consent about a relatively unknown outcome is in place;
  - B. locating donor tissue and considering informed consent for donors and families;
  - D. all of the above.
2. Experts agree that despite partial face surgeries in Europe and Asia, the surgery is not technically advanced enough to successfully achieve a face transplant.
  - A. True
  - B. False
3. When prescribing medications for patients, a physician's first and only concern should be finding the best medication for that patient, regardless of cost.
  - A. True
  - B. False
4. According to pediatric bioethicist Douglas Diekema, when a minor seeks alternative treatment in conflict with standard of care, a physician's best route is to:
  - A. continue the dialogue with the patient and family in an attempt to work out a compromise that satisfies everyone.
  - B. refer the patient to another physicians
  - C. summon child protective services and seek court intervention
  - D. go along with the child's wishes, regardless.

## On-line bonus book for MEA subscribers

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