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IN THIS ISSUE

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Research says living wills won't guarantee patients' wishes

Michigan researchers say Patient Self-Determination Act a failure

Since passage of the Patient Self-Determination Act (PSDA) in 1990, the living will — a form of advance directive that spells out the signer's wishes for end-of-life care and termination of care — has become an almost automatic subject in any discussion of death or resuscitative medicine.

But is the living will the useful tool that polls indicate most Americans believe it is? Two University of Michigan researchers say it's not and recently published a report of their evidence-based research they say shows, when it comes to our faith in living wills, Americans are choosing a feel-good step that has no proven value.

The continued urging of adults to draw up living wills is "but the triumph of dogma over inquiry, and hope over experience," wrote **Angela Fagerlin**, PhD, a faculty member at UM's Ann Arbor (MI) VAMC, and **Carl E. Schneider**, JD, the Chauncey Stillman Professor of Law at the UM Law School and professor of internal medicine at UM.

Fagerlin and Schneider published their report, "Enough: The failure of the living will" in 2004, and say it is the first evidence-based study of what they say many in health care and health care law already knew — that living wills do not accomplish what most people think they will accomplish.

An unfunded mandate

Living wills and other forms of advance directives **(See chart for explanation of types of advance directives, p. 3.)** became commonplace with the passage of the PSDA and soon were the source of a great deal of new paperwork and expense for hospitals and, ultimately, patients, Fagerlin says.

"One thing that concerned us was that, when the PDSA was enacted, no research was done to see if living wills would be an effective tool. And Congress didn't fund the PDSA, so suddenly hospitals were required to [fund it]," she explains.

Living wills are recognized in all 50 states, but to varying degrees. Some state courts uphold living wills as legal documents, while others have no laws recognizing them as anything other than an expression of a patient's wishes.

The PSDA encourages all people to make choices and decisions now about the types and extent of medical care they want to accept or refuse should they become unable to make those decisions due to illness. The PSDA requires all health care agencies receiving Medicare and Medicaid reimbursement to recognize the living will and power of attorney for health care as advance directives. Under the PSDA, health care institutions must ask patients whether they have advance directives and must provide patients with educational materials about their rights under that particular state's laws.

All that costs money, and the cost issue is a key component to what Schneider and Fagerlin see as the failure of living wills.

"Living wills consume patients' time and energy, [and] when doctors or lawyers help, costs soar," they wrote. One study determined that the PDSA imposed on all hospitals a start-up cost of $101,569,922; expenses continue as the program is administered.

"I wish this would see some policy change. We have 45 million people without health care, but we spend millions on making copies and processing forms," says Fagerlin.

If living wills were free, the authors say, their lack of effectiveness would not be such a problem. Conversely, if they were more effective, the cost of creating them and administering the PDSA would be more justifiable, Fagerlin says.

"But there is no convincing evidence that living wills reduce the cost of end-of-life care," she says.

Zero-for-five on the success scorecard

Fagerlin and Schneider devised five conditions to determine what the living will would need to accomplish to function as its creators intended. Out of those five, the authors say, evidence shows that living wills in general meet none. The conditions, and the authors' findings, are:

1. People must have living wills. Most people don't have them. Surveys indicate that while people think living wills are a good idea, only about 18% of adults actually have living wills. "People don't have living wills probably because they trust their families to make decisions for them," Fagerlin says. "One study asked people if they had made an advance health care decision, and their family thought it was a bad one, would they trust their family to overrule them. Most said they would."
2. They must decide beforehand what treatment they would want should they become incompetent to decide. "People who have living

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Living Wills and Advance Directives

Living Will
A living will (or "medical directive" or "declaration" or "directive to physicians") is simply a written instruction spelling out any treatments you want or don't want if you are unable to speak for yourself and terminally ill or permanently unconscious. A living will says in effect, "Whoever is deciding, please follow these instructions!" On its own, a living will is very limited — it usually applies only to end-of-life decisions, and standard instructions tend to be general. Unless you have a good crystal ball, it is impossible to anticipate every future medical scenario.

Health care power of attorney
A health care power of attorney (or health care "proxy," or "medical power of attorney") is a document that appoints someone of your choosing to be your authorized "agent" (or "attorney-in-fact" or "proxy"). You can give your agent as much or as little authority as you wish to make health care decisions. The decisions are not limited to just end-of-life decisions. Appointing an agent provides someone with authority to weigh all the medical facts and circumstances and interpret your wishes accordingly. A health care power of attorney is broader and more flexible than the living will.

Health care advance directive
A comprehensive health care advance directive combines the living will and the health care power of attorney into one document. In addition, you may include any other directions, including organ donation or where and how you prefer to be cared for. Because it is more comprehensive and more flexible than the other tools, it is the preferred legal tool.

Source: American Bar Association, www.abanet.org/publiced/practical/directive_livingwill.html.

wills, we found, hadn't really thought through what their instructions are in a way that a life-or-death decision would demand," Fagerlin says. Furthermore, the authors found that patients' wishes changed with their circumstances. What they thought they wanted before they became sick changed once they were actually in the hospital and facing a medical crisis.

3. The writers must accurately and lucidly state what their preferences are. Often, patients' proxies or family members were not able to accurately state, from what was written in the living wills, exactly what the patient's wishes would be in a given situation.
4. The living will must be available to the people making decisions for a patient. In many cases, living wills are drafted, signed, and stored away years before they are ever needed, and when a medical crisis arises, the person making decisions does not have the living will at hand. Also, 62% of patients with living wills never give copies of them to their physicians, so their physicians don't always know their wishes.
5. People must grasp and heed the living will's instructions. The Michigan researchers wrote that a 1998 study on effects of advance directives found that living wills do not alter care. Hospital and ICU lengths of stay, as well as health care costs, were similar for patients with and without advance directive statements.[1] Another study found that in 30 of 39 cases in which a patient was incompetent, and the living will was in the patient's medical record, the surrogate decision-maker was not the person the patient had appointed.[2] In a third study, care received by one-quarter of the patients was inconsistent with the wishes spelled out in their living wills.[3]

Fagerlin says there are three primary reasons living wills are not successful in meeting their intended goals: 1) they are not interpreted

SOURCE

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correctly; 2) the patient is never recognized by his or her surrogate as being hopelessly ill, and 3) family members are not present or are unable to advocate for the patient.

The five conditions for a successful living will, Schneider and Fagerlin wrote, "are unmet and largely unmeetable."

Fagerlin says one question she continues to pursue after 10 years of research into end-of-life issues is, "Can we really know what we will want until we are actually in a situation?"

She says her studies have shown people's beliefs change with time, change in life circumstances, and change in times of medical crises. So expecting someone to be able to accurately predict what they will want at the end of life, unless that time is imminent, is unrealistic.

"There's something about what happens in a hospital that can make people change," Fagerlin says. "They may not think they'd want life support before, but when they're in the hospital, they can change their mind. Then, afterward, after some time has passed and they're out of the hospital, their beliefs return to what they were before.

"So how can you know what your true preference is? It's a fascinating question."

Power of attorney may be more useful

Schneider and Fagerlin say they aren't advocating the total elimination of living wills. They say living wills can be useful in times of crisis when the patient has strong, specific, delineative wishes, and has special reason to prescribe his or her own care.

Durable power of attorney for health care, however, is a broader, more flexible, and — in the eyes of the states — more weighty instrument for protecting patients. Fagerlin says durable powers of attorney are probably a better choice for most patients but still are reliant upon the designated proxy to know just what the patient would want done on his or her behalf.

Fagerlin and Schneider's report concludes with a call to drop emphasis on living wills, promote powers of attorney, and repeal the PSDA.

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'Wealthcare', or a return to basics of health care?

Retainer/'concierge' medicine growing trend

Critics call his practice "boutique medicine" or "wealthcare," but the way Michigan physician **John Blanchard**, MD sees it, he and his partners at Premier Private Physicians are putting control of health care back in the hands of their patients.

Blanchard and a growing number of other general practitioners are treating patients who pay the physicians from $65 a month to more than $1,500 per year for the privilege of not having to wait to see their doctors; controlling what tests, procedures or medications they want (or don't); and — the greatest luxuries of all — house calls and 24-hour phone access.

In essence, the physicians are on retainer, much as clients would contract with an attorney or accountant who is paid a retainer. And while the number of patients signing up indicates there are plenty of people in the United States who are willing to pay a price for more personal attention, there are also critics of this type of health care delivery. Blanchard serves as president of the national Society for Innovative Medical Practice Design (SIMPD), an association of physicians whose practices are based on retainer, retail, or cash pay models that was formed by the merger of the American Society of Concierge Physicians and the Charleston, SC-based National Organization of Retail Medicine. Blanchard estimates there are approximately 200 physicians in the United States who are running their practices this way.

"Essentially, health care is not subject to free-market forces," says Blanchard, whose practice has offices in Clarkston and Grosse Pointe Woods, MI. "Two competing primary care physicians are not

really competing with each other. They sign up with an insurance company, and they get all these patients. But the competition is at the insurance level, not at the provider level.

"So what happens is, you drive down quality and drive up cost. A free market drives down cost and drives up quality."

As is often the case in medicine, Blanchard, as a young physician, found himself unable to deliver the kind of care to his patients that he'd dreamed of as a medical student. The third-party pay system, he says, took the practice of medicine away from him.

"The reality of insurance-related issues pressured us to see more patients, while spending less time providing quality medical care," he says. "We, like our patients, were dissatisfied with the assembly-line approach to health care. We wanted to take the time to thoroughly assess our patients' medical history, explore their current health issues, and develop an all-inclusive program to facilitate optimum health. The system, however, was concerned with patient volume, not patient satisfaction."

Blanchard points out that 100 years ago, and even into the 1940s and 1950s, patients had relationships with their physicians that were lifelong and personal. Family physicians knew their patients and provided what they needed, when they needed it. And patients paid physicians directly for their services.

But today, he says, the relationship between patients and physicians is almost adversarial, and he blames that on our system of health insurance.

"Basically, there's this big bucket of money that insurance companies hold. And over time it has increased in size, and in health care, whoever is savvy enough to extract money from the bucket, wins," he says. "For the insurance companies, the motivation is to offer the most coverage for the least amount of [patient] premiums, combined with restricting access to those covered services, and the physician is forced into the middle."

That arrangement doesn't work in favor of physician-patient relations, because it causes the patient to get mad at the doctor and the doctor to be unable to always provide the best possible care to his or her patient, Blanchard claims.

Paying for the health care they want

Critics say, for doctors to return calls promptly or at odd hours should be just a routine part of health care, not a paid "extra." Also, questions have arisen about what happens to those patients who can't or won't pay their primary care physician the retainer fees when he or she converts a traditional practice to a concierge practice.

Proponents of the idea say getting out from under the thumb of third-party payers means physicians are free to cut their patient load back, charge lower fees, and have the time to give patients the attention and time they agree are deserved.

Some retainer practices accept insurance for covered expenses, and the monthly or annual fees charged to patients are for perks such as no-wait appointments, ready access by phone, and house calls.

Other practices refuse insurance altogether, and patients pay for all medical expenses in addition to the retainer fee.

As to the expense for all this personal attention, Blanchard points out that many people who do not consider themselves wealthy might be surprised at the money they spend on items or services less critical than health care.

"There are many people out there spending $90 or more every month for a cell phone, and $3 a day on lattes, which amounts to about $100 a month," he says. "Most fees charged by practices like ours don't add up to even that much."

Those who can't pay still need care

Still, not everyone wants retainer care, nor can everyone afford it, and the American Medical Association recognized the dilemma this poses when a traditional practice converts to retainer care. In its 2002 Council on Ethical and Judicial Affairs report on retainer medicine, the AMA points out that it has always been the responsibility of physicians to provide care to those who cannot afford it.

"If a practice switches from regular, insurance-paid care to retainer care, and low-income patients can't afford to sign on, does that create a burden for the patients?" the report states.

Blanchard says retainer practitioners build subsidized care and free care into their practices, to maintain their ethical responsibilities to render care to those in need.

The AMA's position is, because the conversion of an existing practice to a retainer practice forces some patients to seek new physicians and establish relationships with them, physicians converting their practices must facilitate the transfer of the patients to new physicians and ensure a

smooth transition of care. Physicians are required to transfer departing patients' records to their new providers at no charge.

"Costs in concierge care are going down, and our patients are surprised at how much we can do for how little," says Blanchard. "If people can't afford my practice, they pay what they can afford. So there is some percentage of these [retainer] practices reserved for subsidy and free care."

Is there an ethical dilemma?

The AMA, in its guideline on retainer medicine, has determined that such practices "appear to be consistent with a system based on pluralistic means of financing and delivery of medical care." Under AMA principles of medical ethics, physicians are "free to choose the environment in which to provide medical care" and, except for emergencies, are free to choose their patients.

The AMA urges that a retainer provider not present the arrangement as a way to more or better diagnostic and therapeutic services, however. The standard of care cannot be based on a patient's ability to pay, so a discrepancy in the quality of medical decisions in a mixed practice (in which the provider treats retainer patients and insurance-only patients) "would be particularly condemnable," the AMA guidelines state.

On the other hand, the AMA points out, it is possible that the personalized attention and patient satisfaction that could result from a retainer arrangement could lead to better patient-physician communication and patient compliance, which could improve outcomes in certain cases.

The response from insurance companies has been mixed. Some networks are including concierge practitioners in their network of providers (still, only paying for regular, covered expenses). Others have determined that the idea of retainer contracts is in opposition to their mission to provide health care to as many people as possible and for member physicians to accept new health plan members without restrictions.

But practitioners must be alert to the dangers of billing Medicare patients for services already covered by Medicare. The U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a warning in 2004 reminding physicians of the liabilities they could face if they request any other payment from Medicare patients for covered services.

"Participating providers may also, of course, charge beneficiaries for any Medicare deductibles and coinsurance without violating the terms of their assignment agreements," says **Dara Corrigan**, JD, a Washington, DC-based attorney who was acting principal inspector general when the alert was issued. "If participating physicians decide they want to charge patients additional fees, they should be mindful that they are subject to civil money penalties if they request any payment for already covered services from Medicare patients other than the applicable deductible and coinsurance."

The OIG in 2004 alleged that a physician committed just such a violation when a retainer contract asked patients to pay an annual fee of $600. Among services offered under this contract were the coordination of care with other providers, a "comprehensive assessment and plan for optimum health," and extra time spent on patient care — all of which the OIG deemed were already covered by Medicare. The physician agreed to pay a settlement amount to OIG and to stop offering the contracts to his patients.

Specialty practices employing the idea

A handful of specialists, including cardiologists, dermatologists, and obstetrician-gynecologists, have begun incorporating the idea of retainer medicine into their practices.

Blanchard says some specialties are more suited

SOURCES

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- **U.S. Department of Health and Human Services**, Office of Inspector General, OIG Alert, March 31, 2004. "OIG Alerts Physicians about Added Charges for Covered Services." Web site: www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA033104AssignViolationI.pdf.

than others for the retainer models. Because they often see patients only on a referral basis and only for short periods of time, a retainer contract would be difficult to design and sell. Others, like cardiologists and obstetricians, know they will see patients for a longer time and can incorporate the concierge model into their practices.

Michael Blau, JD, a Boston-based health care attorney who has helped some specialists design retainer practices, said specialists rely on a "practice within a practice," a two-tier arrangement that allows them to take referrals and consult with primary care physicians and others, with the traditional insurance reimbursement, and to establish retainer arrangements with patients who are longer term.

Blanchard says retainer-based practices "are a tiny, tiny part of the whole health care system, hardly a blip on the radar."

"You can't predict the future, and the future of this type of practice depends on the future of health care in this country, but the idea is to restore the traditional physician-patient relationship. I think it has the potential to offer a level of service head and shoulders above what people can get in the traditional health care setting." ■

Poorest to reap most from Medicare Part D drug plan

But 7 million may have more out-of-pocket expenses

Low-income people with Medicare who sign up for new Part D drug plans and receive the additional subsidies — an estimated 8.7 million people — are projected to pay 83% less for prescription drugs in 2006 than they would have spent if the Medicare drug law had not been enacted, according to a recent report by the Kaiser Family Foundation. Patients who enroll in the new drug benefit but do not receive the low-income subsidies — an estimated 20.3 million people — are projected to pay on average 28% less out of pocket for their prescription drugs as a result of the new law, the analysis finds.

The report is based on a model developed by Actuarial Research Corporation (ARC) for the Menlo Park, CA-based Kaiser foundation, and estimates out-of-pocket drug spending in 2006 among the 29 million people the Congressional Budget Office (CBO) expects will sign up for Medicare drug plans.

"This analysis shows that the prescription drug law will provide the most help to seniors with low incomes and very high drug bills, just as Congress intended," foundation president **Drew Altman**, PhD, says. "Congress faced budget constraints and had to make trade-off decisions. The question is whether the law they passed will meet seniors' expectations."

The simulation model generally conforms to CBO's assumptions and projections about Medicare drug benefit spending and participation rates for the new benefit, known as Medicare Part D, and for the low-income subsidy. The projections of out-of-pocket drug spending are based on the likely response of Medicare beneficiaries to the new law. They do not reflect the effects of supplemental coverage that beneficiaries might obtain or take into account premiums paid by beneficiaries, which are estimated by CBO to average $420 for the new Medicare benefit in 2006.

Most help for beneficiaries with low incomes

The Medicare drug law targets substantial resources to low-income beneficiaries. To qualify for the law's low-income subsidies, people with Medicare must have annual incomes of less than 150% of the federal poverty level and limited assets, or must qualify for full Medicaid benefits. Those who receive the low-income subsidies are projected to pay 83% less on out-of-pocket drug costs in 2006.

However, Part D enrollees who meet the income requirements but do not receive the additional financial assistance, either because of their assets or because they do not sign up for the extra help, will pay substantially more than they would if they were to receive low-income subsidies, the foundation report states.

For example, Medicare beneficiaries with incomes that fall below 100% of the federal poverty level (in 2004, $9,310 for an individual) who enroll in the benefit and receive low-income subsidies are projected to spend, on average, $90 out of pocket for drugs in 2006. The estimated 2 million people at that income level who do not receive the additional subsidy are projected to spend 10 times as much, or $943 on average.

"Low-income subsidies will clearly make an enormous difference for many seniors struggling to pay for their prescriptions, but unfortunately, many are expected to go without this extra assistance," says **Tricia Neuman**, ScD, Kaiser foundation vice

SOURCES

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- **Tricia Neuman**, ScD, Vice President, Kaiser Family Foundation; director, Medicare Policy Project. E-mail: medicare@kff.org.
- **The Kaiser Family Foundation's report on Medicare's Part D drug program**, "Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006: Modeling the Impact of the MMA," is available on-line in PDF format at: www.kff.org/medicare/med112204pkg.cfm.

president and director of the Medicare Policy Project. "This demonstrates the need for an all-out effort to help low-income people on Medicare get the assistance promised by the new law."

Almost 7 million in 'doughnut hole'

The new analysis projects that 6.9 million people — or nearly one in four who sign up for the new drug benefit — could have spending in what the foundation calls "the doughnut hole," where those with total drug costs exceeding the initial benefit limit ($2,250 in 2006) are projected to have out-of-pocket costs exceeding $750 in 2006. Of the 6.9 million people who are expected to reach the doughnut hole in 2006, 2 million people (28%) have incomes less than 150% of the federal poverty level (in 2004, $13,965 for an individual); 2.8 million (42%) are in fair or poor health; and 3.8 million (55%) are women.

According to this analysis, the new drug benefit will substantially reduce projected average per capita out-of-pocket spending among Part D participants whose spending exceeds the $3,600 out-of-pocket catastrophic threshold. Nearly half (3.1 million people) of those who reach the doughnut hole are projected to receive catastrophic coverage under the new benefit because they incur at least $3,600 in out-of-pocket drug costs. Under the new law, this group is expected to pay $3,784 out-of-pocket, on average, in 2006, compared with a projected $5,980 on average in the absence of the new law — a reduction of 37%.

Overall, the analysis projects that three out of four who enroll in plans offering the new benefit (21.6 million people) are expected to have the same or lower out-of-pocket spending in 2006 than they would have without the new Medicare drug law.

The other one in four (7.4 million people) are expected to have higher out-of-pocket spending without taking into account the premium costs for the new coverage, unless they get supplemental coverage from another source. For most (about 5 million people), the increases are expected to be modest — $250 or less. This group includes many people with limited incomes who currently pay little or nothing for prescription drugs under their state Medicaid program, as well as people with low drug spending who currently have coverage for prescription drugs with a low or no deductible (such as through a Medicare Advantage plan). Under the standard Medicare drug benefit they will have to pay a $250 deductible before coverage begins, thus raising out-of-pocket costs above previous levels.

The 2.4 million people who are projected to face even higher out-of-pocket costs under the new drug benefit in 2006 includes those with relatively high out-of-pocket drug costs who are projected to lose access to more generous prescription drug coverage than the new Medicare benefit provides, especially people who lose their employer plan coverage.

"Most are projected to get helped, and some will get helped more than others, but in any single year we would expect one in four to spend more out of pocket under Part D than they would have under the prior system," wrote **Jim Mays**, the report's lead author and ARC vice president. ■

UNOS condemns deceased donor solicitation

Hospitals urged to avoid privately obtained organs

In a move the transplant medicine community anticipated for several months, the United Network for Organ Sharing (UNOS), the entity designated by the U.S. Department of Health and Human Services to coordinate organ transplants and donations in the United States, has adopted a position statement opposing private efforts to solicit deceased organ donors for transplant candidates when no personal bond exists between the patient and donor or donor family.

The position statement was drafted by UNOS and the Organ Procurement and Transplantation Network (OPTN), the entity operated by UNOS to bring together medical professionals, transplant recipients, and donor families to develop organ transplantation policy. The statement was

announced at the UNOS/OPTN semiannual meeting in November, following several months of study.

The position statement addresses only donations solicited from dying donors or the families of deceased donors. The practice of soliciting living donors — those who are willing to donate a kidney, for example, to someone in need of a transplant — still is under study by UNOS, and a position statement is expected within a few months.

The controversial practice of soliciting deceased donors gained national attention in the summer of 2004, when Houston resident Todd Krampitz was diagnosed with a severe liver cancer that left him too sick to be considered a candidate for a donor liver through UNOS.

Krampitz's family launched a billboard and online campaign to find a family who would direct their deceased loved one's liver to Krampitz, in what is called a "directed donation," and within a month, a donor was found and the transplant took place.

He and his family have since become proponents of organ donation, but critics say the damage done by the publicized transplant, which they say leap-frogged Krampitz past better candidates for transplant, could have long-term effects on the system through which organs have always been allocated.

"Organ donation is a gift, not a transaction," according to OPTN/UNOS president **Robert Metzger**, MD, echoing earlier statements by UNOS and ethicists who have been dismayed at the surge in private networks through which patients in need of organs solicit them from living donors or the families of deceased donors, effectively side-stepping the sometimes years-long wait that transplant patients experience through the traditional UNOS route.

Critics of the private organ solicitations say obtaining organs outside the UNOS system can mean organs go to less-sick individuals and mean additional delays for patients whose needs may be more life-threatening.

"Most deceased organ donation takes place anonymously through the national organ distribution system," Metzger stated in a press release accompanying the announcement. "At times donors or donor families want to donate to a specific person they know, and we support that. But we strongly oppose public or private appeals that effectively put the needs of one candidate above all others and pose concerns of fairness."

SOURCE

- **United Network for Organ Sharing,** 700 N. Fourth St., Richmond, VA 23219. Phone: (804) 782-4800. Fax: (804) 782-4817. Position statement on solicitation of deceased donor organs is available on-line at: www.unos.org.

UNOS is urging its 410 member organizations (every transplant hospital program, organ procurement organization, and histocompatibility laboratory in the United States) to help "ensure equity within the transplant system."

"If an OPTN member institution is involved in a situation concerning a public plea for donation of deceased donor organs to a specific individual, the Board recommends that the member reinforce to the candidate and/or donor family that the OPTN system is designed to allocate organs equitably according to the greatest need and/or benefit of all candidates," the position statement urges. "Should the candidate or donor family persist in their wishes, the member institution should act foremost to ensure equity within the transplant system, with additional consideration of relevant medical facts, ethical guidelines, and applicable laws and allocation policies."

Metzger says public appeals and private brokering of donor organs erodes the public's trust in the fairness of the established allocation system. The majority of deceased donor transplants occur anonymously and without specifying an intended recipient of the donated organ, with rare cases of families of deceased patients specifying to whom they wish organs to go. The UNOS statement does not condemn directed donations among family members or other patients and donors who have an established relationship.

"The existence of a personal bond that would cause a donor or donor family to favor a named transplant candidate is rare," according to the UNOS statement. "Attempts to develop such a personal bond through unsolicited contact with or public appeals to families of deceased donors are problematic."

UNOS/OPTN maintain that the national transplant allocation system maintains fairness for all candidates. Organizations and individuals who support the private solicitation of donor organs, however, say the long waits on UNOS recipient lists justify family members doing all they can to obtain lifesaving transplants for their sick relatives.

"Recognizing that organ donation and

transplantation are founded on altruism and equity, the OPTN/UNOS Board of Directors opposes any attempt by an individual transplant candidate (or his/her representatives) to solicit organ donation from a deceased donor ahead of other waiting candidates in a manner that subverts the established principles and objectives of equitable organ allocation," the UNOS statement continues. "This is a particular concern when commercial space is utilized to solicit directed donation from a member of the public for a specific candidate. Such efforts may divert organs from patients with critical need to those who are less ill. In addition, such appeals, although well-intentioned, compromise the principle of fairness."

The UNOS position statement left no doubt that the organization officially condemns soliciting organ donations through advertising. The position statement is not an official policy, meaning transplant centers and surgeons can choose to ignore it.

Sherril Lanthier, director of Houston's Multiorgan Transplant Center at The Methodist Hospital, where Krampitz's transplant took place, said in a press statement following the announcement of UNOS' position statement that the hospital will review the new recommendation.

"We look at everything that comes from UNOS and we follow their guidelines," Lanthier said. "We will look at it ourselves and make a policy within the hospital."

More than 87,000 people in the United States are awaiting organ transplants, and more than 6,000 people on the list die each year while waiting, UNOS data reflect. An estimated 17,000 patients are waiting for liver transplants.

Directed donations of organs, from living or deceased donors, is legal in many states; however, it is illegal in all states for any party involved in an organ donation to profit from the gift. ■

Center for Pediatric Bioethics set for Seattle

Children's Hospital receives federal appropriation

Should a terminally ill 10-year-old have a say in determining her end-of-life care? Can a teenager make an informed consent to treatment? Questions of this type will be the mainstay of the Center for Pediatric Bioethics, the nation' first center for bioethics solely dedicated to pediatrics, which will be located at Children's Hospital and Regional Medical Center in Seattle. A $340,000 federal appropriation has been secured, and Children's Hospital has dedicated $1 million in start-up funding for the center.

"The center is integral to Children's mission to foster a spirit of inquiry aimed at preventing illness, eliminating disease, and reducing hospitalization and its impact on children and families," according to **Treuman Katz**, president and CEO of Children's. "By addressing the complex ethical issues that affect patients, families, health care institutions, and research involving children, the center will promote the highest standards of medical ethics and protections of patient rights in pediatric research and health care."

The center will focus on four primary areas of pediatric bioethics:

- researching pediatric bioethics;
- educating medical students, health care professionals, and the public;
- providing a resource for families and health care professionals facing ethical dilemmas in clinical care;
- serving as an advocate for children who are receiving care and participating in research.

First of its kind in the nation

"The Center for Pediatric Bioethics will be the first of its kind in the nation, and it will provide a model for the study of policies, practices, and standards in ethical issues in pediatric research and health care that can be applied nationally and internationally," according to **Norman Fost**, MD, MPH, director of the Program in Bioethics at the University of Wisconsin. "This center has the potential to dramatically increase our understanding of ethical issues in the way health care and research for children is conducted."

The study of pediatric bioethics is particularly important because it requires more than simply adapting the concepts applied to adult health care. Delivering health care to children and the involvement of children in research raises different questions.

For example, the extent in which children can participate in the decision making for their health care varies with each child and each situation. The relationship and communication that occur between a parent, health care provider or researcher, and a child are critical in assuring that

SOURCE

- **F. Bruder Stapleton**, MD, Pediatrician-in-Chief, Children's Hospital and Regional Medical Center, 4800 Sand Point Way N.E., Seattle, WA 98105. Phone: (206) 987-2000.

the best interests of the child are served.

"Building on the strengths of one of the premier children's hospitals in the nation, the center will explore key issues faced by health care professionals, researchers, and parents, and will help create an environment that supports families in making informed choices about research participation and the use of innovative treatments," says **Wylie Burke**, MD, PhD, professor and chair of the department of medical history and ethics at the University of Washington.

The center's first undertaking will be to encourage collaboration among national experts in pediatric bioethics by hosting the first annual Conference on Pediatric Bioethics in July. The first of its kind in the United States, the conference will be a forum for institutions, researchers, and physicians to discuss the relationship between pediatric research, health care, and the pharmaceutical industry.

A national resource

"We hope the center will become a national resource for physicians, researchers, policy makers, parents, and patients," says **F. Bruder Stapleton**, MD, pediatrician-in-chief at Children's and Chairman of the Department of Pediatrics at the University of Washington School of Medicine. "We have initiated the recruitment of a world-class pediatrician-bioethicist to direct the center and serve as chief of the newly created Division of Bioethics in the Department of Pediatrics." Doug Diekema, MD, MPH, a respected bioethicist, will serve as interim director, according to Stapleton.

Bioethical challenges the center hopes to tackle include the involvement of children in research; quality of life for children with terminal illness; end-of-life decision-making; and religious considerations in health care decisions for children.

Best interest of the child

At the center, experts will assist health care professionals and families with difficult decisions by looking for ways they can work together to determine what is in the best interest of the child. Pediatric bioethics also helps children to participate in their own medical decisions, which can include determining if innovative therapies or participation in research studies is appropriate.

In addition to faculty bioethicists, the center will be staffed with pediatric-trained patient advocates who will work directly with patients and families to ensure appropriate safeguards and to facilitate and enhance communication with medical and research staff. ■

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided at the end of each semester and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

COMING IN FUTURE MONTHS

- Unnecessary cesarean births increasing
- Religious beliefs and cultural traditions considered at end of life
- Your medical history on an implantable chip?
- Dealing with impaired physicians

Clarification

In the **October 2004** issue, in an article titled "Postmortem procedures controversy unresolved," comments from **Mary Beth Foglia**, RN, MSN, evaluation specialist for the Veterans Health Administration National Center for Ethics in Health Care, should have made clear that in stating that VHA ethics specialists found no evidence to support claims that clinical training would be compromised if fewer corpses were available because of consent requirements, she was referring to findings from literature searches conducted by herself and others, not to original, empirical research conducted by the VHA Center for Ethics in Health Care. Additionally, while the VHA is located in Washington, DC, Ms. Foglia works in the center's Seattle office. For more information on the VHA National Center for Ethics in Health Care's findings on research into medical procedures on the newly dead, visit www1.va.gov/vhaethics/download/NET11.19.03.doc. ■

CME Questions

1. Of the five criteria developed by Fagerlin and Schneider to determine whether living wills accomplish what they are intended for, the researchers found that living wills meet two of the five conditions.
   A. True
   B. False

2. If a physician decides to convert his or her practice to one providing retainer-paid care and some patients elect not to stay with the practice under those conditions, the physician is required to:
   A. Do nothing.
   B. Transfer patient records to a new provider, for a fee.
   C. Make the transfer as easy as possible for the patient, transferring records at no fee.
   D. None of the above

3. It is projected that nearly one in four Medicare patients who sign up for the new Medicare drug benefit could end up in a "doughnut hole" in 2006. How much are these people anticipated to have to pay in out-of-pocket drug costs?
   A. More than $750
   B. Nothing
   C. Less than $25
   D. Unknown at this time

4. What sanctions may hospitals face if they violate the UNOS position statement condemning private solicitation for deceased donor organs.
   A. $10,000 fine
   B. None. It is not a binding rule.
   C. The violation will be reported to JCAHO for action.
   D. None of the above

Answers: 1-B; 2-C; 3-A; 4-B.