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Richmond group to oversee face, hand transplants

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RICHMOND, Va. (AP) - When you check the organ donor box on your driver's license application, you're probably thinking your heart, kidney or liver might go to save someone's life in the event of your untimely death.

You're probably not thinking that your face, hands or arms could also be removed and used to help someone who is seriously disfigured by burns, bomb blasts or disease.

Under new federal transplant policy, faces and hands and other body parts classified as vascularized composite allografts - VCAs for short - will fall under the National Organ Transplant Act.

That means face and hand transplant programs will have to meet the same strict regulations and standards as heart and liver programs, for instance - which could have been the case before but there wasn't the formal oversight from the United Network for Organ Sharing, the Richmond-based organization that has a federal contract to oversee and manage the nation's transplant system.

It means the supply of faces and hands for transplant might increase exponentially, and will require sorting through delicate issues such as whether signing an organ donor card covers consent for donating one's face or hands.

"For most people when they sign on to their state registry or they check off the box on their license, they really are not thinking they are signing on to donate a hand or a face," said Dr. Suzanne V. McDiarmid, chairwoman of a new UNOS committee that is developing transplant policy for faces, hands and other VCAs.

"I think that we would not assume consent for hand and face transplantation at this stage of the journey," said McDiarmid, medical director of the hand transplantation program at UCLA Health. "So even though in many states signing on to your registry is legally binding, and in theory your family cannot override your decision, the sensitivity of donation for hand and face, I think we would be very cautious."

That is just one of the issues before the new committee, which met for the first time by conference call Nov. 22 and will have an in-person meeting in Chicago in coming weeks.

The committee includes a UNOS staff member and experts from leading transplant programs, among them Brigham and Women's Hospital, the Cleveland Clinic Foundation and Johns Hopkins Hospital.

The federal rule change will take effect July 3. Currently, faces and hands and other VCAs are classified as tissue and regulated by the federal Food and Drug Administration. They are called vascularized composite allografts because they are composites of skin, tendons, fat, nerves, blood vessels, muscle and other tissue.

In late 2011, the U.S. Health Resources and Services Administration announced plans to shift the oversight from the FDA and received public comment before publishing the final rule this past July. Many transplant officials had pushed for such a move.

"Through our trade organization, the Association of Organ Procurement Organizations, all 58 organ procurement organizations were very much in agreement to have UNOS integrate the vascular composite allografts into their allocation system," said Tim Jankiewicz, vice president for transplant services and executive director of Virginia Beach-based LifeNet Health's organ procurement organization.

Organ procurement organizations, or OPOs, are federally regulated agencies that work closely with transplant programs to recover organs from deceased donors. Each OPO works in a specific geographical region.

One reason the OPOs supported the change, Jankiewicz said, is that it is difficult to match such specialized donations as faces and hands between a donor and recipient in a limited region. Factors such as skin complexion and a person's sex, for instance, have to be considered.

"Having a larger wait list and including all OPOs throughout the country will provide a larger mix of potential organ donors," he said.

McDiarmid said many of the same things required of traditional organ transplantation have to be done for face and hand transplants.

"For example, a hand or a face procurement requires that the donor is, generally speaking, a brain-dead donor. So it's not something that can be procured many hours after brain death or even cardiac death as you can with a tissue such as bone or skin," McDiarmid said.

"And it requires just like when you are procuring a heart or a kidney that the donor has a circulation in place to keep that organ, the hand or the face, very well perfused in order to protect the structure of the tissue."

McDiarmid said there have been about six face transplants and 22 hand transplants in the U.S. These are estimates because there has not been formal reporting required. Many of the estimates rely on news reports of cases.

It's hard to know how many potential candidates there are for face and hand transplants. The Federal Register notice about the rule change cites a 2010 Department of Veterans Affairs report that estimates there to be as many as 200 wounded troops who might be eligible for face transplants and about 50 who might benefit from hand transplants.

"The list is not that great," said Susan Stuart, president of the Association of Organ Procurement Organizations. The shift to UNOS oversight, she said, "is going to make the whole process of allocation of hands and faces much more efficient."

"It's going to ensure that the patients who need these hand and face transplants have access to them," said Stuart, also president and CEO of the Pittsburgh-based **Center for Organ Recovery & Education**, an organ procurement organization serving parts of western Pennsylvania, West Virginia and a portion of New York.

Some transplant experts say much more research is needed before face and hand transplants are widely undertaken. Transplanting a heart or a liver is a life-saving surgery, but replacing a badly burned face or a missing hand typically is not. As with other transplants, there is the risk the body will reject the face or hand transplant.

There have been cases where transplanted hands have had to be amputated. A 2012 paper by Cleveland Clinic researchers on outcomes of 17 face transplant recipients done worldwide since 2005 notes that two recipients had died.

In Virginia, about 3.6 million people - approximately 57 percent of the adult population - are registered organ or tissue donors, according to Donate Life Virginia, a coalition of organ procurement organizations, hospital transplant programs and other groups involved in organ donation and transplant.

"Certainly, there are very special families that would agree to this type of donation because there is going to be their loved one, if it's a face donation, that's going to be replicated very closely in the recipient," Jankiewicz said.

"So certainly (there needs to be) complete disclosure to the family, trying to make sure they understand the gravity of this, what it does mean to a recipient and if they are in fact comfortable with it," he said.

The new UNOS committee has three general public members, including Lindsay Ess, a Richmond woman who had a rare double-hand transplant in September 2011 at the Hospital of the University of Pennsylvania. In 2007, she lost her hands and legs to a life-threatening infection after surgery.

Ess described her transplant experience and outcome as "ideal" but added that "there is always going to be a chance of the unknown, of why things work and don't work."

She said she has had two small rejection episodes, which were managed.

"In my opinion, my experience and my level of function in my hands is great. I wouldn't take it back for a second," Ess said.

But it is a "big deal," she said.

"I take immunosuppression medication. You have to constantly be aware. You have to do blood draws monthly so that they can make sure that your levels are OK and adjust accordingly," she said.

"They take biopsies of your donor hand once they are attached pretty often in the first year, less often in the second year, and then after the second year it's once a year unless you have a rejection episode."