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IN THIS ISSUE

Have infertility specialists pushed the genetic envelope too far this time?

No oversight for controversial technique

Following disclosure by a group of New Jersey infertility doctors that an assisted reproduction technique they pioneered led to the birth of babies with altered mitochondrial DNA, ethicists are calling for increased federal oversight of privately funded medical research that may result in inheritable germline modification (IGM).

Whether federal oversight is achieved or not, ethics committees will no doubt have to revisit policies regarding assisted reproductive technology.

"The United States, as far as I know, is the only developed country where there is no oversight over private-sector work with human subjects," says **Audrey R. Chapman**, PhD, director of the Program on Science and Human Rights and the Dialogue for Science, Ethics and Religion at the American Association for the Advancement of Science (AAAS) in Washington, DC. "In the area of genetic technologies, the distinction we currently have — where federal regulation only comes if there are federal funds involved — is anachronistic and completely inadequate. This work is going to have significant repercussions for this and future generations."

In the March 2001 issue of the journal *Human Reproduction*,[1] researchers at the Institute for Reproductive Medicine and Science of St. Barnabas at St. Barnabas Medical Center in West Orange, NJ, acknowledged that a technique known has ooplasmic transfer led to the birth of approximately 30 children worldwide, with 18 babies conceived at the institute itself.

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COMING IN FUTURE ISSUES

■ **Examining the ethics of bioethicists:** Prominent scholars warn that medical ethics professionals need to turn a critical eye on themselves

■ **Impaired caregivers:** Can you balance compassion for the worker, and protect patients and other providers at the same time?

■ **Religion and genetics:** Developing resources for conflicted patients

■ **Disputes at the end of life:** Resolving communication problems between terminally ill patients, caregivers

■ **Medical marijuana:** What's next?

The technique, also known as cytoplasm transfer, involves the injection of a small amount of cytoplasm from a donor egg into a female patient's egg. (Cytoplasm is the jellylike fluid surrounding the nucleus of a cell. It is called ooplasm if taken from an oocyte, the female human reproductive cell.) The procedure is used in women whose own eggs, due to mitochondrial abnormalities or unknown reasons, do not produce embryos that develop properly.

"Cytoplasmic transplantation has caused apprehension, since the mixing of human ooplasm from two different maternal sources may generate mitochondrial heteroplasmy [both recipient and donor mtDNA] in offspring," the authors wrote.

A follow-up study of blood samples from two 1-year-old children conceived using this procedure revealed that both children did indeed have mitochondrial DNA from both their mother and the cytoplasm donor in their cells.

"This report is the first case of human germline genetic modification resulting in normal, healthy children," the authors concluded.

Going where no one else has gone

The report is also the first known case of scientists modifying the "germline" or group of human genes inherited from one generation to the next in human beings, say ethicists concerned about the development.

Several countries ban experiments or procedures that would result in altering the human germline in such a way that the alterations could be passed on to future generations — IGM. In the United States, the National Institutes of Health's Recombinant DNA Advisory Committee (RAC), the body that oversees federally funded research into genetic technologies, states that it would not "entertain any proposals" that involve altering the germline because of the unknown risks to future generations and the ethical issues involved, says Chapman.

In addition, a special working group convened by the AAAS and made up of scientists, ethicists, and religious scholars from across the country recently completed two years of work examining the issue of inheritable genetic modifications and concluded that such experimentation, at this point, would be unethical.

"We concluded that you could not undertake generational genetic modification safely and responsibly because the techniques that we are

currently using, and the vectors that we have, don't meet the standard of assuring that the corrective genes are going to be delivered to the intended location within the cells, you can't assure proper gene expression over time, and, if you were to do this and leave the mutation in place, you would have no idea what would happen in subsequent generations," Chapman explains.

Drifting across the germline

However, the AAAS working group and the RAC almost exclusively focused on the issue of IGM related to modification of nuclear DNA (which contains the genes that control almost all human characteristics, such as stature, eye color, hair color, and propensity to disease) and did not really consider modifications of mitochondrial DNA, admits **Erik Parens**, PhD, associate for philosophical studies at The Hastings Center for Bioethics in Garrison, NY.

"This is sort of 'backing across' or drifting across the germline," he explains. "We always assumed that when this line was crossed people were going to be adding genes to the nuclear DNA — manipulating mitochondrial DNA was not a possibility that was even considered. It is a new technology."

There is no small amount of scientific debate about the role of mitochondrial DNA in our genetic makeup, he adds.

Mitochondria are small, rodlike structures found in the cytoplasm outside the nucleus of a cell, which serve as "energy factories" for the cell.

Because mitochondrial DNA is not known to affect the phenotype or physical characteristics of an organism, altering it would not have the same consequences as alterations of nuclear DNA, proponents of the transfer technique have argued. **(See related story, p. 77.)**

"The fact is, we really don't understand what the phenotypic effects of mitochondria are," he says. "We know they are involved in energy production, surely this is important for all sorts of basic physiologic functions, presumably how well a muscle is going to perform, for example."

A variety of illnesses and syndromes in humans have been linked to mitochondrial abnormalities, including schizophrenia, cerebral palsy, autism, nerve deafness, and developmental delays.

"The relationship between mitochondrial DNA and nuclear DNA is quite complicated and not well-understood," he says, adding that it is much more disturbing that these reproductive techniques were pursued, resulting in genetic modifications in humans, even if the modifications were inadvertent.

"They stated that the purpose was to transfer cytoplasm as opposed to transferring mitochondria, but we all know that with cytoplasm goes mitochondria," he says. "They might not have set out to insert mitochondrial DNA into the egg, but that is what happened."

Whether mitochondrial or nuclear DNA was

CME questions

1. Mitochondrial DNA is:
   a. found in the nucleus of an oocyte.
   b. contained in rodlike structures in the cytoplasm of a body's cells.
   c. not inherited from one generation to the next.
   d. undetectable in genetic tests.

2. The human "germline" consists of:
   a. the group of genes that are inherited in humans from one generation to the next.
   b. the bodies' protective defenses against cellular defects.
   c. the group infectious diseases that affect humans.
   d. the genetic information contained in nuclear DNA.

3. Donor compensation models considered in some states:
   a. involve tax credits to businesses who employ living organ donors.
   b. involve reimbursements for funeral or burial expenses to families of organ donors.
   c. would not involve payment directly for organs, but are designed to remove "disincentives" to donation.
   d. all of the above

4. Hospital-based palliative care programs:
   a. help support and reinforce the delivery of palliative care to all inpatients with serious, chronic, or terminal illness.
   b. are designed to establish palliative care as a "separate" medical specialty.
   c. can take the place of community hospice programs.
   d. exist in many urban acute-care hospitals across the nation.

affected this time, or whether the result was intended, are beside the point in terms of the need for a new approach to allowing this sort of practice to continue, says Chapman.

"They intentionally injected these fertilized eggs with cytoplasm; it was not accidental," she says. "They did it in a completely experimental environment, and I think it shows that people who come to fertility clinics are often desperate enough that even if they provide informed consent, they do so under great duress."

There needs to be widespread public discussion of the risks vs. the benefits of genetic technology and genetic engineering before such experimentation becomes commonplace, she says.

"This industry is not regulated and I predict that we will see someone try enhancement techniques [altering the nuclear DNA] to get favorable physical characteristics, such as height, eye color, etc., in the not-so-distant future," she says.

Industry decries reckless image

The researchers at St. Barnabas refused to grant interviews about the procedure, but released a statement saying the procedure had been performed since 1996, was safe, and that all participants were informed of the potential risks.

"All research into cytoplasmic transfer complies with stringent medical guidelines and the rigorous restrictions set forth by the St. Barnabas internal review board (IRB), a committee comprised of physicians, religious representatives, patients, ethicists, and others to oversee all medical procedures," the statement adds.

Reproductive specialists are not scientific "loose cannons" attempting to improve birth rates at every turn, regardless of the consequences, adds **James Grifo**, MD, a professor of obstetrics and gynecology specializing in reproductive medicine at New York University Medical Center in New York City.

"We are the most heavily regulated specialty in the country," he notes. They answer not only to their respective IRBs, but to state medical boards, as well as SART — the Society for Assisted Reproductive Technology, a subgroup of the American Society of Reproductive Medicine.

"We have come together voluntarily for the last several years to develop standards of practice, ethical guidelines, and policies to improve the specialty and improve the practice of the specialty," he says.

Specialists in assisted reproduction are focused on helping their patients in the safest and best way possible, not on breaking scientific taboos or gaining money or notoriety, he emphasizes.

"The effect of this increased coverage and increased focus on what we do, by people who are not scientists and not researchers and not involved in patient care, most will have the effect of preventing us from helping patients."

Despite the good intentions of the specialty, a wider public examination of the possible consequences of inheritable genetic modification and other genetic technologies is essential, argue Chapman and Parens.

In addition to safety concerns, modifying the human germline raises significant ethical concerns, Chapman says. "Human germline modification might change attitudes in society toward the human person, toward the nature of human reproduction, and parent-child relationships. In addition, it could exacerbate prejudices against persons with disabilities."

In a society without universal access to health care, this technology could raise significant justice issues that need to be examined on a societal basis, not just among medical professionals or the scientific community, she adds.

"Insofar as the new germline techniques can raise the same ethical issues as the old germline techniques, then the new techniques ought to be thought about in the same ethical context and evaluated in the same fashion," adds Parens.

He and others have argued that federal legislation should increase RAC's oversight to include privately funded gene research or a separate body be formed to do so.

"We have been happy for the most part to leave reproductive technologies to the private sector with professional regulation," he adds. "On the other hand, we have this really robust public conversation about genetics. For a long time, it's worked pretty well. But, at the moment, we are seeing these two technologies converging — it no longer makes sense to think about reproductive technology vs. genetic technology. We should really be speaking about reproductive genetic technologies. This example really illustrates why we need to rethink how we are going to regulate this."

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Conception at any cost: Experts question procedure

Cytoplasm injection at the center of controversy

Is the assisted reproduction technique of cytoplasmic transfer safe? Pioneering infertility specialists say yes, but some scientists say it's too soon to tell and using this technique in humans is questionable.

In March, researchers at the Institute for Reproductive Medicine and Science at St. Barnabas Medical Center in West Orange, NJ, revealed that they had used cytoplasmic transfer — the practice of injecting cytoplasm from a donor egg into the egg of a female patient with defective cytoplasm — to produce 18 pregnancies in women previously unable to conceive.

In follow-up testing on two babies born using this technique, it was discovered that the children had mitochondrial DNA "heteroplasmy" — meaning their mitochondrial DNA was a mixture of their mothers' and the egg donor's.

Researchers acknowledge that the experiment has modified the genetic makeup of these children, but say that the impact is minimal.

"The injected cytoplasm [which includes mitochondrial structures that are the cell's energy producers] replaces missing and/or abnormally functioning components of the recipient egg," says a statement from St. Barnabas about the procedure. "The genetic blueprints of the mother and father are retained."

A list of frequently asked questions about the procedure, found on the institute's web site (www.sbivf.com) even states that the procedure should not be considered "gene manipulation."

"The primary purpose of this technique is to correct the problems within the egg without changing the genetic blueprint in the nucleus," the document reads. "The fuel, or cytoplasm, is altered to allow it to further the development of the nucleus. This procedure is not gene therapy or any form of genetic engineering. Cytoplasmic DNA does not determine the individual's genetic code."[1]

Mitochondria are the same in one human being as the next, adds **James Grifo**, MD, professor of obstetrics and gynecology at New York University Medical School in New York City and president-elect of the Society for Reproductive Technology.

"The impact [of changing mitochondrial DNA] is nothing measurable at all," he says.

But experts in mitochondrial-related diseases fear otherwise.

Scientists are just beginning to determine the true impact that mitochondria have on human development and functioning, says **Robert Naviaux**, MD, co-director of the Mitochondrial and Metabolic Disease Center at the University of California at San Diego in an interview with the web publication *BioMedNet News* in May.[2]

Gene manipulation

It has been known for years that mitochondrial deficiencies have been linked to a variety of illnesses in humans, including mild muscle weakness, epilepsy, autism, cerebral palsy, deafness, diabetes, amyotrophic lateral sclerosis, developmental disabilities, and dementia.

Researchers have found that even a small degree of heteroplasmy can lead to one mitochondrial genome completely replacing another in some tissues, as well as in subsequent generations, Naviaux says.

"You can have a mom who has only 5% heteroplasmy and seems normal," he notes, "and she may have two or three kids with severe mitochondrial disorders."

Cytoplasmic transfer should not continue to be performed in humans until more animal studies are done, he told the web magazine. And, the children already born should be followed closely over time.

Fundamentally, the practice is gene manipulation, he added. "Subtle variations in mitochondrial gene function can alter nuclear gene expression. That's what we're seeing in animals when only 10% of the cytoplasm comes from a donor oocyte."

There have been some indications already that the procedure may carry an increased risk of disorders in offspring.

An article in the May 18, 2001 *Washington Post* alleges the St. Barnabas researchers failed to report two instances of Turner's syndrome among the 18 fetuses conceived using cytoplasmic transfer, an incidence of seven or eight times what experts consider normal, the newspaper reported.

Turner's syndrome is a rare genetic disorder in which one X chromosome is present, but a Y chromosome is mysteriously missing. People with this syndrome are infertile, and often have incomplete reproductive organs.

One of the pregnancies involving an affected fetus ended in a miscarriage and the other fetus

SOURCES

- **Erik Parens**, The Hastings Center for Bioethics, The Hastings Center, 21 Malcolm Gordon Road, Garrison, NY 10524–5555.
- **Audrey R. Chapman**, American Association for the Advancement of Science (AAAS), Science and Human Rights Program, Directorate for Science and Policy Programs, 1200 New York Ave. N.W., Washington, DC 20005. Web: www.aaas.org.
- **James Grifo**, New York University, School of Medicine, 660 First Ave., New York, NY 10016.
- **Institute for Reproductive Medicine**, St. Barnabas Medical Center, East Wing, 4th Floor, 94 Old Short Hills Road, Livingston, NJ 07039.

was aborted after physicians detected the abnormality during prenatal screening.

In a statement, St. Barnabas officials acknowledged that it is too soon to tell whether the incidence of Turner's syndrome was related to the medical procedure.

"Turner's syndrome is not a mitochondrial disease, but rather, an anomaly that occurs, along with other congenital defects, after natural as well as assisted reproduction," the statement reads. "The rate of first trimester spontaneous miscarriage following assisted reproduction is between 10%-15%. As much as 70% of such pregnancy losses are associated with chromosomal abnormalities. The most common single abnormality in this group is Turner's syndrome, with an incidence of between 20%-25%."

The two incidents of Turner's Syndrome were disclosed at several scientific conferences and had been reported in a previous issue of *Human Reproduction*,[4] the statement added.

The abnormalities also were reported to the St. Barnabas institutional review board and explained in the patient consent form given to all patients considering the experimental procedure.

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Recommended Reading

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Justified compensation or organ selling?

Experts debate plans to increase donation rates

Wealthy dialysis patients faced with a worsening prognosis and a long wait for an available donor organ are able to secretly contact a "broker" — a mysterious figure who can arrange to buy a kidney from a living donor in another country, and for a price, take the patient abroad for a transplant operation.

Impoverished young men and women in countries such as India, Jordan, and Iraq line up outside hospitals seeking to sell a kidney for a meager cash payment (often less than $1,000), their best shot at a better life.

A doomsday prediction of the future? Not at all.

An article in the May 27 issue of *The New York Times Magazine*[1] detailed the complex and widespread international market in human organ trafficking. While illegal in almost every country in the world, organ selling flourishes in countries such as India, Iran, and Turkey, and benefits wealthy patients in countries with low organ donation rates, particularly Israel and the United States.

"A single transaction often crosses three continents: A broker from Los Angeles matches, say, an Italian with kidney failure to a seller in Jordan, for surgery in Istanbul," wrote journalist **Michael Finkel** in the article "Complications."

Desperate patients pay brokers hundreds of thousands of dollars to find a matching organ, locate a hospital in another country, hire a transplant surgeon, and pay the seller and seller's expenses. The sellers are often paid between $1,000 and $30,000, but there is no written contract — because the sale is illegal — and there is no recourse for the patients if there are medical

complications or, for the sellers, if the payment is not made.

Though condemned by every international medical association and outlawed in almost every country, some ethicists and even some medical professionals are questioning the current absolute reliance on altruistic donation of human organs for transplant, particularly with regard to human kidneys.

Given the crippling complications of kidney dialysis and the high number of patients who die waiting for a transplant, Radcliffe-Richards and colleagues,[2] writing in a 1998 issue of the *Lancet,* call for a re-examination of the practice of allowing people to sell their kidneys.

"Since most potential kidney vendors will never become unpaid donors, either during life or posthumously, the prohibition of sales must be presumed to exclude kidneys that would otherwise be available," the authors write. "It is therefore essential to make sure that there is adequate justification for the resulting harm."

Even though those offering to sell their kidneys are very poor, and thus face financial coercion in making the decision, removing the option for their consideration is not necessarily a more ethical path, the authors argue.

"[Critics claim that] poverty has so restricted the range of options of the very poor that organ selling has become the best, and therefore in effect, that the range is too small," they explain. "If our ground for concern is that the range of choices is too small, we cannot improve matters by removing the best option that poverty has left, and making the range smaller still. The only way to improve matters is to lessen the poverty until organ selling no longer seems the best option; and if that could be achieved, prohibition would be irrelevant because nobody would want to sell."

The increasing number of people needing transplant organs coupled with the very small number of available organs is leading many health care professionals — even those opposed to organ selling — to call for changes to the current absolute prohibition on compensation to donors.

In the United States alone, 6,254 people died awaiting transplants last year — 2,583 of those were kidney patients, according to statistics kept by the Richmond, VA-based United Network for Organ Sharing (UNOS). Between 1990 and 1999, the organ transplant waiting lists grew five times as fast as organ donations.

But even though some changes should be considered, allowing organs to be bought and sold as commodities should never be an option, many experts say.

"Does anyone think the well-off and the rich will be selling organs?" asks **Arthur Caplan**, PhD, director of the Center for Bioethics at the University of Pennsylvania in Philadelphia. "The poor would, of course, be the primary sellers. One might hope that in the United States, you might be able to find more humane forms of making a living than selling your body parts."

More people are not becoming organ donors in this country because of the inequities in access to health care between the rich and poor, Caplan argues. Creating a "market" that would allow wealthier people to "purchase" lifesaving organs from poor people who cannot hope to afford similar treatments only worsens the current situation.

"Arguments about equity would be more persuasive if those zealously pursuing markets had even spent a few minutes trying to insure access to transplants for the poor," he says. "The poor know they stand a worse chance of getting a transplant and this demonstrable inequity chills their altruism. Throwing some money toward them for their body parts does not solve the inequity-in-access problem in any way."

Compensation without buying and selling

However, there have been recent moves by several states to develop models of compensation that remove the economic "disincentives" to become an organ donor.

In 1994, Pennsylvania passed a law creating a fund to support organ donation, says **Howard Nathan**, president of the Gift of Life Donor Program, the organ and tissue procurement organization serving Pennsylvania, New Jersey, and Delaware.

Part of the law allowed people to donate a dollar when they renewed their driver's license or when you register an automobile.

"Ten percent of the money was to be used for a pilot program to provide reimbursement to families for expenses of organ donors related to the funeral or burial or expenses not already reimbursed by the donor program," he explains. "The expenses were reimbursed directly to the funeral home or other organization, not directly to the family, because that would be illegal under federal law."

However, the Pennsylvania Department of Health stopped the pilot program because of concerns about its legality. Though the department

has proposed alternatives, no other program is currently in place, he says.

"I think that is a shame because a pilot program would test the theory that, for some families — particularly those who are trying to bury someone — that [organ donation] is acknowledged by the state as an important gift from one person to another. Certainly, we feel altruism has worked pretty well, but in some cases, it may help families to feel that there is additional value in giving the gift to someone else."

Incentives to donate

Other states have proposed similar initiatives, for example giving tax credits to families of donors or establishing government-paid life insurance policies for people who agree to be organ donors, he adds.

Pennsylvania also is considering a law that would provide tax credits to employers of people who agree to be living kidney or liver donors. The tax credits would be designed to offset the cost of paying the workers' salaries while they take time off to have the operation and recover.

"At this point in time, because legislation that exists really doesn't permit it, many of these types of ideas have hit a brick wall," he says.

Nathan, whose organ procurement area has led the nation in donations since 1995, disagrees with the contention that legalizing organ sales would solve the transplant shortage.

"I have met with thousands of families and, for the most part, they are motivated because this is what their loved one wanted," he says. "The transplant system, the way that it is, is not only ethical, but safe. The concern is, once you start mixing in financial incentives, that people would not disclose potentially important information about their medical history in order to donate. Right now, that doesn't happen."

He also points to the rise in the number of living donors in the United States as evidence that people can be persuaded to donate without financial incentives.

"If you look at the UNOS statistics, the biggest increase we had last year was in the number of living donors," he says. "We had 5,600 people nationwide who donated either a kidney or a part of their liver. That was a 16% increase over just the previous year."

Improved medical techniques — including a laparascopic procedure to perform kidney removal — has contributed to more people being willing to donate an organ while they are still alive, he says. "Fifteen or 20 years ago, it was only a relative — brother, sister, mother, father — now husbands and wives donate, friends donate, and there has been an occasional anonymous donation, where there is no blood relation. But, these are also the types of situations where you want to make sure that they are doing it for the right reasons."

In his experience, removing logistical obstacles will do much to increase available organs for transplant.

For instance, part of the 1994 Pennsylvania law created a computer registry of people with signed donor cards; this eliminated a lot of confusion about whether a person wanted to donate or not.

And, the state instituted the concept of "routine referral." Hospitals report all deaths, regardless of age or cause of death to the regional organ procurement organization. The officials at the procurement organization then are responsible for determining whether the patient could be an organ donor and approaching the family with a request.

"Since then, we had a 63% increase in donations," he says. Routine referral is now a mandated practice in all U.S. hospitals accepting Medicare patients.

But, even if everyone who is eligible to be an organ donor after their death agreed to do so, only 14,000 people a year would be eligible to be a donor, he acknowledges.

"Right now, there are 80,000 people on the waiting list, so one of the things we are going to have to do is look at other options, this includes living donors," Nathan says. "But, we need to make sure that it is in an ethical and altruistic manner."

SOURCES

- **Arthur Caplan**, Center for Bioethics, University of Pennsylvania, 3401 Market St., Suite 320, Philadelphia, PA 19104-3308.
- **Howard M. Nathan**, President, Gift of Life Donor Program, Delaware Valley Transplant Program, 2000 Hamilton St., Suite 201, Philadelphia, PA 19130-3813.

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Palliative care 101: Know where to start first

Programming, educational support vital elements

Even with broad philosophical support among caregivers for providing better end-of-life care, many hospitals are finding they need help firmly establishing a palliative care program at their institution.

The answer, many are finding, is to establish a dedicated team of health care professionals — physicians, nurses, other health care providers, chaplains, and social workers — solely dedicated to studying and implementing palliative care ideas and protocols at the facility.

"Most physicians and nurses in the field of palliative care medicine believe that palliative care should be a core component of the approach to treatment of any patient with any serious illness, regardless of their prognosis and regardless of the plan of care and disease modifying or curative treatments," says **Diane Meier**, PhD, co-director of the New York City-based Center to Advance Palliative Care.

"It's a way of thinking about the patients' and families' needs that should be automatic and universal. But, in order to promote that kind of shift in practice for nurses and physicians and other health professionals, there needs to be a cohort of people with additional rigorous training in palliative care who can serve as faculty educators."

Develop a business plan

To that end, the center, a project of the Princeton, NJ-based Robert Wood Johnson Foundation at the Mt. Sinai School of Medicine, is sponsoring several educational seminars for health care professionals about establishing palliative care programs at their institutions. In addition, they are gathering case studies of established programs on their web site (www.capcm.org) for others to follow.

For example, how do you draw up a business plan for a palliative care program that will convince hospital administrators to support the effort? How do you code for reimbursement for palliative care consultations? Should you have a designated inpatient palliative care unit? What is the best way to manage hospital-hospice collaborations?

These are some of the questions that the center tries to answer.

"We no longer have to make the case for palliative care, or to do the job of convincing," says Meier. "But, we need to give people the tools to go back to their institution and hit the ground running."

The U.S. Department of Veterans Affairs (VA), one of the nation's largest providers of medical education through its health care system's hospitals, also is dedicating new resources to improving the provision of palliative care to seriously and chronically ill patients.

The VA recently announced the formation of its Interprofessional Fellowship Program in Palliative Care, which will fund four one-year fellowships in palliative care at each of the six demonstration sites throughout its system.

"At each of the sites there will be up to four fellowship trainees, and at least one — but no more than two of these — will be physicians, but the other two will be nonphysician trainees, people in nursing, pharmacy, psychology, or even chaplaincy," explains **Stephanie H. Pincus**, MD, chief of the office of academic affiliations at the VA, the office that oversees the agency's medical education programs. "We want these people to learn about palliative care fully in a way that they are interacting with each other; we can spread the knowledge to more than just physicians."

Different VA sites will compete to host each of the six fellowship programs, and one of the sites also will be charged with coordinating a curriculum, she adds. "A unique feature is that each of the sites will also be required to develop an educational dissemination project, and the purpose of that is to enhance the education of all health care professionals in the area and to spread the quality of care to patients at additional sites."

It is important to emphasize that the program's purpose is to not only improve the care of patients nearing the end-of-life, Pincus adds.

"We are talking about comprehensive management of the patient's physical, psychological, social, spiritual, and existential needs as well," she explains. "It is really anybody with a serious or life-threatening medical condition for which we really want to have a patient-centered approach."

Deciding to promote dedicated programs is not without controversy, Meier notes. There is some debate in the field about whether designating "palliative care" as a specific area of expertise, or medical specialty or subspecialty, is a good idea.

"There is a risk that the concept of palliative care will be seen as 'sending the patient to someone else,' which we don't want to convey," she admits.

SOURCE

- **Diane Meier**, Center to Advance Palliative Care, Box 1070, One Gustave L. Levy Place, New York, NY 10029-6574.

"There is a tension between acknowledging that every provider needs to know this stuff and be good at it, at least a minimum level depending on what they do. But, if you don't have this well-trained, acknowledged, employed group of people who say, 'My main job is palliative care' who consider themselves educators and researchers, the educational effort that is going to be required here isn't going to happen."

A key resource for hospitals interested in palliative care will be local hospice organizations, adds Meier.

Facilities can develop consulting, contractual, and even cooperative efforts with local hospices to improve patient care of terminally and chronically ill patients.

"There hasn't been medical school and residency education about palliative care and there are only 19 fellowships in palliative care across the country," she says. "So, how do you get manpower into the hospitals with people with the skills necessary to lead palliative care programs?"

The knowledge base is in the hospice community, she says. "I would say, 'Know your community, collaborate with the best, and bring that nursing, social work, and medical expertise into your hospital.'" ■

Lawmakers consider nondiscrimination measure

Federal lawmakers will again consider a proposed federal standard that would prohibit all companies and health insurers from using genetic information to preclude health coverage or employment — the measure would supersede a patchwork of varying state laws covering use of genetic information by employers and insurers.

The bill, H.R. 602/S 318, known as the Genetic Nondiscrimination in Health Insurance and Employment Act, introduced in the House by Rep. Louise Slaughter (D-NY) and in the Senate by majority leader Tom Daschle (D-SD), would prohibit health insurance and employment discrimination against individuals and family members based on predictive genetic information or genetic services.

Health information professions and medical ethicists have long argued that such federal legislation is important to protect patients' vital privacy rights and prevent widespread discrimination. Although the Health Insurance Portability and Accountability Act (HIPAA) of 1996 prohibits the release of individually identifiable patient information without the patient's consent, critics have argued that some breaches of confidentiality are inevitable and employers and insurers must be prohibited from using genetic test results and information that may be disclosed as criteria for denying employment or health coverage.

A similar bill, proposed last year, did not make it to a vote in both houses. "Health information confidentiality must be extended to all health information," says **Linda L. Kloss**, MA, RHIA, executive vice president and CEO of the American Health Information Management Association in Washington, DC, in a statement announcing the organization's support for the new legislation.

"The current piecemeal approach — consisting of state laws and regulations, presidential executive orders, and the final HIPAA regulation — establishes standards for the privacy of health information that leaves too much information, especially paper-based and nongenetic, unprotected. Comprehensive federal legislation governing the handling of all health information would create a single law of the land and be effective in protecting the nation's health information."

History of discrimination exists

There is historical evidence to support the fear that, unless a law like this is passed, people will suffer discrimination based on their genetic information, says Slaughter.

Several studies have indicated that some companies screen prospective employees and that genetic monitoring occurs in some large businesses, she notes in a statement on her web site

in support of the legislation.

"From the 1960s until 1993, the Lawrence Berkeley National Laboratory secretly tested black employees for sickle cell anemia, until workers filed a lawsuit that resulted in a 1998 decision by the U.S. Ninth Circuit Court of Appeals that this practice was unconstitutional," she notes.

In addition, during the late 1990s, a study conducted by Northwestern National Life Insurance found that by the year 2000, 15% of employers planned to check the genetic status of prospective employees and dependents before making employment offers. A survey of members of genetic support groups with a variety of genetic conditions indicated that 22% believed they had been refused health insurance because of their conditions, and 13% reported denial or dismissal from employment because of their conditions. Between 17% and 18% had deliberately not revealed genetic information to insurers or employers.

The current bill was introduced in both houses on Feb. 13, 2001, and currently is under review by the House Committees on Ways and Means, Education and Workforce, and Energy and Commerce, as well the Senate Committee on Health, Education, Labor, and Pensions. ■

MCO accreditor to certify quality of health web sites

The American Accreditation Healthcare / Commission (URAC), a nonprofit organization formed in 1990 to develop standards for the

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Editor: **Cathi Harris**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Leslie Coplin**, (404) 262-5534, (leslie.coplin@ahcpub.com).
Managing Editor: **Kevin New**, (404) 262-5467, (kevin.new@ahcpub.com).
Production Editor: **Nancy McCreary**.

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Editorial Questions

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managed care industry, will turn its attention to accrediting health web sites in a new collaboration with Health Internet Ethics (Hi-Ethics) Inc.

Hi-Ethics is a cooperative group of Internet health sites and content providers. Member sites include: adam.com, allHealth.com / iVillage, LaurusHealth.com, Medscape, PersonalMD, WebMD, VeritasMedicine, and WellMed.

In May of 2000, Hi-Ethics released a set of 14 guiding principles to ensure their web sites adhered to consumer-friendly, ethically sound policies and procedures. The stated goals of the principles are to ensure health sites:

- provide Internet health services that reflect high-quality and ethical standards;
- provide health information that is trustworthy and up to date;
- keep personal information private and secure;
- employ special precautions for any personal health information;
- empower consumers to distinguish on-line health services that follow their principles from those that do not.

URAC will now incorporate these principles into its Health Web Site Accreditation Program, and will verify a site's adherence to these principles. (For a complete list of the 14 guiding principles, see the Hi-Ethics web site at www.hiethics.org). Click on "Principles" on the guide at the left.)

"The Internet provides a unique opportunity to empower consumers to make choices based on quality," says **Garry Carneal**, president and CEO of URAC. "Accreditation will provide an important tool to assist consumers trying to distinguish between health web sites."

Consumers need trustworthy information

It's important that consumers are able to have independent verification that health information they obtain on a web site is trustworthy, says **Donald W. Kemper**, chairman of Hi-Ethics and CEO of Healthwise Inc. "By combining the efforts of these two health Internet quality leaders, the URAC Health Web Site Accreditation program becomes the best and clearest pathway for health web sites to demonstrate their compliance with ethical standards."

Organizations who wish to join Hi-Ethics must meet the following criteria. The criteria help assure that Hi-Ethics can successfully meet its objectives. The organization must:

- currently operate a health web site or have plans (committed to writing) to be in operation within 120 days;
- be a health web site that is intended for use by consumers or develops health-related content or services for use by consumers. Health web sites that are exclusively business-to-business are ineligible for membership in Hi-Ethics at this time;
- be a U.S.-based health web site;
- intend to comply with the Hi-Ethics principles within four months of being accepted as a member. The organization must also be willing to participate in the e-Health Seal program administered by TRUSTe. For an organization to maintain its membership in Hi-Ethics, it must be in compliance with the e-Health Seal requirements;
- Pay a $20,000 annual membership fee, payable quarterly, and $5,000 for the first quarter is due with the letter of application and will be deposited upon acceptance of the application. (Organizations joining after the first quarter still are responsible for the full annual fee and must submit an initial application check for the quarters to date.) ■

American Health Consultants
Education and Training Fax-back Survey

We would like to learn more about training and education needs for you and your staff. Please circle the number corresponding to your level of interest in the following topics.

	No Interest		Some Interest		Much Interest
HIPAA privacy rules	1	2	3	4	5
Stark II	1	2	3	4	5
EMTALA	1	2	3	4	5
Aftermath of ergonomics	1	2	3	4	5
OSHA compliance	1	2	3	4	5
Post-exposure prophylaxis	1	2	3	4	5
Influenza update	1	2	3	4	5
Antibiotic resistance	1	2	3	4	5
Adverse drug reactions	1	2	3	4	5
Drug interactions	1	2	3	4	5
Medication errors	1	2	3	4	5
Herb-drug interactions	1	2	3	4	5
Nosocomial infections	1	2	3	4	5
Patient falls	1	2	3	4	5
Basic information for frontline workers	1	2	3	4	5
Needlesticks	1	2	3	4	5
Latex sensitivity	1	2	3	4	5
TB compliance	1	2	3	4	5
Restraints and the violent patient	1	2	3	4	5
Pain management	1	2	3	4	5

	No Interest		Some Interest		Much Interest
Palliative care	1	2	3	4	5
End-of-life care	1	2	3	4	5
Assisted suicide	1	2	3	4	5
Genetic testing	1	2	3	4	5
Organizational ethics	1	2	3	4	5
Human research protection	1	2	3	4	5
Informed consent documentation	1	2	3	4	5
New accreditation standards	1	2	3	4	5
Observation units (23-hour care or recovery beds)	1	2	3	4	5
ED diversion	1	2	3	4	5
Avoiding lawsuits: What to say when something goes wrong	1	2	3	4	5
Improving documentation for nurses and physicians	1	2	3	4	5
Nursing shortage	1	2	3	4	5
Bioterrorism	1	2	3	4	5
Disaster planning and mass casualties	1	2	3	4	5
Safety and security	1	2	3	4	5

What training format is preferred for you and your staff? Rate the following methods using the scale below.

	Least Preferred				Most Preferred
On-site speakers	1	2	3	4	5
Travel off-site to live conferences	1	2	3	4	5
Subscription-based newsletters/journals	1	2	3	4	5
Outside-sponsored teleconferences	1	2	3	4	5
Outside-sponsored videoconferences	1	2	3	4	5
Web-based conferences	1	2	3	4	5
Resource books	1	2	3	4	5
Other _____	1	2	3	4	5

What is your title?_____

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Thank you for your assistance.

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