NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10084 Ex-situ machine perfusion devices for lung transplants

Final scope

1. Introduction

The technology included in this NICE HealthTech evaluation is an ex-situ machine perfusion device for lung transplants.

The technology is proposed to be assessed for early use. Early-use assessment considers HealthTech products that could address a national NHS unmet need. It rapidly assesses products early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

A lung transplant may be an option for some people with end-stage respiratory failure who have not responded to other medical treatments. The NHS Blood and Transplant annual report on lung transplantation reports that the most common causes for adult lung transplants are fibrosing lung disease and chronic obstructive pulmonary disease. For children, the most common

causes are cystic fibrosis and bronchiectasis, and primary pulmonary hypertension. There were 185 adults and 8 children on the UK active lung transplant list as of 31 March 2025. Between 2024 and 2025, 146 adult lung transplants and 5 child lung transplants were done.

3. Current practice

People identified as needing a lung transplant are placed on a waiting list. The UK nationwide lung allocation scheme was introduced by NHS Blood and Transplant in 2017, where donor lungs are allocated depending on how urgently a person needs a transplant. The national UK median waiting time for an elective lung only transplant is less than a month for urgent adults, over 18 months for non-urgent adults and over 7 months for non-urgent children. But, this varies across transplant centres (NHS Blood and Transplant, 2025).

Within the NHS, lung transplants are done by specialist cardiothoracic transplant surgeons in 6 centres (5 centres for adults and 2 centres for children) across the UK.

Standard care for lung transplants involves removing the lungs from deceased donors after either brainstem death (DBD) or circulatory death (DCD). Donor lungs are retrieved by the NHS Blood and Transplant national organ retrieval service in line with NHS Blood and Transplant's national organ retrieval service standards. The decision of whether donor lungs are suitable for transplant depends on donor characteristics, organ physiology and function, and the compatibility between the donor and the recipient. Donor lungs that do not meet the 'standard' criteria for transplantation, known as 'marginal' lungs, are often used for transplants to increase the number of donor lungs available. But, using donor lungs that do not meet the standard criteria may come with additional risk.

In-situ normothermic regional perfusion (NRP) may be done before organ retrieval where abdominal organs are also being removed from donors after circulatory death. This process aims to improve outcomes for abdominal organs, but experts stated that it does not usually benefit the lungs.

In adults, lungs are transplanted as a whole organ. In children and small adults, larger lungs can be trimmed down to size, but appropriately sized lungs are preferred if available. According to experts, lung trimming is more commonly done at specialist paediatric lung transplant centres.

Donor lungs are typically preserved using static cold storage. This involves flushing the donor lungs with cold organ preservation solution and then placing them in a sterile bag in a cold storage icebox for transport. This is done by a specially trained team before the donor lungs are transferred to the selected hospital for transplantation as soon as possible. But, experts stated that it is becoming more common for lungs to be transported and stored at warmer temperatures (between 8 and 12ºC) to help prevent organ damage and extend storage time.

Lung transplant surgery is performed at a specialist centre. This may be a single- or double-lung transplant, depending on the person's condition. The operation typically lasts several hours, followed by a hospital stay for recovery and early monitoring. In complex or high-risk cases, extracorporeal membrane oxygenation (ECMO) may be used to provide temporary support for the lungs. ECMO may be used during surgery to maintain oxygenation and circulation during implantation or after surgery in cases of primary graft dysfunction or severe respiratory failure. The length of time a person will stay in hospital after a transplant can vary depending on the complexity of their condition and operation. After discharge, people with lung transplants will require lifelong follow-up, including regular clinic visits, immunosuppressive treatment and close monitoring for signs of rejection and infection.

NICE's HealthTech guidance for extracorporeal preservation of lungs for transplant states that the procedure is supported by evidence on safety and efficacy and should be used under normal arrangements. In the UK, ex-situ machine perfusion of lungs for transplant is usually initiated at the hospital of the recipient of the transplant after the lungs have been transported from the donor hospital. According to experts, ex-situ machine perfusion technologies are not currently used in the UK to perfuse donor lungs during transportation.

This is because travel times are relatively short in the UK compared with larger countries. Maximum lung preservation time is shorter than other organs at around 6 to 8 hours.

British Transplant Society guidelines on transplantation from deceased donors after circulatory death recommends using ex-situ machine perfusion in cases of uncertain graft performance to safely extend donor and procedural criteria. An ongoing NHS Blood and Transplant pilot creating organ assessment and recovery centres (ARCs) aims to evaluate whether organ perfusion services can be delivered through centralised hubs rather than by individual transplant centres to improve efficiency. Under the pilot model, donor lungs are transported to the ARC instead of being sent directly to a transplant centre, where they will undergo machine perfusion and functional assessment. Organs considered suitable for transplantation are then repackaged and transported to the recipient transplant centre for implantation.

A list of relevant NICE guidance and guidance from other organisations can be found in appendix A of this document.

4. Unmet need

There is a shortage of high-quality organs available for transplant in the UK. This shortage means that people on the waiting list may become too unwell to have a lung transplant or die before a suitable organ becomes available. According to experts, prolonged time on the waiting list is associated with increased morbidity, including recurrent hospital admissions, worsening conditions, increased resource utilisation and worsening mental health. All these factors may decrease a person's chances of having a transplant or have a negative impact on their outcomes after a transplant. NHS Blood and Transplant's annual report on lung transplantation reported that between 2024 and 2025, 21% of adults registered as urgent and 14% registered as non-urgent died whilst waiting for a lung transplant.

Currently, only around 20% of adult donor lungs and 10% of donor lungs from children are transplanted. A person's cause of death, trauma or infection can

mean that donor lungs are considered unsuitable for transplant. Organ donors in the UK are also becoming older, which is associated with a higher risk of comorbidities. A number of strategies currently exist to increase the number of transplantable lungs available and reduce waiting list mortality and morbidity. But, there are still not enough organs considered suitable for transplant to meet the current demand. Once put in static cold storage, it is not possible to do a formal assessment of how well the donor lungs are functioning. Any uncertainties around function may lead some clinicians to decline to transplant organs that could potentially be used.

The Department of Health and Social Care independent report for Honouring the gift of organ donation (2023) and the NHS Blood and Transplant strategy 'Meeting the need' (2020) both highlight the need to embrace technological solutions such ex-situ machine perfusion devices to maximise the use of available organs to meet demand. But, in the absence of UK clinical guidance on the use of ex-situ machine perfusion devices for lung transplants, differing practices have emerged across lung transplant centres, leading to variation in access to this technology across the UK.

5. The technology

This section describes the properties of the technology based on information provided to NICE by the manufacturer and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

Ex-situ machine perfusion devices for lung transplants may allow marginal donor lungs which are working poorly to be assessed and reconditioned so that they can be used in lung transplant. The technology circulates a warm perfusion solution through the vessels of the lungs while also ventilating them. It allows clinicians to monitor lung function, treat infection and, if necessary, remove unwanted fluid, and re-expand areas of lung that have collapsed. If the lungs recover well enough, they may be considered suitable for transplant. The technology may increase the number of donor lungs available and improve the safety and success of lung transplantation.

Experts stated that ex-situ machine perfusion devices are currently used in 4 adult centres in the UK. Only 1 technology is currently commercially available in the NHS, but centres may use in-house ex-situ machine perfusion circuits as part of their services. These circuits are typically made from a combination of commercially available disposable components and local generic components and have functions similar to commercial technologies. Early clinical studies in the UK used these custom-built circuits.

Section 5.1 describes the included technology. This technology was available to the NHS at the time of writing this scope.

5.1 XVIVO Perfusion System XPS (XVIVO Perfusion AB)

The XVIVO Perfusion System XPS (XVIVO Perfusion AB) is a system for ex-situ machine perfusion of donor lungs prior to transplantation (CE marked class IIa). It is intended for use in adults aged 18 and over. The technology consists of the reusable XPS perfusion system and disposable components including:

- XVIVO disposable lung circuit (CE marked class III)
- XVIVO organ chamber (CE marked class IIa)
- XVIVO PGM disposable sensors (CE marked class IIa)
- XVIVO disposable lung kit (CE marked class IIb)
- and STEEN solution (CE marked class III).

Donor lungs are connected to the XVIVO Perfusion System XPS on arrival at the recipient hospital (or specific site for perfusion) where they are perfused with STEEN solution (a liquid that imitates blood plasma that is designed to support the lungs outside of the body). The system warms the donor lungs to body temperature, pumps STEEN solution through the vessels and ventilates the lungs to mimic breathing. This allows transplant teams to assess the function of the lungs. The technology can be used for continuous perfusion up to 6 hours. The XVIVO Perfusion System XPS can be used for standard and extended-criteria (marginal) donor lungs from both DCD and DBD donors. The company provides a training course before the device can be used and

recommends that it is operated by a minimum of 1 transplant surgeon and 1 perfusionist.

5.3. The place of technologies in the care pathway

This assessment will consider the use of ex-situ machine perfusion devices for marginal donor lungs. The technology would be used at the recipient hospital or ARC, after the lungs had been transported using static cold storage or refrigeration. For this assessment, the use of ex-situ machine perfusion devices for lungs during transportation is out of scope.

5.4 Innovative aspects

Ex-situ machine perfusion technologies are designed for the assessment and reconditioning of donor lungs. The technology also allows the delivery of treatment during perfusion, such as delivery of medicines, fluid removal or expansion of collapsed areas of the lungs. The main aims of ex-situ machine perfusion technologies include:

- improving access to donor lungs for people on the waiting list
- reducing the number of people who die on waiting list or become too unwell to receive a transplant
- increasing the number of donor lungs that are transplanted
- extending the period during which the lung can be stored, allowing more flexibility when arranging transplant operations.

6. Comparator

The comparator for this assessment is standard care. Current standard care is static cold storage or refrigerated storage at 8 to 12ºC.

7. Patient considerations

Waiting for a lung transplant is likely to be a stressful time and can cause anxiety and depression for both the person and their family or carers. The uncertainty about when an organ might become available, the physical limitations caused by end-stage respiratory failure, the risk of health

worsening while waiting, fears about surviving the transplant, and concerns about surgical and post-operative complications all contribute to this stress.

This stress and deterioration of health may also reduce a person's ability to engage in everyday life, including work, their social lives and other meaningful activities. For many, this results in withdrawal from normal social participation and a reduction in independence, which can further affect their family and household life. This can also increase the strain on carers, who may need to adjust their work commitments or take on additional responsibilities.

People waiting for a transplant are often required to attend the hospital at very short notice, sometimes before the death of the donor has been confirmed. Not all organ retrievals lead to transplants, and some surgeries are cancelled due to medical issues, logistical challenges, or last-minute clinical decisions. Preparing for and attending transplantation surgeries that ultimately do not proceed can be very distressing for people and their families. It may also be upsetting for the families of donors when donated organs are not used in transplantation procedures.

People waiting for a lung transplant may also face a difficult decision about whether to accept a particular donor lung offer, particularly when the need for transplant is urgent. In children and young people under 18, organ transplantation requires appropriate consent, often in emotional and stressful circumstances. Some organs carry more risk than others, and it is not possible to accurately predict when another suitable lung will be matched. Some people are more likely to get offers for donated lungs than others. This could be due to blood group compatibility, body size or urgency. The longer a person is on the waiting list, the more likely they may be to accept an organ with higher risks and the more difficult their recovery may be after their transplant.

All people on the waiting list are reviewed regularly to check whether they still meet national eligibility criteria for lung transplantation. If a person's condition changes, either improving or becoming too unwell to benefit from a transplant, they will be temporarily or permanently removed from the waiting list.

People who receive transplants require lifelong follow-up and ongoing immunosuppressive therapy. For children and young people this will include a structured transition to adult services. Without careful planning and support, this transition can be a vulnerable period, and may be associated with reduced adherence to medicines, increasing the risk of graft rejection.

Understanding the transplant process, coping with long-term medicines and hospital visits, and managing school and social development may be particularly challenging for children and young people, and their families.

8. Potential equality issues

End-stage respiratory failure can significantly affect a person's daily life. Under the Equality Act 2010, a person has a disability if they have a physical or mental impairment that has a substantial and long-term effect on their ability to do typical day-to-day activities.

NHS Blood and Transplant's annual report on lung transplantation reports that adults from white ethnic groups on the non-urgent lung transplant waiting list have shorter waiting times compared with people from Black ethnic groups.

All the major religions and belief systems in the UK are open to the principles of organ donation and transplantation. Organ donation is a personal choice and views on the matter can vary even among individuals within the same faith (NHS Blood and Transplant).

Fewer lung transplants are done in children and young people compared to adults. NHS Blood and Transplant's annual report on lung transplantation reports that, between 2024 and 2025, only 5 lung-only transplants in children were done across 2 specialist lung transplant centres. Finding suitable donor lungs is more difficult for children and young people due to the need for appropriate size matching and for the donor lungs to support the child over a longer time. As there are fewer specialist centres for children and young people than adults, they may need to travel further or have more difficulty attending regular hospital appointments. They may also have access to fewer respiratory specialists, services or technologies compared with adults, which

could mean that they experience delays or experience variation in the care that they receive.

Age, disability, race, and religion or belief are protected characteristics under the Equality Act (2010).

Other considerations include:

- People living in more rural areas or further away from transplant centres may have more difficulty attending regular hospital appointments. They may also have access to fewer respiratory specialists in their area, which could mean that they experience delays in referral, assessments and being put on the waiting list.
- Some lung transplant centres may also have access to more specialised services or technologies. People receiving transplants at centres without access to these services may experience variations in care compared with people with access. This may impact a person's opportunities for transplant or their outcomes after surgery. The introduction of ARCs may give people more access to machine perfusion devices, potentially reducing geographical health inequalities.

9. Guidance type

Ex-situ machine perfusion devices for lung transplants are proposed to be assessed for early use. This approach to guidance development is proposed because:

- limited evidence is available for the technology
- the technologies have the potential to address a high unmet need in the NHS.

10. Decision problem

The key decision questions for this assessment are:

- Does offering ex-situ machine perfusion for lung transplants have the potential to be a clinically and cost-effective use of NHS resources?
- Are there gaps in the evidence base and what are the key gaps?

Table 1: Decision problem

Proposed type of assessment	Early use
Population	People active on the lung transplant waiting list
Interventions	XVIVO Perfusion System XPS (XVIVO Perfusion AB)
Comparator	• Static cold storage • Storage at 8 to 12ºC
Setting	Specialised lung transplant centres
Outcomes and costs (may include but are not limited to)	System outcomes: • Proportion of donor lungs that proceed to transplant rather than being discarded (utilisation rate) • Proportion of donor lungs having machine perfusion that proceed to transplant (conversion rate) • Size and duration of lung transplant waiting list • Number of people who die on the transplant waiting list (mortality) • Number of people removed from the waiting list because they are too unwell for surgery • Length of and type of organ storage • Length of perfusion Clinical outcomes: • Recipient survival post-transplant • Graft survival post-transplant • Primary lung graft dysfunction (PGD) • Graft injuries • Use and duration of life support, including ECMO or mechanical ventilation • Measures of lung function • Serious adverse events Patient-reported outcomes: • Health-related quality of life (including impact on mental health and social functioning) Costs and resource use:

	• Cost of the technology (for example, purchase or lease costs, consumable costs and cost of training, including costs for procedures that do not result in transplantation) • Cost of organ retrieval and transplant surgery, post operative care, management of complications & hospital length of stay (including use of life support) • Cost of managing the condition on the transplant waiting list, including hospitalisation episodes • Staff time and cost according to specialism and level of pay, including theatre staff • Proportion and cost of daytime procedures compared with night-time procedures
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

11. Other issues for consideration

Experts also stated that ex-situ machine perfusion devices designed for adult lungs may need altering for children. This can include modifications to tubing and connectors. Using ex-situ machine perfusion devices for lung transplants in children and young people may depend on targeted staff education and training, supporting paediatric-specific protocols and coordination between ARCs based at adult specialist centres and paediatric transplant centres.

Where possible, the assessment will consider potential changes to the national lung transplantation pathway, in line with proposals by NHS blood and transplant, including the use of ex-situ machine perfusion devices at assessment and recovery centres.

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Appendix A: Related NICE guidance and guidance from other relevant organisations

NICE Guidance

- Ex-situ machine perfusion for extracorporeal preservation of lungs (Ex-situ lung perfusion) for transplant (2021) Formerly Interventional procedures guidance 695, now HealthTech guidance 580
- Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (2011) NICE guideline CG153. Last updated 2016

Other related guidance

- NHS Blood and Transplant lung candidate selection criteria policy (2025)
- NHS Blood and Transplant donor lung distribution and allocation policy (2024)
- European Society of Organ Transplantation (ESOT) consensus statement on machine perfusion in cardiothoracic transplant (2024)
- British Transplantation Society UK guidelines on transplantation from deceased donors after circulatory death (2023)
- NHS Blood and Transplant cardiothoracic – logistic back-up offering policy (2021)
- NHS England service specification for lung transplantation service in adults (2017)