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Xenotransplantation – are we there yet?

Can animal-to-human transplantation reduce transplant waiting lists?

Published: 20 July 2026 **Author:** Rommel Ravanan **Read time:** 5 Mins

The transplantation of animal tissues and organs – xenotransplantation – is being studied as a potential solution to the high demand for patients awaiting a transplant. In this article, Rommel Ravanan explores the current state of xenotransplantation, with clinical trials underway in the USA and an advisory group set up by the UK Department of Health and Social Care.

Organ transplantation, enabled by living or deceased human organ donation, has increased significantly over the last 5 decades. It saves and improves lives for many thousands of patients each year. The success of this treatment has led to a progressively widening demand-versus-supply gap for suitable organs, and to patients waiting longer to receive a transplant. Every year in the UK, approximately 450 patients die while on organ transplant waiting lists,[1] and many more are removed from the waiting list because they have become too unwell and are no longer able to benefit from transplantation.

Policy initiatives (e.g. opt-out legislation), campaigns to increase public acceptance of organ donation, and efforts to improve donor identification and conduct expert conversations with relatives of the deceased, as well as maximising living donor transplantation opportunities, have all helped to increase organ transplant activity. Despite these successes, organ transplant waiting lists continue to grow, providing impetus to search for additional solutions.

A novel technology

Xenotransplantation (XT) is one such solution. XT is defined as any procedure that involves the transplantation, implantation or infusion into a human recipient of either live tissues or organs retrieved from animals, or human body fluids, cells, tissues or organs that have undergone ex-vivo contact with live non-human animal cells, tissues or organs.[2]

Attempts at undertaking XT in research settings and in living human recipients have been recorded for more than 50 years. In the early 1990s, the UK was at the forefront of XT research, as well as policy development, ethical evaluation and regulation of this novel technology. For a number of reasons, the research activity exited the UK by the early 2000s.

The recent advent of revolutionary gene-editing technologies, such as CRISPR, has accelerated the possibility of XT moving from bench to bedside – or to operating theatre. Reports from the USA in 2022 describing successful short-term heart XT in living patients[3] were followed in subsequent years by reports of successful short-term kidney[4] and liver[5] XT in humans from the USA and China. The US Food and Drug Administration approved clinical trials with xeno-organs in kidney (2025), liver (using ex-vivo perfusion through a xeno-liver, 2026) and heart (2026) transplantation. Beyond organs for XT, research is also active on genetically engineered pigs as a source of blood products and tissues (e.g. cornea).

Difficulties in implementing XT for humans

Research has identified several biological hurdles for successful XT. The initial focus was mostly on polysaccharide antigens present in cells of animal origin, but not in humans, which provided a ready target for human immune system-mediated damage of such cells. This led to creating 'triple knock out' (TKO) animals, where the polysaccharide xeno-antigens were removed by genetic engineering techniques. Transplantation of such organs in non-human primate models achieved better outcomes compared to organs from wild-type animals.

However, for translation into humans, further hurdles related to compatibility of human coagulation and complement systems (present in the blood of the human recipient) and their interaction with receptors on the endothelium of the xeno-organ needed to be addressed. Novel technologies like CRISPR have enabled human complement and coagulation compatible proteins to be 'knocked into' the animal genome in addition to TKO modifications. Finally, to address zoonoses concerns, especially due to porcine endogenous retroviruses (PERVs), researchers have developed PERV-free animals by either selective breeding or CRISPR-enabled gene edits. Such advances have accelerated the translation potential and resulted in the recent spate of successful short-term XT in living human recipients.

Practical and ethical obstacles

Research in XT has until recently focused on non-human primate models. In the last few years, this has shifted to a predominantly porcine model as the preferred organ source. Reasons for this include physiological compatibility (e.g. organ size and anatomy, left ventricular stroke volume, blood pressure), porcine products already being in established use for medical purposes (e.g. porcine insulin, pig heart valves), and commercial (litter size, short interval to grow to adult size) and societal reasons (acceptability of sacrificing animals for human food consumption).

Many of the ethical issues raised by the 1996 Nuffield Council on Bioethics publication[6] on XT remain. Patient selection and safety, animal welfare, interplay with human organ transplantation, equity of care for patients with faith- or non-faith-based objections to products of animal/porcine origin, and impacts on family or wider society from XT are some of the ethical considerations that need transparent and inclusive debate. Public and patient attitude surveys have shown heterogenous results with variations associated with demographics, religion, cultural attitudes and relative access to human organ transplantation.

Trials for future implementation

Following reports of successful short-term XT in the USA, the UK Department of Health and Social Care (DHSC) established a XT advisory group to derive recommendations for this emerging technology. The advisory group reviewed and have made recommendations[7] on the legislative, regulatory and operational frameworks needed for safe introduction and evaluation of this technology.

The advisory group recommended that XT should be evaluated in a clinical trial setting with ongoing national coordination by the DHSC. The recommendations were accepted by DHSC ministers. The EU and several other countries are also similarly reviewing safe evaluation and adoption of XT in their jurisdictions.

Despite significant advances in genetic engineering technology to achieve short-term successful organ transplantation, further developments are needed to improve organ/tissue compatibility to humans, as well as to understand and define the appropriate immunosuppression treatments for recipients. Research to understand patient attitudes, especially tailored to relevant country populations, and cost-effectiveness analyses are also essential to develop a rounded assessment of this technology.

Clinical trials (combined Phase 1, 2 and 3) have commenced in the USA. It is possible that trial participation will extend to the UK and other countries over the next few years. If trial evidence reports outcomes equivalent to human organ transplantation with a similar risk profile, and the technology is affordable, then XT would be a welcome addition to the suite of solutions needed to meet the current organ demand–supply gap.

References available on our website.

Meet the author

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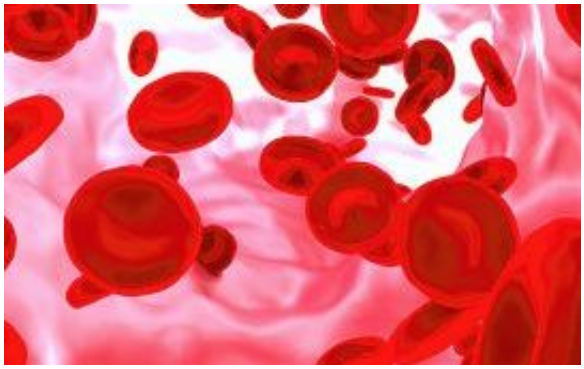

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