Are face transplants still research, or regular care?

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In this Wednesday, Aug. 24, 2016 file photo, former Mississippi firefighter Patrick Hardison, 42, center, views a video showing progression of his face transplant, during a press conference marking one year after his surgery, at New York University Langone Medical Center in New York. Hardison was disfigured while trying to save people from a house fire in 2001. Is replacing a severely disfigured person's face with one from a dead donor ready to be called regular care, something insurers should cover? Mayo Clinic has raised that question by doing the first U.S. face transplant that's not part of research. (AP Photo/Bebeto

Matthews)

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Faces, hands, wombs and even a penis have been transplanted in recent years. Unlike liver or heart transplants, these novel procedures are not life-saving but life-enhancing.

Who pays for care that can cost $700,000 or more is a growing concern. Ethics and liability issues also may arise when they're done without the oversight of an institutional review board, a hospital panel that ensures research participants' rights are protected.

The group that runs the nation's organ transplant system, the United Network for Organ Sharing, plans a conference to help guide policy.

"It's time to come together and really ask the question, 'Is this going to become a standard of care?'" said Dr. Scott Levin, a University of Pennsylvania surgeon who heads the UNOS panel on this.

He has done several hand transplants and no longer considers them experimental, though insurers won't pay. Worldwide, about 100 hand, face or other, newer body-part transplants have been done, and "that's not a lot of cases" to judge safety and effectiveness for some types, he said.

Andy Sandness' operation last June was Mayo's first face transplant. Worldwide, roughly two dozen have been done, about half of them in the

U.S. Four recipients have died.

At Mayo, "we wanted to do it as a clinical program" and felt there was no research question to be answered because the operation uses standard surgical techniques, said the plastic surgeon who led it, Dr. Samir Mardini. Without a transplant, Sandness would have needed 15 other reconstructive procedures and the cost would be 30 to 40 percent higher, Mardini said.

Hospital management and multiple committees reviewed the case, including an ethics panel, a social worker and transplant psychiatrist, to ensure Sandness knew the risks and was giving informed consent.

"It's critically important that he understand what he would be putting himself through," Mardini said.

Sandness' insurance company would not agree in advance to pay; so, a fund from a donor to start a hand and face transplant center at Mayo paid. Talks on paying for after-care are ongoing.

The long-term medical and psychological effects will be studied as part of formal research, even though the operation itself was not, Mardini said.

"I don't particularly agree with the argument that it's not research," said bioethicist Arthur Caplan, who advised New York University on its first face transplant, in 2015.

There's a higher bar to ensuring informed consent for research versus a new therapy, and "questions about competence, experience and even liability are different" when something is called regular care, Caplan said. "In my view it's still highly experimental."