Experts ponder the ethics of xenotransplantation

The field of xenotransplantation—transplanting cells, tissues, or whole organs from one species into another—is racing forward and promises to be a growing area of biomedical research if ethical concerns are resolved, according to panelists at a July conference at the National Academy of Sciences (NAS). The conference followed two new reports on the ethics of xenotransplantation, one by the Institute of Medicine (IOM), and the other by the London-based Nuffield Council on Bioethics. Both reports found that the potential benefits of animal-to-human organ transplantation outweigh the risks involved.

"What we are seeking is to assure patients of protection and yet at the same time assure the pursuit and advancement of research," said Keith Reemtsma, chair of Columbia University's Center for Health Outcomes and Innovation Research and a pioneer in primate-to-human kidney grafts. Reemtsma called the renewed support for xenotransplantation "a vindication of a field that was on the back burner for three decades."

Xenotransplantation is being driven by a shortage of human organ donors. Some 47,000 patients are on the national registry for organs, a number that increases substantially each year. Half are expected to die before a suitable organ can be found.

After the first attempts in the 1960s to transplant baboon and chimpanzee organs to humans failed because of rejection by the immune system, research into xenotransplantation came to a halt in the United States, although other nations continued to experiment. In the 1980s, with advances in immunosuppressive drugs, US attempts began anew, including the transplantation of a baboon heart into Baby Fae and the recent grafting of baboon bone marrow into an AIDS patient. Cell and tissue transplants are moving more quickly than organ transplants because the risk of rejection is lower. Among many clinical trials now underway are those testing whether pig fetal tissue transplants can be used to treat Parkinson's disease.

As xenotransplantation technologies improve, experts are beginning to confront ethical questions raised by interspecies organ transfer. A major concern for the NAS conference participants was the potential that infectious disease organisms might be introduced into humans from animal donors. "Any xenograft clinical trials should be done carefully under consistent guidelines that can be applied nationally," said Stephen Morse, an epidemiologist at Columbia University. The IOM report recommends that clinical trials include screening of donor animals for infectious organisms and disease surveillance of patients and their families.

Other ethical concerns discussed at the conference included the challenge of gaining informed patient consent for a procedure that is full of unknowns, at least in the early trials. Fair allocation of both xenografts and allografts (human-to-human organs) must be determined, and public education must be continued to make sure the human donor pool does not shrink as the use of animal organs grows. Although animal rights were not a major concern, there was discussion about which species should be used. Some participants were hesitant about using primates, in part out of fear that the more closely related the donor species is to humans, the greater the risk of infectious disease spreading. For now, pigs are the donor of choice because they grow quickly and their organs are similar in size to human organs.

The IOM report recommends that before clinical trials expand, guidelines should be in place. Federal guidelines governing xenotransplantation are "well-advanced," according to William Raub, science advisor to the US Department of Health and Human Services. "The hard question is how to take the guidelines and embed them into the regulatory structure," he said.

With industry already pouring hundreds of millions of dollars into xenotransplantation research, several conference participants complained that the federal government needs to move more quickly. The guidelines were promised a year ago, a transplant surgeon pointed out. But both commercial and academic researchers expressed fear that the guidelines, once issued, might prove burdensome, especially to small labs. "The more you put guidelines in, the more people like me can't afford to do the [research]," said Denise Faustman, director of the Immunobiology Laboratories at Harvard Medical School, in an interview. "It stifles the academic research of small, innovative labs."

If there is genuine concern about the spread of infectious disease, Faustman and other researchers said, then the US government should stop ignoring research done in other countries. "Sweden has ten years of clinical trials that no one has bothered to look at," says Faustman, adding, "If we're not banning people from working in slaughterhouses or eating meat, then why are we trying to regulate a few scientists working on carefully controlled studies?"

Beth Baker is a freelance science writer based in Takoma Park, Maryland.