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At an international conference, researchers at the forefront of animal-human transplantation compared notes and allowed themselves the first real optimism in decades.

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By Roni Caryn Rabin
Roni Caryn Rabin reported from a scientific conference on xenotransplantation held in Geneva.

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In a modern glass complex in Geneva last month, hundreds of scientists from around the world gathered to share data, review cases — and revel in some astonishing progress.

Their work was once considered the stuff of science fiction: so-called xenotransplantation, the use of animal organs to replace failing kidneys, hearts and livers in humans.

But as the scientists traded notes, it became ever more clear that it wasn't fiction anymore. They were nearing breakthroughs that might help alleviate the shortage of donor organs plaguing every nation.

Transplants with organs from genetically modified pigs, designed not to trigger rejection by the human body, have begun to show great promise. "The future is here," said Dr. Muhammad M. Mohiuddin, the outgoing president of the International Xenotransplantation Association, which hosted the conference.

Attendees were told that two patients in their 60s — a man in New England and a woman in China — had survived for more than six months with kidneys from genetically modified pigs. (The organs had to be removed, and the patients returned to dialysis.)

Several clinical trials of such organs are getting underway in the United States. The first participant in a study run by United Therapeutics, a biotech company, has just received a kidney from a pig with 10 gene edits.

Next year, another company, eGenesis, will begin a trial of kidneys transplanted from pigs that have undergone 69 gene edits. The biotech firm will also start testing pig livers to be used outside the body by patients with chronic liver disease.

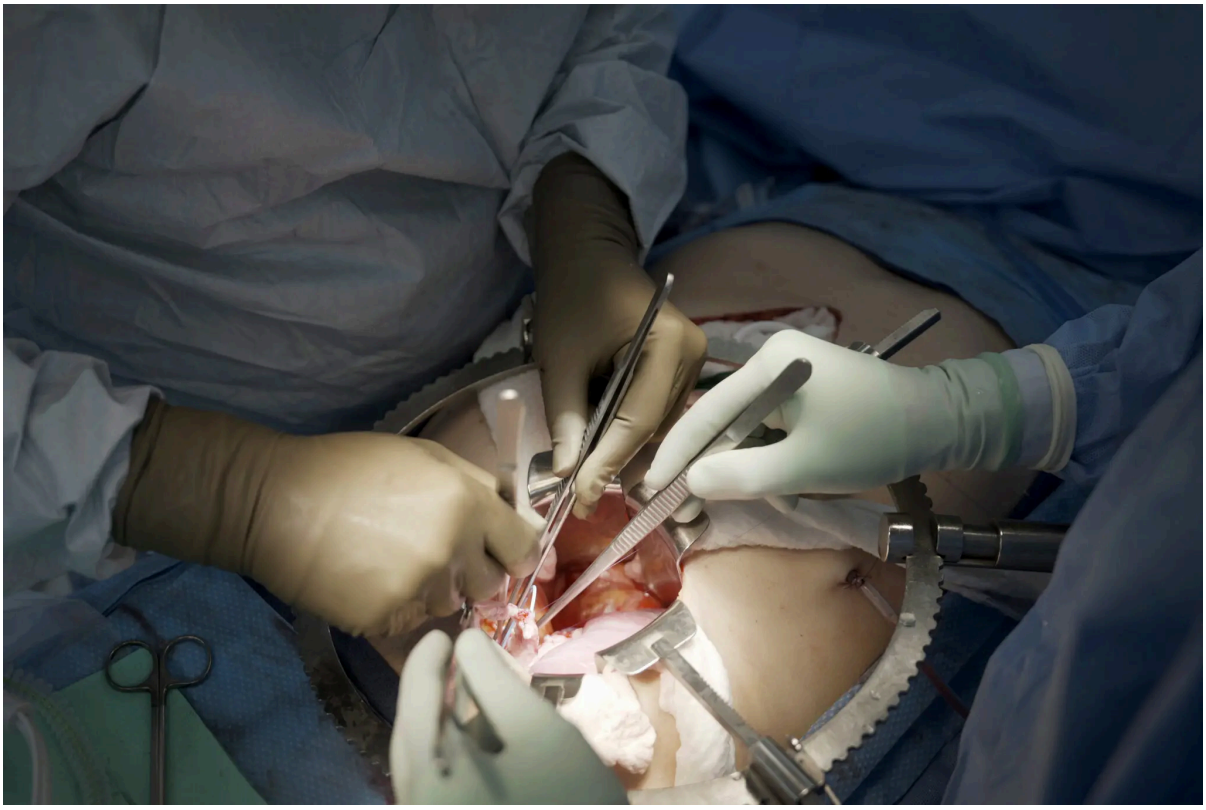
The company also hopes to start offering pig heart transplants to babies born with a rare serious congenital heart defect.

And in China, where over a million people suffer from kidney failure, workers are building the largest facility of its kind to house thousands of genetically modified pigs whose organs will be used for transplants.

Significant hurdles remain. Even as scientists learn more about tamping down the immune system, which rejects foreign tissue, they are finding that porcine kidneys are not functioning as well as they'd hoped in humans.

And even though the genetically modified pigs are raised in pathogen-free facilities and tested before their organs are harvested, viruses or viral genetic matter have slipped through the dragnet on at least two occasions, and were detected in transplanted organs.

Scientists disclosed one such instance for the first time at the conference. The fear is that infected organs could set off a wave of viral infections in humans.



Surgeons at NYU Langone Health prepared to transplant a pig's kidney into a brain-dead man in New York in 2023. Shelby Lum/Associated Press

Nevertheless, scientists viewed the obstacles as puzzles to be solved. Many compared their progress to the state of human-to-human organ transplantation around 1983, when the powerful immunosuppressant drug cyclosporine became available and helped prevent the rejection of transplanted organs.

"I think we are at a turning point," said Dr. David K.C. Cooper, a Harvard scientist and a consultant to eGenesis, which produces genetically modified pigs for organ transplants.

"We've already shown, with the few transplants that have been done, that the pig organs are going to work OK."

Dr. Cooper said he expected regulators to welcome a coming rush of transplants from genetically modified pigs, given that patients often have no other options.

"I think the F.D.A. will be very relaxed about enabling a larger number of people to receive porcine organs," he said. "So we'll see more and more transplants, and their results will get better and better."

Cultural Taboos

The interest in sourcing organs like kidneys from genetically altered pigs has grown worldwide. Chronic diseases like diabetes and high blood pressure damage kidneys, and they are on the rise everywhere, fueled by poor diet, smoking, alcohol consumption and lack of physical activity.

Even rising global temperatures can take a toll on the kidneys because of dehydration.

Kidney disease is now the ninth-leading cause of death globally and is projected to become the fifth-leading cause by 2040, Deusdedit Mubangizi, director of health products policy and standards at the World Health Organization, told the conference.

In more affluent nations, patients can be maintained on dialysis, though treatment is grueling. But in low- and middle-income countries, dialysis is not as accessible and kidney failure is tantamount to a death sentence, Mr. Mubangizi said.

Kidney disease is now the ninth-leading cause of death globally and is projected to become the fifth-leading cause by 2040. Billy Hickey for The New York Times

Donor human organs for transplant are in short supply all over the world. “Everywhere you go, you hear of the queue waiting for transplantations,” Mr. Mubangizi said. While some 170,000 organ transplants are performed each year globally, he said “it is barely 10 percent of the need.”

In China, for example, fewer human-to-human kidney transplants are done than in the United States — although the country’s population, 1.4 billion people, is more than four times larger.

Cultural beliefs that place a premium on burying the body whole and intact are deeply entrenched in many societies, contributing to the acute shortage of donated organs.

In Japan, that belief drives a critical shortage of donated kidneys, according to Dr. Takayuki Hirose, an assistant professor at Hokkaido University Hospital. Japanese patients can wait 15 years or more for a kidney, Dr. Hirose said, and 300,000 people are on the waiting list.

Many Japanese believe that the body contains the individual's spirit even after death, which is a barrier to organ donation, he said. Only about 2,000 kidney transplants are performed each year in Japan, and most of those organs are provided by living donors like family members.

Because of the long waiting lists for kidneys, older patients are discouraged from even putting their name on the registry. "If you register for a kidney when you're 55," Dr. Hirose said, "you're going to wait until at least 70 — and you can't get one once you're over 70."

Fears of a Novel Infection

One of the greatest challenges in xenotransplantation is tamping down the patient's immune system enough to prevent damage to the organ and rejection, but not so much that it causes harm to the patient.

The early experimental work involved transplanting pig organs into nonhuman primates. But doctors are now seeing stronger responses from memory T cells — which protect against previously encountered pathogens — in human patients, Dr. Tatsuo Kawai, a Harvard professor who has led successful xenotransplantation surgeries at Mass General Brigham, told conference attendees.

That may be because humans eat pork and primates do not, Dr. Kawai suggested, and so humans may be sensitized to pig organs. "If a patient has never consumed pork meat, xenotransplantation may be easier," he said.

Immune responses may also be playing a role in another persistent problem with the transplanted pig kidneys: The organs can spill high levels of protein into the patient's urine. The syndrome, called proteinuria, means the pig kidneys aren't functioning properly — and may not last that long.

Blood clots that can damage the organs have also been found in the tiny blood vessels of some of the transplanted pig kidneys.

In late October, surgeons in Boston removed a pig's kidney that had been transplanted into a 67-year-old New Hampshire man after the kidney's function deteriorated. The patient, Tim Andrews, who received the transplant in January, had lived with a pig kidney for longer than any other patient so far.

Dr. Leonardo Riella, left, at Mass General Hospital checking on Tim Andrews and his transplanted pig kidney in February. Mr. Andrews had to have the kidney removed last month. Billy Hickey for The New York Times

Scientists don't really understand what causes transplanted pig kidneys to malfunction. Some researchers have suggested that additional gene edits to the pigs could resolve the problem by helping the organ better escape the body's

immune response.

Alternatively, more intense suppression of the recipient's immune system may be required to protect the transplanted kidney.

"We can expect patients now to survive these operations and be off dialysis," said Dr. Richard N. Pierson, a professor of surgery at Harvard Medical School and the Massachusetts General Research Institute, who has done extensive research on pig heart transplants.

"But will they be plagued with protein loss problems, or will that be a manageable nuisance, with more medicines or more changes to the pig? That is the main challenge right now."

It is not the only one, however.

Scientists also need to reassure the public that xenotransplantation won't introduce new animal pathogens into the human population. But regulatory frameworks to ensure patient safety and protect public health are still spotty in most of the world, even in Europe.

Among some 30 nations that responded to a survey by the European Committee on Organ Transplantation, one third said they had no legislation in place covering the transplantation of animal organs, tissues and cells into human recipients, said Ralf R. Tonjes, a scientist who heads the committee's working group on xenotransplantation.

Traces of a cytomegalovirus known to infect pigs were found in the first recipient of a heart from a genetically modified pig. The surgeon who performed the operation, Dr. Bartley Griffith of the University of Maryland, said the latent virus may have "hitched a ride" in the transplanted organ and may have been responsible for the recipient's rapid decline and death.

At the conference in Geneva, investigators disclosed that they had detected RNA from a different porcine virus in the body fluids of a patient who had received a pig's kidney at NYU Langone Health last year. The virus, called atypical porcine

pestivirus, or APPV, is not associated with disease in humans, and no human cells were infected.

A test done subsequently on a sample from the pig showed that it was the source of the virus, and APPV was found in the transplanted organ itself.

Though pigs raised for organ transplants are screened for some 16 pathogens, neither the animal nor the herd had been tested for the virus because it "is not considered a pathogen of concern," the research scientist, Simon H. Williams, said in response to questions.

"To date, there have been no instances of APPV infections in any host outside of pigs," Dr. Williams said. "In fact, there have been no instances of human infection with any viruses from the pestivirus genus — they are mostly livestock viruses."

Nevertheless, "there should always be follow up and risk assessment." He emphasized that only RNA was detected, not the virus itself, and that "RNA alone is not infectious, whereas viral particles may be."

Scientists say that metagenomic screening that can detect any nonhuman DNA, not just test for specific viruses, can be used to test pigs for pathogens.

The great fear is a pig virus may mutate and infect a human transplant patient, setting off an epidemic or pandemic. Fear of animal-to-human disease crossover looms large not only among the general public, but also among the patients with kidney failure who stand to benefit most from xenotransplantation.

If there were a risk that zoonotic disease would be passed on to them and to their families, they would be far less likely to consider receiving a pig organ, said Heather Murphy, who presented the findings of a large National Kidney Foundation survey of kidney patients at the conference.

"This was the greatest concern for patients," Ms. Murphy said. "Once the risk expands to their loved ones and the greater community, this becomes a deal breaker for many patients."

Roni Caryn Rabin is a Times health reporter focused on maternal and child health, racial and economic disparities in health care, and the influence of money on medicine.