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Trends and Forecasts in Medical Ethics

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Special Report: Trends and Forecasts in Medical Ethics

Is your hospital morally ready for its next Magna Carta?

Examine core values and mission first

As market forces continue to squeeze health care resources, it will become more important than ever for hospitals to expand their concept of "medical ethics" to include more than just individual patient care issues, many experts say.

Health systems must be prepared to explicitly examine their mission as health care providers and make hard choices about how administrative, business, and policy decisions will make that mission a reality.

"We have a situation that health care is carried out in the moral framework of the medical profession. At the same time, it has to be carried out in an economic framework that is shaped by the market," says **Ann Neale**, PhD, senior research scholar in the Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC. "That is inherently tension-filled because the professional values are quality, compassion, access, and service. Market values — if you are talking about a free-market economy — are productivity, efficiency, profits — or, if we are nonprofit — profit margins."

Too many health care administrators want to leave the examination of "ethics" up to the designated ethics committees debating individual patient care decisions such as end-of-life care and informed consent, and consider business and administrative

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Special Report: Trends and Forecasts in Medical Ethics

decisions separately, Neale says. But, in order for clinical ethics committees to continue to function, they must have some sense of the goals and values of the organization for which they work.

"Organizational ethics greatly impact the clinical," she says. "Morally significant ethical decisions in many ways define the possibility of acting with integrity at the level of patient care." The hospital's hiring practices are a good example, she explains.

"Do we hire enough qualified, competent caregivers?" she asks. "If we don't, then care is not going to be of good quality. Decisions about staffing ultimately reflect budget constraints and resource allocation. All of these organizational decisions ultimately affect the possibility of acting with integrity at an individual patient level."

And, as important as resource allocation and hiring practices are, they are just a tiny fraction of the issues that hospitals need to place under the umbrella heading of "organizational ethics" considerations, she adds.

"There's a lot of talk about organizational ethics in health care, but a lot of confusion about what that term means," Neale says. "I think you can distinguish it by saying clinical ethics are involved with decisions about direct patient care, and with organizational ethics, you are dealing with issues of moral significance that occur in health care organizations that do not pertain directly to patient care. It has different subject matter and different primary decision makers."

So, where do you begin?

For hospitals and health systems beginning to consider organizational ethics, the starting point is to define the organization's "core values" and what it sees as its mission in the community, says **Carolyn Ells**, RRT, PhD, assistant professor of bioethics at Dalhousie University in Halifax, Nova Scotia, and coordinator of the Department of Bioethics' Hospital Collaboration.

"Defining the core values — that's the right place to start, but usually we don't have the luxury of starting there," she notes. "Organizations often have identified values and value statements, but they may not be the values that are actually driving the organization."

Hospital executives and boards of trustees must be willing to examine their strategic plans, budgets, and current organizational structure and decide whether they reflect the goals contained in their mission statements or corporate codes of ethics, say both Ells and Neale.

To put it bluntly, Neale says, the budget should be viewed as the organization's real "pre-eminent moral statement."

"Let's say as an individual, I keep talking about my concern for the environment, the poor, educationally deprived children," she explains. "But, what do I do with my life? Where do I live? Where do I spend money? Where do I shop, and with whom do I associate? Those are the decisions that really tell you what my values are. I don't mean that ethically you have to go live in the ghetto and teach in underprivileged schools. But, money talks."

Seek outside help

For hospital executives unused to dealing with concepts of ethical frameworks and translating values into practice, this may seem overwhelming, notes Ells.

Ells is coordinating a project between the Department of Bioethics and Health Law Institute at Dalhousie and three Halifax-area hospitals — IWK Grace Health Centre, Nova Scotia Hospital, and the Queen Elizabeth II Health Science Centre.

The hospitals are receiving ongoing consultation in legal and ethical issues in health care organization and administration, while the academic institutions are researching how organizational ethics theory can best be applied in practice.

To determine where the hospitals should start in terms of ethical organizing, Ells and her colleagues performed a needs assessment, she says. They surveyed almost everyone in the hospitals: clinicians, administrators, ethics committee members, and other staff members to find out what ethical issues they felt were pressing.

The results were telling.

"We surveyed a broad section of people, and almost universally, they were more concerned with institutional issues than with patient care [and] ethical issues," she says. "People were interested in organizational issues: communication, how risks are dealt with, how mistakes are dealt with. And there was a lot of interest in the policy process; how policies were made and implemented."

She was able to use the responses in the needs assessment to begin planning activities to help the hospital decision makers begin to examine the organization's ethics, she says.

"Right now, we are in the middle of a six-month series of ethics education with the hospital board and senior executives," she illustrates. Of the three hospitals, two recently merged and those executives have been particularly interested in the project.

"The first thing they wanted to address was

CME questions

1. According to Ann Neale, PhD, senior research scholar in the Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC, organizational ethics is different from clinical ethics in that:
   A. it is much broader in scope.
   B. it deals with issues of moral significance.
   C. it does not pertain directly to patient care.
   D. all of the above

2. George Agich, PhD, chairman of the department of bioethics at the Cleveland Clinic, advises hospitals developing an organizational ethics program to:
   A. adopt a new overall framework.
   B. set aside a new committee.
   C. involve senior management.
   D. all of the above

3. Genomic medicine, according to Paul Billings, MD, founding fellow of the American College of Medical Genetics and co-founder of the Internet genetic information company GeneSage, will:
   A. provide reclassifications of disease.
   B. provide insight into disease pathophysiology.
   C. be useful for disease management and prognosis.
   D. all of the above

4. Most likely, genomic medicine's future, according to Vivian Weinblatt, MS, president of the National Society of Genetic Counselors, will:
   A. move out of the traditional medical setting.
   B. be reimbursed by government funding.
   C. create a new specialty for physicians.
   D. all of the above

the issue of ethical problem solving, and they wanted to talk about allocation of resources," she says. "And, we are beginning to talk about ethical policy-making."

Executive support is essential

Some hospital clinical ethics committees have attempted to "expand" the scope of their work into organizational ethics, notes Neale. But without support from senior management, they are not likely to be successful.

"There can be very explicit resistance to dealing with organizational ethical issues," she says. "As ethics committees run into the impacts of these blocks of market and resource constraints, they begin to think, 'Maybe we should expand our agenda.' And, in a lot of cases, they are told, 'No, you handle the patient care issues, we'll handle the staffing and resource issues.'"

The question of who should be "in charge" of organizational ethics is still up for debate. Can clinical ethics committees expand their mandate and cover these issues? Or should an entirely different group of experts and interested parties be gathered for this purpose?

"If clinical ethics committees are going to expand to organizational ethics, they need to at least revisit their composition," she continues. "If there are not budget people, planning, marketing, and human resources people on the committee, they won't be prepared to take on these issues."

Implementing organizational ethics requires more that hospitals adopt a new overall framework than they set aside a new committee to look at those issues separately, says **George Agich**, PhD, chairman of the department of bioethics at the Cleveland Clinic.

"There has to be more of a way of including the ethical perspective in all decisions," he says. "So, we are not considering the moral implications separately, but that they are considered at the same time."

And, Agich says education of the key decision makers at the hospital's highest levels is necessary.

"Ethics committees cannot just decide that they want to 'do organizational ethics' and not have the support of the executives and board, it won't work," he says.

Essentially, it's up to the key decision makers to balance the tension between the market values and the professional values, agrees Neale.

"In our lexicon of values, the market values should serve the professional values," she notes. "If at the board level, the management level, and the departmental level, we are always honoring the market values without attending to what they are doing to the professional values, we are in jeopardy of the organization's losing its integrity. I am not saying there aren't situations in which the market value necessarily has to win out over the professional value, but if it does, it should be done with eyes wide open, knowing that it regrettably makes it impossible to fulfill your obligation to the community in some way." ■

SOURCES

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Will we buy genetic profiles with our milk and eggs?

Age of 'genomic' medicine magnifies concerns

Over the course of the next decade, genetic technologies are expected to completely reshape the health care landscape, with the availability of new genetic tests and genetic therapies that are almost unimaginable at this point in time.

"I am optimistic that genomic medicine will provide important reclassifications of disease and, at the same time, insights into the pathophysiology of disease that will be useful for disease management and prognosis," predicts **Paul Billings**, MD, founding fellow of the American College of Medical Genetics and co-founder of the Internet genetic information company GeneSage in San

Francisco. Billings also is the former chief medical officer of the Heart of Texas Veterans Health Care System. "From that knowledge, will also be the development of new management strategies and the production of new therapies."

However, whether those promising technologies will be available to all segments of society remains a big question mark in the minds of Billings and many other experts.

The issue of genetic medicine highlights issues of equity of access to care more profoundly than almost any other aspect of medicine, says Billings.

"We already have a problem with unfair access to certain technologies — you can get certain things quicker if you are wealthy than if you are not wealthy," he explains. "But when you think about genetics and how it is about all of us. We all have a very basic right to know our own genome if we wish or to be left alone, it magnifies the issue. The dilemma for the health care system is how do we — with a small field and limited number of skilled practitioners — deliver the benefits broadly and equitably."

Already, many currently used genetic diagnostic tests are not covered by government payers, nor by some private payers, says **Vivian Weinblatt**, MS, president of the National Society of Genetic Counselors (NSGC) in Wallingford, PA.

Weinblatt specializes in the area of prenatal genetic counseling and testing for heritable diseases.

"What if I have a Medicaid patient at risk for alpha-thalassemia?" she says. "This is a disorder that can, if the fetus is affected, kill the fetus and also make the mother very, very ill. It is an inheritable disorder that is most common in people of southeast Asian ancestry. There are very routine genetic tests that would indicate if both parents were carriers, but it can cost up to $2,000 for the DNA analysis, and Medicaid doesn't pay."

Unless there are unforeseen changes, Billings predicts, the use of genetic testing for estimating a person's risk of developing certain diseases in the future will likely move completely out of the traditional medical setting into a separate consumer industry where those who can afford the testing will be able to receive it.

"We already have single gene tests; we are going to see multigene tests that can establish a person's risk profile," he says. "This will be mixed with other kinds of data that are predictive of risk. At various stages of our lives, we will have the opportunity to assess the genetic component of our health risk and, hopefully we will have strategies to modulate that risk as well."

But it is not likely that such options will be routinely available in a doctor's office, he adds. Currently, primary care physicians don't have the appropriate education or the time to spend with their patients on this service. And insurance plans frequently don't cover genetic testing.

"One of the things that I see happening is that there is going to be this sort of partition in the sense that risk analysis of healthy people and prevention may become more of a consumer business as opposed to an activity of the health care system," he says.

In fact, not all health care systems in the United States will have equal access to genetic technologies because of a scarcity of medical expertise to provide accurate analysis of genomic information, he adds. "Genomics has never been a significant issue for health care until now. The notion that health systems that want to expand in this area can simply hire more expertise doesn't work because there simply isn't any."

National societies like the NSGC and the National Coalition for Health Professional Education in Genetics are trying to remedy that situation by encouraging medical societies to offer educational programs in genetics for their members and by encouraging medical schools to make genetics education a requirement for graduation, says Weinblatt.

"Right now, I think that the level of knowledge is pretty uneven around the country," she says. "There are some primary care doctors who are extremely sophisticated about genetics; they have an interest in it and are able to provide some of the preliminary information to patients. But, there are also some providers who have a lot less comfort with the area of genetics."

Is it research or clinical consent?

Increased availability of genetic testing and the growth in genetic research will require that hospitals and health providers clarify their procedures for obtaining informed consent from patients.

"Are we properly informing people when they

are participating in research settings, or is it clinical consent that we are really obtaining?" Billings wonders. "We need to clearly distinguish between clinical consent in episodic care and consent to participate in research."

More important signed document

Patients who give clinical consent usually are consenting to let a physician perform tests for a particular diagnosis and be treated for a particular illness, he says; whereas, research consent means that the patient has been informed of all of the risks and benefits and has given consent anyway.

With the potential for genetic research protocols to change given different findings and factors of the community studied, research consent should be more dynamic in that setting.

"It is increasingly being recognized that the consent process should be ongoing and should involve two-way interaction between participants and researchers," he says.

In the age of genetic medicine, research consent will have to be much more than a "signature on a piece of paper," agrees Weinblatt. "Informed consent is a process that involves communication and discussion."

Even obtaining appropriate informed consent for episodic clinical care is more complicated in the arena of genetic information, she adds.

"Many genetic tests are not deterministic," she notes. "For example, the BRCA1 test; if it is positive for the mutation, absolutely confers increased risk to the person carrying the mutation. But, it does not say you will definitely get breast cancer. That distinction is really very hard for patients to understand. Informed consent for a test like that is also critical."

Legislative protections needed

In order to enable health care providers to make strong progress in increasing the availability of the benefits of genetic technologies to patients, state legislatures must pass better patient protections, adds Weinblatt.

"There are some protections. Kennedy-Kassenbaum [the Health Insurance Portability and Accountability Act of 1996] and the Americans with Disabilities Act provide some," she says. "But there are holes, and there needs to be a better, more universal approach."

Although ensuring the privacy and confidentiality of medical information is important, it does not replace the need to have legislation that prohibits employers and insurers from discriminating against people based on their genetic information.

"In case somebody is able to hack into some computer somewhere and get the information, the information then needs to be rendered useless," she says.

Many people who want to take advantage of predictive genetic testing may choose not to because of the fear that the information may one day fall into the wrong hands.

"People need to be able to decide to have a test or not, [and] have a test based on the merits of the information alone and not the fear of what is going to happen to them later." ■

SOURCES

- **American College of Medical Genetics**, 9650 Rockville Pike, Bethesda, MD 20814-3998, Telephone: (301) 530-7127. Fax: (301) 571-0677. E-mail: acmg@faseb.org. Web: www.faseb.org/genetics/acmg.
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What do kidneys and pigs have in common?

Unique methods could change transplantation

Imagine a world where there's no need for matching potential organs with anxiously waiting recipients — without ever getting on a waiting list.

Several events are shaping the future of organ transplantation and could ultimately mean an end to the shortage of available organs. In April, the Scottish biotechnology company that created

Dolly the sheep revealed it has created the world's first transgenic-cloned pigs.

The biotechnology company, PPL Therapeutics, has the ability to produce a pig that could become the industry's standard for xenotransplantation, says PPL's research director **Alan Colman**. The five piglets, born in its United States laboratory in Blacksburg, VA, have a foreign marker gene within their DNA structure.

The company actually cloned its first pigs last year, but they were not transgenically modified. The modification is vital because it prevents the human immune system from rejecting transplanted pig organs. The piglets are called *knock-out* pigs because the alpha 1-3 gal transferase gene is inactivated.

Controversy or saving grace?

Critics of xenotransplantation no doubt remain skeptical of PPL's achievement. Critics argue that xenotransplantation opens the risk of animal viruses being transmitted to humans, also known as graft versus host disease (GVHD).

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research recently issued a draft of proposed guidelines for public comment. The 62-page set of guidelines, titled *Guidance to Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans*, appeared in the Feb. 7, 2001, *Federal Register*.

The FDA draft guidelines suggest the benefits and risks of xenotransplantation should be evaluated for the recipient and the welfare of public health. Here's what the guidelines say about potential risks: "Infectious disease is among the potential risks both to the recipient and to the public posed by the use of xenotransplantation products. Transmission of microbial agents from xenotransplantation products could lead to systemic disease (for example, infection or neoplasia) or failure of the xenotransplantation product in the recipient. Immunological risks include rejection of the live xenogeneic cells, tissues or organs, and in some cases, GVHD. In addition, transmission of infectious agents could result in outbreaks of zoonotic disease, silent transmission of latent viruses, or emergence of new strains of pathogens. Experience has shown that widespread horizontal or vertical transmission of new pathogens is possible before the pathogens are recognized (such as HIV)."

The Chicago-based American Medical Association's Council on Ethical and Judicial Affairs recently issued a report on xenotransplantation: *The Ethical Implications of Xenotransplantation*. **(See list of recommendations, insert.)**

A kidney for a kidney

Xenotransplantation may sound years away from being a reality, but the New England Medical Center in Boston is taking a more contemporary but unusual approach to organ transplantation.

Called Hope Through Sharing, the program was approved in February after nine months of review by the Richmond, VA-based United Network for Organ Sharing (UNOS). The program, which some physicians say is unethical, allows a patient to move up on the waiting list if a family member donates one of their kidneys to a stranger. Currently, the program only involves kidneys.

The program does not violate any ethical issues because the only benefit the donor receives for their kidney is another kidney for the loved one, says **Richard Rohrer**, MD, the chief of transplant surgery at New England Medical Center. "It is assigning a value to a kidney donation, and the value is exactly a kidney. On that basis, we feel very comfortable," he says.

Mark D. Fox, MD, a medical ethicist at the University of Rochester (NY) Medical Center, says everyone benefits from this program in the end. He likens the process to a "good-faith donation." Fox served on the UNOS panel that evaluated the program.

Kidneys are distributed by waiting time, unlike other organs that are distributed based on urgency.

SOURCE

For more information on the FDA draft guidelines, contact:

- **Stephen Ripley**, Center for Biologics Evaluation and Research, HFM-17, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Telephone: (301) 827-6210. Web: www.fda.gov/cber/guidelines.htm.

This program could cut down the amount of time for many patients, says **Richard Luskin** of the New England Organ Bank in Boston. "It's really an addition to the total available pool of organs," adds Luskin.

The national waiting time averages five years, but in Massachusetts, it's only three to four years, according to UNOS data.

Live donors more common

In yet another advancement, researchers at the Lahey Clinic Medical Center in Burlington, MA, are determining what factors constitute a successful match for livers between donor and patient and whether the procedure is safe for donors. The main obstacle to live donor transplantation between adults is determining how much liver one can take from a donor and not harm them, and whether it is sufficient for the person who needs it, explains **Elizabeth Pomfret**, MD, PhD, director of live donor liver transplantation at Lahey.

Results of the research appear in the April issue of the *Archives of Surgery*.[1] Ultimately, 15 of 66 volunteers completed the surgery. Donors regenerated 80% of their livers within a month following surgery and 90% a year later, notes Pomfret.

"This is a feasible operation, but needs to be done in centers where there is a strong commitment to doing this," adds Pomfret. Many volunteers were disqualified after their health was evaluated. The most common cause for disqualification was having a liver that was too small. Potential donors diagnosed with hepatitis C or other liver disorders also were disqualified.

Reference

1. Pomfret E, Pomposelli J, Lewis D, et al. Live donor adult liver transplantation using right lobe grafts. *Arch Surg* 2001; 136:425-433. ■

Thompson takes his case to big business

Initiative emphasizes corporate help in donations

The recent string of announcements about advances in organ transplantation, which could radically reduce the disparity between available organs and patients who need them, couldn't come at a better time.

The Richmond, VA-based United Network for Organ Sharing (UNOS), the organization responsible for maintaining the organ procurement and transplantation network for the federal government, stated in March that the national waiting list surpassed an unprecedented 75,000 mark. The magnitude of the organ shortage is sobering, says **Patricia Adams**, MD, president of the organization.

"Of those 75,000 men, women, and children, probably less than a third will get the transplant they need this year," adds Adams. In fact, a decade ago, the difference between the number of transplants and the number of patients listed was less than 5,000, according to UNOS data. **(See chart, p. 57.)**

But Department of Health and Human Services (HHS) Secretary Tommy Thompson already is taking strides at reducing the wide disparity among organ donors and those who need organs. As governor of Wisconsin, Thompson helped increase organ donation levels, and his views on how to distribute donated organs were greeted with skepticism by some health care providers when he joined President Bush's cabinet.

The HHS campaign focuses on donation rather than distribution and hopes to lure businesses and unions into promoting organ donation. Called Workplace Partnership for Life, the program already is being touted by Thompson, who encourages audiences at speaking engagements to sign organ donor cards. The program's goal is to increase participation in organ, blood, marrow, and tissue donations.

HHS is asking Congress for an additional $5 million in funding for organ dona-tion next year, which is a 33% boost for the department. And the donation initiative comes on the heels of the announcement that HHS is introducing a national donor card that will enable transplant coordinators to proceed with donations when family members are reluctant. The national donor card would be a legal document with more weight than driver's licenses or unofficial donor cards.

Patients Waiting on the U.S. Waiting List at Year End: 1990-2000

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Number Patients	20,481	23,198	27,563	31,355	35,271	41,179	46,925	53,123	60,299	67,079	73,951

Transplants Performed in the U.S. 1990-1999

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Number Patients	15,004	15,753	16,134	17,640	18,308	19,369	19,721	20,283	21,442	21,693	22,827
Total											208,174

Source: United Network for Organ Sharing, Richmond, VA.

"With employers and employees working together, we can literally save thousands of lives," Thompson said in a statement. "This includes not only large corporations and unions, but also the local employer and the small staff of employees. Everyone has a contribution to make."

Nearly 20 companies and organizations already have signed on, including Aetna, General Motors, DaimlerChrysler, Ford Motor Co., Verizon, 3M, the U.S. Postal Service, and the United Auto Workers. A new web site (www.organdonor.gov) will provide ideas on how to encourage organ donation and chronicle efforts at increasing organ donor levels.

The HHS initiative also includes reviewing the potential of a national organ donor registry, creating a national medal to honor the families of organ donors, and developing a model curriculum on donation for state driver education courses.

Long wait prompts action

The longer wait times for patients needing organs is contributing to the increase in organ donations from the living. Living donations jumped 16% last year, the largest increase on record. Living donations now account for nearly half of all donors, and at the current rate, living donors will outnumber cadaveric donors within a year or two, according to projections from UNOS.

"When you have to tell patients the wait is going to be three or four years, you say, 'I'd look around and see who might donate a kidney," says Adams. ■

MDs need support with suicide requests

A new study led by a researcher at the San Francisco Veterans Affairs Medical Center (SFVAMC) has found that most physicians whose patients request help in ending their life deal with those requests alone, absent any advice or discussion from their colleagues.

Researchers interviewed 20 physicians in Seattle and San Francisco who have received at least one request from a terminally ill patient for help in committing suicide. The results, which were published in the March issue of the *Archives of Internal Medicine,* showed that half of physicians helped a patient end his or her life; the other half had not.

The most surprising finding is that physicians rarely discuss these often heart-wrenching suicide consultations with other physicians. "Most physicians who received these requests really dealt with them alone," says lead author **Jeffrey Kohlwes**, MD, MPH, University of California at San Francisco assistant clinical professor, and physician in general internal medicine at SFVAMC. "They perceived an unspoken code of silence on the topic amongst their colleagues," Kohlwes says.

The physicians reported the most difficulty in coping with requests from patients who wanted to die because they felt their lives had lost meaning, not for reasons related to physical pain and suffering.

The researchers recommended that physicians who care for terminally ill patients do the following:

- improve their skills in managing pain and suffering;
- learn to watch for and treat depression;
- strive to communicate openly and clearly.

Researchers also pointed to the need for the medical profession to support doctors by encouraging discussion of requests for help with suicide.

Although physician-assisted suicide is illegal in every state except Oregon, physicians who care for terminally ill patients receive suicide requests with some regularity. Some guidelines have been written to assist physicians in dealing with those requests, but there has not been much documentation of the different ways in which physicians handle suicide requests from their patients.

Aside from its illegality, the topic of physician-assisted suicide is considered taboo among physicians, a perspective that dates back to a passage of the Hippocratic oath, which admonishes "give no deadly medicine to anyone if asked." A few of the physicians also said they were worried about becoming publicly known as the "local Kevorkian," Kohlwes says.

The isolation experienced by these physicians creates a heavy emotional burden, Kohlwes says. Four of the physicians cried during the interviews, a response that Kohlwes says "seemed more related to a lack of processing their actions rather than any regrets over their actions."

"Somehow the medical community needs to create an environment where these physicians can discuss their decision-making process," he says, suggesting physicians should try to avoid the moral debate over physician-assisted suicide and instead discuss the processes they use to handle those requests.

"Improving the professional dialogue will improve care, and hopefully obviate the need for many assisted deaths," he said.

Although physical and psychological suffering were reasons given by many patients for wanting to end their lives, some physicians in the survey said patients frequently cite more existential reasons.

"Many terminally ill patients feel that their meaningful lives are over because they are no longer able to do the things they love, such as interacting with loved ones, being active, and generally being in control of their lives," he says. "Physicians reported that these existential cases were the most difficult for them to intervene in."

The physicians in the study who felt most comfortable managing this existential suffering favored open discussions with the patient, and tended to view their discussions with the patient as a therapeutic tool rather than an avenue to some other intervention, Kohlwes says.

The good news, says Kohlwes, is that most requests for a physician's assistance in suicide can be successfully handled simply by treating either physical pain or depression. "Most physicians we interviewed used those requests as a warning flag to aggressively treat a patient's physical discomfort, and in many cases they felt this was effective," he adds.

Most physicians in the study reported treating their patients with antidepressants, which another study has shown to reduce terminal patient requests for suicide. ■

Advance directives ease family stress

Researchers at Oregon Health Sciences University (OHSU) in Portland found in a recent study that family decisions to remove life support resulting in the death of a hospitalized loved one can cause high stress levels for as long as six months.

Specifically, researchers observed families in which dying patients were unable to voice their own decisions near the very end of life. Researchers affiliated with OHSU's Center for Ethics in Health Care and the School of Nursing conducted the research, funded by the National Institute of Nursing Research, a component of the National Institutes of Health.

Results of the study were published in the March / April issue of *Nursing Research*.

The researchers studied 74 family members who had recently experienced the death of a relative in one of four large hospitals in Portland. The doctors and nurses involved in the cases also took part in the study. Researchers focused on hospital deaths because decisions to start and stop life support more often occur in hospitals. In addition to the family and caregiver interviews, family stress was measured through standardized questionnaires used to gauge emotional impact following a traumatic event. Stress levels were measured during two time periods. The first period was one to two months following death of a loved one. The second

period was six to nine months after the death.

Stress levels of all families in this study were extraordinarily high, the study showed. Family stress was similar to reports from people who survived ferry and construction disasters, and was twice as high as the stress reported by people who lost their home to fire. In addition, while study families' stress levels began to taper off, they remained high for as long as six months following the death.

While all study families reported high stress, for families of a loved one who had not provided a verbal or written advance directive, the stress levels following the death were far higher. In families that had verbal advance directives, stress levels were moderate after death. For families whose loved ones had completed a written advance directive, stress was markedly lower.

Advance directives are instructions for care near the end of life previously given by a patient in the event that they are unable to communicate their own wishes in their final days. Currently in the United States, approximately 20% of adults have completed a written advance directive. In Oregon, the statistics are much higher. In another study of recently deceased Oregonians, 68% were reported to have had a written directive.

For many family members who chose to remove life support from a loved one without a verbal or written advance directive, caregiver interviews revealed the decision often haunted them for weeks and months.

In contrast, many family members whose loved ones had previously completed an advance directive reported a sense of peacefulness in doing the right thing. "It was all clear because we talked

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about it and it was all on paper," another study participant explained.

"This study shows that a lot can be done to not only improve care of a patient, but also to improve difficult end-of-life experiences for their family," says **Virginia Tilden**, RN, DNSc, FAAN, lead author in the study, and professor of nursing and associate director of OHSU's Center for Ethics in Health Care. "This research shows that advance directives can lift a tremendous burden from families at the time decisions must be made. Writing down your wishes so that your family members have a clear guide to follow near the end of life will reduce the stress on those you love."

In addition to the need for important family discussions, OHSU researchers note the role nurses and physicians play near the end of life. While better communication within families can do a lot to relieve stress, the study showed that communication and support by doctors and nurses profoundly impacts the experience of families," says **Susan Tolle**, MD, one of the authors of the study and director of OHSU's Center for Ethics in Health Care.

"Families emphasized the need for caregivers to be truthful about the possible benefits of life-sustaining treatments and not to offer false hope," she says. "Following family decisions to remove life support, it's important for caregivers to support family decisions to reduce the long-term feelings of guilt." ■

NEWS BRIEF

Euthanasia gets the OK in Netherlands

The Netherlands last month became the first country to legalize euthanasia. The vote to pass the historic law, however, was marked with thousands of protesters outside the Dutch government building in The Hague.

The passage of the law by its senate approves a bill passed by the lower house last November. Euthanasia has been practiced, however, in hospitals and hospices for decades. As a result, guidelines adopted by parliament in 1993 are now part of the legally binding requirements, including a long physician-patient relationship and excluding the right from nonresidents of the Netherlands.

Physicians involved in voluntary euthanasia or suicide must:

- be convinced that the patient's request was voluntary, well-considered, and lasting;
- be convinced that the patient's suffering was unremitting and unbearable;
- have informed the patient of the situation and prospects;
- have reached the conclusion with the patient that there was no reasonable alternative;
- have consulted at least one other physician;
- have carried out the procedure in a medically appropriate fashion.

Reference

- Section 293(2) of the Dutch Criminal Code. ■

Excerpt from *The Ethical Implications of Xenotransplantation*

Recommendations*

The council recommends the following be adopted and the remainder of the report be filed:

Xenotransplantation includes any procedure that involves the transplantation, implantation, or infusion into a human recipient of either a) live cells, tissues, or organs from a nonhuman animal source or b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. Although xenotransplantation offers a potential source of tissue and organs for medical procedures, research in this area may uncover physical and psychological conditions that require medical attention. As such, physicians need to be involved in developing and implementing guidelines for continued research. Therefore, the following guidelines are offered for the medical and scientific communities:

1) Physicians should encourage education and public discussion of xenotransplantation because of the potential unique risks such procedures pose to individual patients and the public.

2) The medical and scientific communities should support oversight for the development of clinical trial protocols and ongoing xenotransplantation research.

3) Given the uncertain risk xenotransplantation poses to society, participants in early clinical trials may have to agree to postoperative measures such as lifelong surveillance, disclosure of sexual contacts, an autopsy, and waive the traditional right to withdraw from a clinical trial until the risk of late xenozoonoses is reasonably known not to exist. These requirements may continue even if the transplanted tissue is rejected or removed. The informed consent process should include a discussion of the above issues as well as potential risks to third parties and psychological concerns associated with receiving an organ or tissue graft from an animal. Careful attention must be paid to both the content of the consent disclosure and the manner in which consent is obtained.

4) It would be ethical to include to include children and incompetent adults in xenotransplantation research protocols only when the patients are terminally ill and alternative treatments are not available.

5) Allocation protocols must be fair and in accordance with Opinion 2.03, *Allocation of Limited Medical Resources,* which recommends that decisions regarding the allocation of medical resources among patients be based only on ethically appropriate criteria relating to medical need. These criteria include, but are not limited to, the likelihood of benefit, the urgency of need, the change in quality of life, the duration of benefit, and, in some cases, the amount of resources required for treatment.

6) Sponsors of xenotransplantation research should assure that adequate funding exists for lifelong surveillance and treatment of complications arising from xenotransplantation procedures on research subjects.

7) At a minimum, all ongoing research should adhere to the *Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation,* FDA guidelines relating to xenotransplantation, Opinion 2.07 *Clinical Research,* and any additional precautionary measures believed to minimize potential risks to the public or to patients. It is inappropriate to participate in xenograft procedures outside federal guidelines.

8) All xenotransplantation research should continue to promote high standards of care and humane treatment of all animals used in research (H — 460.979) and to apply these standards to the care and treatment of animals used as sources of transplantation material.

*The recommendations will become Opinion 2.169, *The Ethical Implications of Xenotransplantation,* pending House approval and placed into the American Medical Association's Code of Medical Ethics.

Source: American Medical Association Council on Ethical and Judicial Affairs. *The Ethical Implications of Xenotransplantation.* Chicago; in press.