

## **New Limits Debated For Organ Donation**

### **Transplant Group Proposes Barring Donors Who Have Certain Health Problems; Balancing Risk vs. Need**

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*(See Corrections & Amplifications item below.)*

For years, surgeons and patient advocates have battled over whether new protections are needed for people who give away a kidney or a portion of liver. Now, a sweeping set of proposed guidelines on living organ donation hopes to take a step in that direction.

But transplant surgeons across the country are balking. The voluntary guidelines -- which aim to better screen potential living donors and limit who can become a donor -- have already been watered down, and it is unclear if they will be approved at all.

The debate reflects a tension between the need for organ donors and concerns that doctors may be lowering standards for living donors too far or failing to catch problems that could put the donor at unacceptable risk. Many transplant programs now allow people to donate who would have been screened out a few years ago, including those who are obese or have high blood pressure or diabetes.

Often marginally qualified donors demand to be approved, contending the choice is their own to accept the risk when someone they love needs a transplant. Transplant surgeons have also loosened standards for deceased donors, accepting, for instance, organs from much older dead donors than ever before.

The new guidelines -- from the United Network for Organ Sharing, the private organization that runs the nation's transplant network -- include four pieces, of which the most contentious are two sets of voluntary guidelines. The first aims to ensure that potential donors are properly screened, both medically and psychologically; that afterward they are followed to ensure no problems develop; and that people who are at increased risk never make it to the operating room. The second lays out recommendations to ensure donors give their informed consent.

But some surgeons worry that insurance companies or juries will use the guidelines to penalize doctors who don't follow them. Moreover, critics say that UNOS shouldn't be telling doctors how to practice medicine.

"Guidelines ... should be quite broad to make sure donors are protected, but the specifics of it may have to be left up to the center," says Peter Stock, a transplant surgeon at the University of California-San Francisco and chairman of the UNOS kidney committee. What if a father wants to donate to his desperately ill infant child but is a little too fat, he asks. Should the transplant program turn him down?

"Dictating the practice of medicine and surgery is not the role of [UNOS], let alone in the best interests of patients," said a letter from the American Society of Transplant Surgeons protesting the proposals.

The UNOS board of directors will consider all the proposals at its meeting next week in Los Angeles. The two other proposals set mandatory standards for programs that want to perform kidney and liver transplants with live donors, such as how much training surgeons must have.

### **Concern Over Standards**

Some in the transplant community believe that surgeons should take greater care in accepting living donors. "It's troubling," says David Cronin, a transplant surgeon at Yale University, where he says doctors have dropped their standards for donor blood pressure, weight and diabetes. He argues that even if donors fully consent to overly risky operations, doctors shouldn't do them. Otherwise "you've just abdicated your responsibility as a health-care provider."

Still, Dr. Cronin doesn't believe UNOS should be setting guidelines for medical practice. "This is an external agency practicing medicine," he said. "You don't see my patient, and you don't see my donor, and you're going to tell me who I can and can't use?"

UNOS has taken little action over the years to ensure donor safety, even as the number of living organ donors has grown to rival, and in some years exceed, the number of deceased donors. Last year, the Department of Health and Human Services directed the organization to develop policies governing living as well as deceased donation. The guidelines under consideration are part of the group's response.

### **Complications for Donors**

Donor advocates say UNOS has an obligation to ensure that donors are protected, and that it has waited too long to act. Most donors do well during and after surgery, but some have short- and long-term medical and other problems. The complication rate is high for liver donors, particularly those who give away the larger half of their liver. Some kidney donors report problems, too.

The original version of the proposals, put out for public comment in July, suggested potential kidney donors undergo a thorough medical and psychosocial evaluation, including a long list of tests, before being approved. It directed centers to follow donors for two years after surgery. And it said certain people should be ruled out, including those who are obese or have high blood pressure or diabetes, children under 18, and those with illnesses such as HIV or hepatitis. These conditions were labeled "absolute exclusion criteria."

### **Variation in Standards**

The proposals were written by the organization's living-donor committee after reviewing transplant programs across the country. The review revealed "wide variation" in standards, with some centers lacking any formal standards, the committee said.

The reaction from transplant surgeons was largely negative. Of the 11 regions, just four voted to approve the guidelines, with several regions saying they were strongly opposed.

In response, the living-donor committee made changes aimed at mollifying critics. It renamed the "absolute exclusion criteria" as "exclusion criteria." It removed the requirement to follow donors for two years post-donation, deleted mention of certain specific tests and changed the wording in the proposal's title from "guidelines" to "recommendations," to make clear that they were voluntary.

The committee also made significant modifications to its guidelines for informed consent, which received just two yes votes among the 11 regions. It dropped a detailed section on independent donor advocates, who are meant to help potential donors make a decision about donating, because this area was covered elsewhere. And it dropped a section on follow-up care for donors.

### **'Less Prescriptive'**

"We're trying to be less prescriptive so we can get something passed," said Tom Falsey, a member of the committee and the UNOS board, who donated a kidney to a stranger after learning he wasn't a medical match to donate to his ill nephew. His wife also donated to a stranger and, after the surgery, he said she developed pancreatitis and had to have her gall bladder removed.

"We definitely need to have some guidelines," he said. "They're long overdue and they're needed."

Even the new vice chairman of the committee drawing up the guidelines opposes them. Andrew Klein, a surgeon at Cedars-Sinai Medical Center in Los Angeles and vice chairman of the living-donor committee, says his committee isn't qualified to set out medical guidelines. Its members include representatives of the general public, former donors and other nonsurgeons. "Their intentions were correct but in some cases the expertise wasn't there for them to have the same valued opinion as someone who practices this for a living and has the patient's interests at heart," he said in an interview.

### **Looking for an Answer**

Robert Brown, a surgeon at Columbia University Medical Center who is chairman of the living-donor committee, said if anyone disagrees with one of the recommendations they should suggest a change. "The fact that people disagree with various elements does not in my mind justify throwing out the baby with the bathwater," he said.

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### **Corrections & Amplifications:**

Tom Falsey is a member of the board of the United Network for Organ Sharing. An earlier version of this article misspelled his last name. In addition, Andrew Klein, vice chairman of UNOS's living-donor committee, disagrees with the way his organization developed new guidelines to protect living donors. The article incorrectly says he opposes the guidelines.