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Is 'new' reason enough to deny payment for an experimental procedure?

MA case breaks ground on medical necessity, coverage

In a move that many hope will lead to better access to organ transplants for people infected with HIV, a Massachusetts board of appeals has reversed a state payer's denial of coverage for a liver transplant operation for an HIV-positive man.

An appeals board with the Massachusetts Division of Medical Assistance reversed an earlier decision by one of its contracted health plans that denied coverage of a liver transplant consultation on the grounds that the man's HIV status made any such procedure experimental. Procedures considered experimental do not meet the payer's medical necessity guidelines.

"Our client was HIV-positive, but he is asymptomatic and his infection poses no threat to his life," says **Bennett Klein**, an attorney with Gay and Lesbian Advocates and Defenders, a Boston-based advocacy group that represented the patient. "But he is coinfected with hepatitis C and has end-stage liver disease."

The payer's contention that the transplant would be experimental was based solely on the patient's HIV status and not any other clinical criteria, he adds. "But we were able to submit scientific evidence that although this is a new procedure, just being new isn't enough to make it experimental."

Until recent years, patients infected with HIV were considered ineligible for transplants because it was thought that immunosuppressive drugs given to prevent rejection of the donor organ would decimate the patient's immune system and lead to more rapid progression to full-blown AIDS. And prior to

COMING IN FUTURE ISSUES

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advancements made in HIV therapy in the mid-1990s, patients were thought to have too short a life expectancy to benefit from the surgery.

However, advances in both HIV treatments and immunosuppressive therapy have prompted some transplant surgeons, medical ethicists, and AIDS activists to challenge the conventional wisdom that these patients should not be candidates for transplant.

"The past arguments for automatically excluding [someone] from liver transplantation are no longer applicable; they are obsolete," says Klein.

In fact, the Richmond, VA-based United Network for Organ Sharing (UNOS) has never considered HIV infection to be a contraindication to transplant eligibility, and has policies stating HIV-positive people should be included on transplant lists.

Currently, however, only two transplant centers, the University of Pittsburgh Medical Center (UPMC) and the University of Miami (FL), are performing solid organ transplants in HIV-infected patients. Approximately 12 to 20 more centers are considering performing heart, liver, and kidney transplants in HIV patients, but only as part of a controlled, three-year, multicenter research study based at the University of California San Francisco (UCSF).

Most insurers and transplant centers still consider transplanting organs into HIV-positive patients too risky, especially given the severe shortage of available donor organs.

Long-term studies needed

Despite the advances in medical treatment, patients with HIV still face unique complications from undergoing organ transplant surgery, and these procedures need clinical study before being widely performed, some medical experts claim.

"It seems to me that the argument goes that given that HIV is now in many ways a chronic disease with life expectancies in patients of 10 years or more, it makes sense to offer those patients transplants," says **Robert Arnold**, MD, professor of medicine in the division of general internal medicine. Arnold also is chief of the section of palliative care and medical ethics at the UPMC Health System.

Arnold also provides primary care for HIV-positive inpatients at the medical center. "I think we should have some idea of what the success and failures are so that patients and doctors understand, and society understands, what the

true risks and benefits are."

The surgeons at UPMC are confident that they have the clinical knowledge and expertise to perform transplants in some HIV-positive patients, Arnold says. Transplant teams led by UPMC surgeon John Fung, MD, have performed four liver transplants and two kidney transplants on HIV-positive patients since 1995. And UPMC surgeons are collecting clinical data on all of the procedures they perform.

It may be that only performing these transplants at a limited number of centers until more data are collected will yield better results in the long run, than all transplant centers agreeing to do them now, Arnold adds.

For example, appropriately managing immunosuppressive therapy in conjunction with anti-retroviral regimens is a complication for HIV-positive patients not shared by other transplant patients. Instead of a large number of centers experimenting on different patients, a few centers might be able to more quickly ascertain the best practices.

"It is probably a good idea, rather than everyone doing it without clear data, to have it done in a controlled manner," he says.

Some have no time to wait

While it's true that good, hard data on the safety and efficacy of solid organ transplants in HIV patients do not yet exist, it's difficult to argue that HIV patients should not have access to transplants until large-scale studies have been performed, says **Michelle Roland**, MD, assistant clinical professor at UCSF. Roland also is an HIV specialist at San Francisco General Hospital. UCSF has received funding from the National Institutes of Health and private sources for its proposed three-year, multicenter study of organ transplants for this patient group.

Physicians often say that performance of experimental medical procedures should be initially restricted to clinical trials at selected centers until more data are collected. The argument being that, until safety data are first collected, it is impossible to know whether the procedure is actually helping patients, harming patients, or having no real benefit.

"I don't think that's a valid argument in this situation, particularly when you are talking about someone with end-stage liver disease [ESRD]," Roland says. "For patients in liver failure, the only alternative to a transplant is death."

There is no hard evidence that transplants in HIV patients are not safe and effective either, she points out.

As a medical researcher, Roland would like to be able to collect clinical data for her study from every transplant procedure performed on patients with HIV. Such information would allow providers to develop best practice guidelines that much sooner.

However, it's unrealistic to expect that Roland's study will receive the kind of funding necessary to include every center that would like to participate.

"There will be patients who need a transplant, who, for financial or geographic reasons, cannot go to a center that is part of a study," she says. "I cannot argue that these patients should not have access."

As for the coverage issue, Roland agrees with the argument that these transplant operations are experimental, but disagrees that payers should use that as criteria for denying coverage for what is essentially a patient's last hope.

"We need the insurers to cover the clinical costs of performing these operations in order to be able to determine the safety and efficacy," she says.

Decision may affect others' plight

The decision by the Massachusetts board may make other payers less likely to automatically exclude HIV patients from consideration for transplant, hopes Klein. "While it is not a court decision, we have a very detailed, 23-page ruling that includes all of the scientific evidence we presented."

Though he emphasizes the need to collect clinical data, Arnold also says he hopes the increased attention will lead to HIV-positive patients being considered potential transplant candidates.

"HIV patients should be treated the way all other candidates with chronic diseases are treated,"

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he says. "We need to consider whether the organs would be saving lives and what affect they have on the patients' lives. They should neither be more likely to get an organ because of the advocacy of HIV-positive groups, nor should decisions be prejudiced because they have HIV." ■

Egg donation poses risks for fertility clinics

Study questions risk info given to donors

They appear in almost every college newspaper and urban entertainment weekly. Enticing advertisements promise thousands of dollars to young women willing to donate eggs to help infertile couples conceive. For many, this seems like a win-win proposition — you get needed money for school while helping others have a child they desperately want.

But oocyte donation, as the process is more formally known, is not exactly a risk-free procedure. Reported complications include induction of premenstrual syndrome-like symptoms, ovarian hyperstimulation syndrome (OHSS), and a possible increased risk of ovarian cancer due to the strong fertility drugs administered.

With more and more couples seeking donor eggs and a shortage of women willing to part with theirs, some ethicists worry that assisted fertility programs have too much incentive to play down the risks and offer women ever-increasing sums of money.

"Egg donation programs need to recruit oocyte donors to maintain a financially viable business," says **Andrea D. Gurmankin**, MA, a graduate student in psychology at the University of Pennsylvania's Center for Bioethics in Philadelphia. "I think that offering young women thousands of dollars combined with the incentives that these programs have to minimize the risk has the potential to lead to a very bad situation."

Gurmankin published a pilot study in the fall 2001 issue of the *American Journal of Bioethics* that evaluated the risk information provided by several in vitro fertilization (IVF) programs during preliminary phone interviews.

Posing as a potential donor, Gurmankin called 19 different programs nationwide and asked for information about the egg-retrieval process and any risks involved. Here are some of her findings:

• 26% of the programs called did not volunteer information about the procedure or any risks involved.

• 21% of the programs would not answer questions about the procedure or about the risks of the procedure over the phone, instead referring the caller to information that would be sent by mail.

When the information sent by mail was included in the overall consideration of the risk information provided:

• 21% of the programs volunteered information about the risk of infection.

• 32% volunteered information about the risk of vaginal bleeding.

• 32% volunteered information about PMS symptoms.

• 32% volunteered information about the risk of OHSS.

• 5% volunteered information about a possible risk of ovarian cancer.

Only 5% of the programs contacted volunteered any information over the phone about possible risks, while 32% of the programs mentioned the amount of financial compensation given.[1]

The results do not necessarily indicate that the programs don't give complete information prior to accepting women as egg donors, Gurmankin admits. But it does raise questions about whether the donors truly make an objective decision.

"I am not suggesting that they don't get complete and voluntary informed consent before asking the woman to donate," she says. "But I am still worried about the fact that they are not giving complete information at this preliminary phone call point."

Several psychological studies have shown that incomplete information given at a project's outset can bias information that is provided at a later date, she explains.

"There is the concept in psychology called 'lowballing,'" Gurmankin continues. "The idea is that if you can induce a person to make some sort of real commitment — like coming in for a medical screening — toward a desired action, like egg donation, should you later make that action less desirable by fully informing that person of the risks. They are still less likely to back out than they would have been had they known the full information at the outset."

There is a kind of behavioral commitment at the outset that makes it difficult for participants in an activity to "back out" once other people expect them to continue, she says.

"For a young woman, it is conceivable that it is

very difficult to say 'no' once you have made some commitment," she adds. "And just in general, people tend to be unrealistically optimistic about the risks that they may face. I can only imagine how this is enhanced in the face of thousands of dollars in compensation."

Study does not evaluate consent process

Although Gurmankin's project raises some interesting points, the study results don't reliably reflect the risk information provided by these programs, says **Mark V. Sauer**, MD, professor of medicine and director of reproductive endocrinology at Columbia University in New York City. Sauer wrote an accompanying editorial that was published in the same issue as Gurmankin's piece.

"The article had major flaws in study design that greatly limit, if not negate, its importance," he tells *Medical Ethics Advisor*. "That is not to say that problems do not exist. They do, but mainly in the area of informed consent. I do not believe this paper adequately addresses any of these issues and therefore, more and better studies need to be performed."

There is approximately a 1% complication rate in women undergoing these procedures, he notes. These risks are well defined and should be disclosed.

But, Sauer says, the risk issues can only be adequately explained and discussed by trained personnel. Personnel ordinarily available to answer the phone would not be qualified to give out such information.

"Our program, as most good ones, provides a fair amount of information, both written and verbal, to prospective donors prior to enrolling them in the program," he says. "This is a dynamic process, typically involving physicians, social workers, or a mental health professional, and nurses. The process requires several visits and time as well, which gives the donor adequate time to back out if she has concerns."

The preliminary phone conversation has about the same place in the informed consent process as the recruiting ads placed in newspapers, says **Rebecca Dresser**, JD, the Daniel Noyes Kirby professor of law and professor of ethics in medicine at Washington University in St. Louis. Dresser also served on the working group that wrote the Birmingham, AL-based American Society for Reproductive Medicine (ASRM) guidelines on offering financial compensation to egg donors.

"If you're calling up a program, you might get the receptionist," she says. "I don't think she would need to discuss specific medical information. But it seems to me that the receptionist, like the advertisement, should at least say that there are some risks to the procedure. What we said in our [ASRM] statement is that if the advertisement discusses benefits or positive aspects of donation, and usually that is the financial compensation, it should also note the presence of risks, making some general statement to highlight that."

Dresser agrees with Gurmankin's concern that prospective donors' early perceptions of the procedure will color their decision-making process later.

"The way the ads and the initial phone conversation affects the donor's initial perception can be an important influence," she agrees. "The initial impression needs to be balanced."

Are they patients or research subjects?

Part of the problem with ensuring informed consent for oocyte donors is that they sort of fall into a gray area between clinical medicine and medical research.

Their situation is most like human subjects recruited for research studies because they are being asked to undergo a procedure that poses some risks, but for which they can expect to receive no medical benefit, say both Gurmankin and Dresser.

"They are putting themselves at some risk. Yet, as a society, I think we would say it is a reasonable risk," Dresser explains. "But it is a significant risk and it is not really for their benefit."

Using the research subject criteria, fertility programs are obligated to make sure the risks to the donor are not unreasonable, that the donor understands the risks, and that the amount of compensation does not coerce them into consenting.

But, unlike many human research studies that receive federal funding or are conducted at an institution that does, fertility programs are not required to have an IRB approve its informed consent procedures or recruitment protocols, says Gurmankin. "There are no measures in place to protect egg donors, and I think that they are needed."

Though egg donors are in a similar situation to human research subjects, they are not, in fact, serving in a research protocol, notes **Judith F. Daar**, a professor of law at Whittier School of Law in Costa Mesa, CA.

Elements for obtaining ART informed consent

The Birmingham, AL-based American Society for Reproductive Medicine (ASRM) has published a practice committee report on what elements should be included in the informed consent process for people undergoing assisted reproduction technology (ART). Below are the elements that should be covered for participants in oocyte donation.

The complete report can be found on the ASRM web site at: www.asrm.org/Media/Practice/informedART.html.

A. Description of procedure including:

1. Medical and psychological screening including genetic and infectious disease testing as applicable.
2. Use of ovulation induction agents.
3. Monitoring of cycle.
4. Oocyte retrieval.
5. Fertilization of oocytes.
6. Potential cryopreservation of embryos.

B. Potential risks and discomforts (donor) including:

1. Blood drawing.
2. Ovulation, induction agents including allergic reactions, hyperstimulation, and the association with ovarian cancer.
3. Antibiotics.
4. Oocyte retrieval.
5. Laboratory and clinical handling of gametes and embryos.
6. Psychological issues.

C. Special considerations (recipient) including:

1. Monitoring of cycle.
2. Medications
3. Failure to obtain oocytes, sperm, or embryos.
4. Laboratory and clinical handling of gametes and embryos.
5. Risks of congenital abnormalities.
6. Potential Rh incompatibility.
7. Transmission of viral infections, including HIV.
8. Psychological issues.

D. Legal issues.

They are, however, undergoing a medical procedure under the supervision of a doctor that should qualify them as a patient of that physician, she says. What is unclear to her is whether the physicians involved perceive the donors this way.

"I am not even sure that the egg donors are looked at as patients," she says. "I think the argument can be made that if they are not looked at as patients and merely as an instrumentality to achieve a goal of pregnancy for another woman, then they would not be seen as eligible for informed consent. That may be taking it a bit far. I don't think donors are actually treated this way. But the potential is there."

In many programs, one physician supervises both the oocyte retrieval from the donor and the IVF procedure for the woman or the couple seeking treatment, she says.

This raises conflict-of-interest issues that go even beyond the informed consent process.

"If there are complications, such as hyperstimulation of the donor's ovaries, is the physician going to feel an obligation to stop the cycle to protect the health of the donor or continue to obtain the best outcome for the woman who wants to become pregnant?" she asks.

Daar participated in a working group in California several years ago comprised of attorneys who practiced in the area of assisted reproduction. A number of attorneys reported concerns about clients who were oocyte donors, she says.

"They felt that there were not only problems with informed consent, but some felt that there was a neglect of the health of the donors, some of whom were being hyperstimulated and suffering a number of different side effects from the drugs," she states. "They felt these issues were being given little attention by the assisted reproductive technology community as well as the bioethics community."

Many say that such ethical concerns, on top of the dilemmas already raised by the rapidly changing assisted reproduction industry, must inevitably result in some sort of government oversight.

In 2000, the California legislature passed a bill requiring fertility programs to provide oocyte donors with a "standardized" written form detailing the potential risks of oocyte donation. The governor refused to sign the bill into law because the state health department was developing a standardized form to be used by all programs throughout the state, says Daar. The form still is in development.

SOURCES

- **Judith F. Daar**, Whittier School of Law, 3333 Harbor Blvd., Costa Mesa, CA 92626.
- **Rebecca Dresser**, Washington University, Law School-Box 1120, One Brookings Drive, St. Louis, MO 63130.
- **Andrea Gurmankin**, Center for Bioethics, University of Pennsylvania, Suite 320, 3401 Market St., Philadelphia, PA 19104-3308.

The ASRM has published guidelines on informed consent for oocyte donors and on appropriate financial compensation for donors, but compliance with these standards is completely voluntary and is not monitored. **(See box, p. 6.)**

The only way to ensure that fertility programs adhere to certain ethical standards is by state regulation, which is virtually nonexistent across the country now.

"There is no formal review process now and maybe there should be," says Dresser. "There is a lot of conversation now about how this area is unregulated. One way to do it would be to have some sort of institutional review requirement and ensure that the programs have to be approved regularly."

Reference

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Rural bioethics: Smaller communities, various views

Ethics takes on a more practical matter

It probably comes as no surprise that hospitals serving rural communities face ethical challenges foreign to their larger, big-city counterparts. And, unfortunately, they have found little help from the national bioethics community in solving these dilemmas, say those who study ethics in rural health care.

"Those who teach bioethics generally live and work in urban areas, and the scholars who write about ethical issues, and those who serve on review boards that publicize ethics-related books and journals usually have an urban orientation," says **Ann Cook**, PhD, associate professor and director of The National Bioethics Project (NBP) at the University of Montana-Missoula. "The ethical issues that challenge rural health care have not been well investigated."

A NBP survey of hospital administrators in a six-state area[1] found that 58.8% lacked bioethics committees or any similar mechanism to resolve ethical dilemmas. Most hospitals also lacked accreditation by the Joint Commission on Accreditation of Healthcare Organizations. Only 10% of the existing ethics committees met regularly, and most had no role in activities related to policy, advocacy, or case consultation.

A similar survey of nurses in rural hospitals found that most (88%) lacked any access to bioethics-related resources. Only 10%-35% reported access to resources that might be considered ethics-related, such as ethics rounds, staff development programs, ethics consultation services, forums, and continuing education programs.

Even if rural providers had more access to bioethics resources, it's not clear that they would find much that is relevant, note Cook and **Helena Hoas**, PhD, also an associate professor at the University of Montana and project research director at the NBP.

"Fewer than 20% of medical schools have developed ethics courses that address such topics as cultural issues, specialization-specific ethical issues, managing relationships, care of the family and significant others, patient experience of illness, and the use of ethics resources like committees and consultations," she says.

In recent years, the field of bioethics has focused more on complex moral and philosophical issues related to assisted reproduction, biotechnology, cloning, genetics, physician-assisted suicide, stem-cell research, and xenotransplantation.

Yet, surveys of rural providers indicate they need help with more practical issues. And, they want resources that take into account the context in which they practice.

Relationships are primary

For example, though professional codes often discourage "dual relationships" between physicians and patients, most rural physicians report that they have both personal and professional relationships with a number of their patients.

"In rural communities, people are connected to one another, and they expect that those connections

National Rural Bioethics Project

The National Rural Bioethics Project is a research effort based at the University of Montana in Missoula. The project's purpose is to conduct research in four focus areas:

1. Context: What kinds of bioethics-related issues emerge in rural communities and rural health settings?

2. Practices of health care providers: How do health care providers resolve the ethics-related problems that develop in rural settings?

3. Perception of need: Do health care providers believe additional ethics-related resources are needed? If so, what resources would they use?

4. Local values: Are there cultural or contextual issues that shape the ethics of health care in rural communities?

The project recently received a grant from the Agency for Healthcare Research and Quality for a three-year, multimethod intervention study that seeks to develop and disseminate bioethics-related resources that will:

- increase educational opportunities for health care providers;
- address patient safety concerns;
- help reduce medical errors in rural health care settings.

The project has developed a web site and is field-testing an array of resources that may help rural providers resolve ethical issues they encounter. The web address is www.umt.edu/bioethics. ■

will be honored and valued," Cook explains. "Indeed, if a physician is not sufficiently invested in a relationship, his recommendations may be disregarded and his practice less than successful."

In addition, cultural perceptions of the values of privacy and confidentiality are different in a rural setting than in an urban center.

While the bioethics literature — and most urban hospital policies — mandate strict protection of patient confidentiality, this model may not work well in a rural community.

For example, one survey respondent related that a hospital administrator, new to a rural community, realized that a local newspaper was publishing the names of people admitted to the hospital. Immediately, he forbade the release of such information, informing hospital staff, local ministers, and the newspaper that publication of the information was a breach of confidentiality, Cook and Hoas say.

The action was perceived as uninformed by the hospital staff and members of the community, and they quickly found a way around it.

A group of elderly women patrolled the halls of the hospital in the morning, taking note of who was hospitalized and then met at a local coffee shop to relay the information and start a phone tree.

The community needed the information to know which families might need rides to the hospital, casseroles sent to the home, or other types of social support.

Privacy is important to residents of rural communities, but they have a more restricted idea of what information should not be divulged, says Cook.

Financial stresses affect organizational ethics

The economically strained situation of both rural health facilities and residents also affects care delivery in unique ways.

"Several issues are at play," says Hoas. "In rural areas, the levels of reimbursement for health care services are often inadequate, the already high numbers of those who are uninsured are growing, and as a result, profit margins in rural hospitals are narrow."

Financial concerns often lead to the need to ration care in some situations. Hospital personnel are often acutely aware that decisions that adversely affect the hospital's finances could lead to the facility's closure — an event that would lead to loss of a large number of jobs and could leave the entire community without access to tertiary care.

"Quality of care can also be influenced by social and geographic factors, such as the inability of a rural hospital to hire experienced nurses who

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- **National Rural Bioethics Project**, Department of Psychology, The University of Montana, Missoula, MT 59812. Web: www.umt.edu/bioethics/.

have adequate training and education," she continues.

Rural providers need ethics-related resources that are "interactive, accessible, practical, inclusive and nonacademic," says Hoas. "They want practical tools that give them 'words' to address issues with colleagues and patients rather than journals, seminars, or mechanisms like committees."

Many rural providers are committed to remaining in their communities long-term, say Cook and Hoas. And, given the lack of financial resources for hiring outside ethics consultants, it makes more sense to offer educational and ethics training opportunities to providers already committed to rural environments.

However, new models and resources need to be developed that will reflect the cultural values and unique context of rural health care, rather than relying solely on academic principles of bioethics.

"We do think the discipline of bioethics needs to expand," says Cook. "The traditional approach of bioethics and its principalism seems too rigid and too difficult to apply. Our research suggests that bioethicists need to incorporate, in numerous ways, the context in which health care is provided, a sort of 'who does what to whom and how' model. We also think a greatly expanded array of materials, models and resources are needed."

In the meantime, clinicians who are new to a rural community should seek out a mentor who is an "insider" and can teach them the ropes — someone who understands the history of the community, and its people and values.

"This is sensible because more experienced physicians and nurses reported encountering fewer ethical problems, an indication they may have developed skills to cope with common issues like confidentiality, familiarity, and patients who refuse treatment recommendations," she says.

Rural providers might want to explore ethics-related resources on the Internet as well, giving serious consideration to development and dissemination of ethics resources that are useful for patients and community members.

"That constituency needs opportunities to dialogue with healthcare providers in order to define and accept a hierarchy of shared values," says Hoas.

Suggested Reading

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'Theater' helps students interact with community

In rural communities, developing relationships between residents and health care providers is essential in building the trust needed to sustain the local health system. Residents need to know that providers care about them and won't abandon the community. Providers need a way to hear residents' concerns and get a better understanding of community values.

Institutions serving rural areas have recently been experimenting with readers' theater projects as a way to jump-start community / provider dialogue.

Readers' theater is an inexpensive, fun, and thought-provoking way to get members of a community to interact, says **Todd L. Savitt**, PhD, professor of medical humanities at the Brody School of Medicine at East Carolina University in Greenville, NC.

"It's a great way to get small communities to talk to each other and work through issues," he says. "Health care is something we are all affected by. We all can safely have and voice opinions because it affects us."

Savitt started the medical school's Reader's Theater program in 1988. His model has since been used by The National Rural Bioethics Project at the University of Montana and a number of medical schools across the country.

Medical students audition each semester to take part in the program, which offers no payment or class credit.

"We take a short story that has to do with an ethical or social issue in medicine," he explains. "We always use good literature. We don't want stories that have been written for that specific issue. We don't want a teaching story, something

that someone wrote to teach someone about advance directives or something like that. We take stories that are already around."

A playwright adapts the story to be performed by multiple "readers" in a half-hour format. Stories that have been adapted in the past include, Arthur Conan Doyle's *Doctors of Hoyland*, Richard Selzer's *Follow Your Heart* and *A Question of Mercy*, and *A Face of Stone* and *The Girl with a Pimply Face*, both stories by William Carlos Williams.

The students wear a standard uniform, identical T-shirts, and dark pants or skirts, and they only meet one time together to practice the script before reading the play in public.

"You want to read the story reasonably well, but no one has expectations that this is going to be a theatrical performance," he says.

In fact, all action is left to the listeners' imagination. The actors sit or stand in front of the audience, reading from the script. If they look up, they look above the heads of the audience, not at audience members or one another, he says.

"It is like reading, in a sense, all action is left to the imagination. But it is a group experience," Savitt says. "The heart of reader's theater is not the performance, which takes 20 or 30 minutes, but the discussion that follows."

Group reading encourages sharing

Hearing a story as a community of people, rather than reading it to oneself changes a person's experience of the story, Savitt feels.

"When you read a story, you may think, 'Wow! That's a neat story,' then you put it down. You may mention it to someone else. But it is your story. You have read it the way you want to read it, and no one else has the same experience," he says. "But to perform a story the way we do it, which is taking most of the lines in the story and giving voice to them, hearing it is another level."

The group hears the story and experiences the story together and then discusses it.

"What happens is that the audience members hear each other's ideas and play off of them," he says. "People hear each other's ideas and think, 'Hmmm. I hadn't thought of that.' Or, 'I completely disagree with what you are saying.'"

The performance stimulates discussion not just between audience members and the readers, but among audience members themselves.

One story, Selzer's *Follow Your Heart*, always provokes an intense discussion, Savitt says.

The story involves a woman who witnesses her husband's death and is then asked to donate his organs. She does, but cannot cope with the idea that in some way, her husband is still alive in the people who now have his organs.

"She has to resolve whether she feels he is dead or alive," Savitt explains. "She argues with her sister about what happens on the day of resurrection. Who gets the organs? Things like that."

Ultimately, the character resolves her conflict by secretly finding out who received her husband's heart. She goes and listens to her husband's heart beating in the chest of another man.

"That has generated a range of responses — from 'She's loony,' 'What a weird story,' to the exact opposite," he says. "Some people think it is a tender, loving story and a beautiful idea. They think that we should allow organ recipients to know who the donor was, things like that."

The discussions help the medical students understand the values and opinions of different members of the community.

"It's great for the medical students because they get some idea of the roles they will be playing," he says. "They love it because it's a way to get out into the community and hear what real people think."

The program gives them the opportunity to "step back" from being so close to the science of medicine and think about the issues involved, he adds.

Target performances to small groups

When he first started reader's theater, Savitt posted signs around campus announcing the performances — and no one came.

He's since learned that performing for "built-in" groups, such as book clubs, retirement homes, social organizations, is a better way to schedule performances and to stimulate discussion.

"We try to find groups who are already meeting and that way we are sure to have an audience," he notes.

However, too large an audience can be a problem with the format, he adds.

SOURCE

- **Todd L. Savitt**, PhD, The Brody School of Medicine at East Carolina University, Department of Medical Humanities, 2S-17 Brody Medical Sciences Building, Greenville, NC 27858-4354.

"We did a performance at the [Augusta-based] Medical College of Georgia, and they had all 600 of their first-year students who were there for orientation come," Savitt relates. "The performance was great, but you really can't have a discussion with that number of people. Ideally, it is not make for large audiences; it is better with groups of 20-50 people."

Savitt is compiling all of the performed scripts into a book, which he hopes will be an instructional tool for other schools and groups that want to begin doing reader's theater.

"I have written sort of a how-to for the introduction," he says. "It is basically how you do reader's theater, I have included explicit instructions, such as when to sit down or stand up, etc. It is my hope that this will expand to other institutions and we will have more community-based reader's theater. ■

Massachusetts company announces embryo cloning

Drawing criticism from both ethicists and lawmakers, Advanced Cell Technology, a Worcester, MA-based biotech company dedicated to research and development of genetic technologies for agricultural and pharmaceutical research, announced last November that its scientists had successfully cloned a human embryo.

In a report published in the on-line journal *e-biomed: The Journal of Regenerative Medicine*, researchers reported that they used somatic cell nuclear transfer to form pre-implantation embryos. In this procedure, human egg cells are prepared by removing their DNA and adding the DNA from a human somatic (body) cell. The journal reports that the somatic nuclei showed evidence of reprogramming to an embryonic state as evidenced by pronuclear development (a type of nucleus observed only in the fertilized egg) and by early embryonic development to the six-cell stage.

The company did not report on whether it had isolated embryonic stem cells.

Under a measure passed last year by the U.S. House of Representatives, human embryo cloning would be considered a crime punishable by a fine and imprisonment. The U.S. Senate has yet to take action on the proposal.

Announcement gets criticism

Following the company's announcement, a number of ethicists and researchers criticized the findings. Among the critics are National Institutes of Health (NIH) director Harold Varmus and Boston University bioethicist George Annas. Both argue that the researchers had not contributed any new information to the science of stem-cell biology because they had not isolated the stem cells.

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Editorial Questions

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A member of the on-line journal's editorial board, John Gearhart, a researcher at Johns Hopkins Medical Institutions in Baltimore, announced on Dec. 5 that he was stepping down from his position on the board to protest inclusion of the study in the publication.

Therapeutic use is OK

Despite the controversy, seven senators announced their support for therapeutic human cloning in the wake of the report's publication.

Sen. Tom Harkin (D-IA) told the *Los Angeles Times* on Dec. 5 that he would introduce a bill that would outlaw reproductive cloning, but permit scientists to use "therapeutic" cloning as a means to research cures for disease.

A similar bill has already been introduced by Sen. Dianne Feinstein (D-CA) and is supported by four other senators. Sen. Arlen Specter (R-PA), a supporter of stem-cell research under President Bush's guidelines, announced through a spokesman that he supports therapeutic cloning but has not endorsed a particular bill. ■

CE/CME *Questions*

CE/CME subscribers: *Please save your monthly issues with the CE/CME questions in order to take the two semester tests in June and December. A Scantron form will be inserted in those issues, but the questions will not be repeated.*

1. The study performed by Andrea Gurmankin from the University of Pennsylvania evaluated:
   A. The informed consent process used for oocyte donors by most U.S. assisted reproduction programs.
   B. The amount and accuracy of risk information presented during preliminary phone conversations with several assisted reproduction programs with potential oocyte donors.
   C. The impact financial compensation had on the likelihood of college women to decide to become egg donors.
   D. None of the above
2. In the United States, informed consent protocols used by assisted reproduction programs are overseen by:
   A. The internal processes set up by the individual clinics themselves.
   B. Federal regulators.
   C. By federally mandated internal institutional review boards.
   D. All of the above
3. Which of the following is mentioned by Hoas and Cook as a potential ethical challenge faced by rural health providers?
   A. Balancing patient care decisions with scarce financial resources.
   B. Maintaining the trust of community residents.
   C. Developing ethics-related educational resources for clinicians
   D. All of the above
4. Participants in medical school reader's theater programs:
   A. Have opportunities to interact with other members of their community in order to discuss important health care issues of mutual interest.
   B. Are required to memorize complex case studies to present in a theatrical fashion.
   C. Are usually medical students receiving class credit.
   D. None of the above