

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

HealthTech draft guidance

**Ex-situ machine perfusion devices to
preserve deceased donor livers for
transplantation**

Guidance development process

NICE HealthTech guidance evaluates digital technologies, diagnostics and medical devices (including artificial intelligence). It provides evidence-based recommendations about how safe and effective these technologies are, and their cost effectiveness. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible treatments. NICE aims to promote innovations that meet the needs of patients and the healthcare system.

This guidance has been developed as routine-use HealthTech guidance, for HealthTech products that address a national unmet need in the NHS and may be suitable for widespread use.

Find out more on the [NICE webpage on HealthTech guidance](#).

NICE is producing this guidance on ex-situ machine perfusion devices to preserve deceased donor livers for transplantation in the NHS in England. The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE Guidance – Ex-situ machine perfusion devices to preserve deceased donor livers for transplantation

invites comments from the stakeholders for this evaluation and the public.

This document should be read along with the [evidence](#).

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If the committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on ex-situ machine perfusion devices to preserve deceased donor livers for transplantation. The recommendations in section 1 may change after consultation.

More details are available in [NICE's HealthTech programme manual](#).

Key dates:

Closing date for comments: 10 June 2026

Second committee meeting: 25 June 2026

1 Recommendation

1.1 Four ex-situ machine perfusion devices can be used in the NHS as options to preserve livers from deceased donors for people who need a liver transplant. The technologies are:

- Liver Assist
- metra
- PerLife Pro
- VitaSmart Hypothermic Oxygenated Perfusion System.

PerLife Pro can only be used as long as it has the appropriate regulatory approval.

What this means in practice

There is enough evidence to show that ex-situ machine perfusion devices to preserve livers from deceased donors for people who need a liver transplant provide benefits and value for money. So, they should be routinely available across the NHS and paid for using core NHS funding.

Why the committee made these recommendations

There is a shortage of high-quality donor livers in the UK, and many available donor livers do not proceed to transplantation. This can substantially affect quality of life and increase the risk of death for people who are waiting for a liver transplant.

Static cold storage is traditionally used to preserve livers between organ retrieval and transplantation. This minimises damage to the organ caused by a lack of blood supply during transport and preparation for surgery. Ex-situ machine perfusion devices pump a specially formulated solution through the donor organ's blood vessels. In the UK, they are used at the hospital where the liver transplant will take place. They aim to improve organ preservation

compared with static cold storage alone, particularly for higher-risk transplants.

Most UK liver transplant centres already use ex-situ machine perfusion devices. But practice differs across centres and funding often comes from local charitable sources rather than core NHS funding. This has resulted in regional variation in access to ex-situ machine perfusion devices.

Evidence suggests that, compared with static cold storage alone, ex-situ machine perfusion devices improve clinical outcomes for people who have a liver transplant. The devices may also increase the number of donor livers that can be transplanted safely.

Results from economic modelling show that these technologies are likely to be cost effective. So, they can be used in the NHS.

2 Information about the technologies

2.1 Ex-situ machine perfusion devices preserve a donor liver outside of the body before it is transplanted. There are several ex-situ machine perfusion devices available. The precise configuration of each technology varies but they typically include a reservoir, a pump, an oxygenator, and a warming or cooling unit. The donor liver is placed into the device, which pumps a specially formulated solution through the organ's blood vessels. The circulating perfusion solution also clears, and prevents accumulation of, waste products. Machine perfusion is typically performed at hypothermic (4°C to 12°C) or normothermic (around 37°C) temperatures. A donor liver can be perfused for several hours (duration varies depending on the technology and perfusion method) before being implanted into the transplant recipient. The viability of the donor liver can be assessed during normothermic perfusion. Some devices can slowly rewarm livers from hypothermia to normothermia (termed 'controlled oxygenated rewarming') and

some can provide a platform for liver splitting during machine perfusion.

- 2.2 Ex-situ machine perfusion devices may offer better organ preservation compared with static cold storage, with the aims of increasing the number of organs that can be transplanted and improving outcomes for transplant recipients. They can extend how long a donor organ can be preserved, which may allow more flexibility with logistics. Some devices also allow objective assessment of organ functionality, which may increase the number of available donor livers that can be safely transplanted.
- 2.3 Details of the 4 technologies included in this assessment are in table 1. Organ Care System (OCS) Liver was removed from the assessment after TransMedics advised that it would not be making the system available to the NHS for the use case outlined in the scope. As a result, the committee was unable to make recommendations on this technology.

Table 1 Table comparing features for each technology

Technology (company)	Intended population (transplant recipients)	Perfusion strategy	Liver function and viability assessment	Regulatory status (machine unit) and use in NHS
Liver Assist (XVIVO BV)	Children, young people, adults	<ul style="list-style-type: none"> • HOPE • NMP • COR 	Yes, during NMP	<ul style="list-style-type: none"> • CE marked class IIb • Currently used in NHS
metra (OrganOx Ltd)	Adults	<ul style="list-style-type: none"> • NMP 	Yes	<ul style="list-style-type: none"> • UKCA marked class IIa (CE class IIb) • Currently used in NHS
PerLife Pro (Aferetica Srl)	Children, young people, adults	<ul style="list-style-type: none"> • HOPE • NMP • COR 	Yes, during NMP	<ul style="list-style-type: none"> • CE marked class IIa • Working towards registering with the MHRA, so that it can be available to the NHS.
VitaSmart Hypothermic Oxygenated Perfusion System (Bridge to Life Ltd)	Children, young people, adults	<ul style="list-style-type: none"> • HOPE 	No	<ul style="list-style-type: none"> • CE marked class IIb • Currently used in NHS

Abbreviations: COR, controlled oxygenated rewarming; HOPE, hypothermic oxygenated machine perfusion; MHRA, Medicines and Healthcare products Regulatory Agency; NMP, normothermic machine perfusion.

Sustainability

2.4 For information, Carbon Reduction Plans for UK carbon emissions are published here for each company:

- [Bridge to Life’s webpage on corporate social responsibility, which includes their Carbon Footprint Policy](#)
- [XVIVO’s webpage on carbon reduction, from which the Carbon Reduction Plan can be accessed](#)
- Aferetica and OrganOx did not disclose their Carbon Reduction Plans for UK carbon emissions.

3 Committee discussion

The medical technologies advisory committee considered evidence on ex-situ machine perfusion devices to preserve livers from deceased donors for liver transplantation from several sources. This included evidence submitted by 4 companies, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the [project documents for this guidance](#).

The condition

- 3.1 Liver transplantation is the only potentially curative option for people with end-stage liver disease and some people with liver cancer or acute liver failure. In adults, the most common reasons for liver transplantation are alcoholic liver disease, primary sclerosing cholangitis and cancer. In children and young people, the most common reason for liver transplantation is biliary atresia.
- 3.2 These populations are at increased risk of dying from condition-related complications and symptoms can severely affect quality of life.

Current practice

- 3.3 People identified as needing a liver transplant are placed on a waiting list. The national UK median waiting time for an elective liver-only transplant from a deceased donor is about 5 months for adults and 6 months for children and young people, but this varies considerably across transplant centres ([NHS Blood and Transplant \[NHSBT\] annual report on liver transplantation, 2025](#)). Clinical experts noted that differences in provision of ex-situ machine perfusion devices across transplant centres may contribute to this variation.

- 3.4 In the NHS, transplants are done by specialist liver transplant surgeons in 7 centres for adults and 3 centres for children and young people, located across the UK.
- 3.5 In the UK, the majority of livers suitable for transplantation come from donation after brainstem death (DBD) or donation after circulatory death (DCD). In adults, most donated livers are transplanted as a whole organ. In children, young people and small adults, split liver transplants are more common. This is because children, young people and small adults require smaller grafts and there is a limited supply of whole livers from these populations. Livers for splitting are usually obtained from carefully selected low-risk adult donors. The smaller left lobe is transplanted into the child, young person or small adult. If usable, the larger right lobe may be transported to an adult liver transplant centre and used for an adult.
- 3.6 A donor liver for transplant is usually preserved using static cold storage (SCS). This involves flushing the donor liver with cold organ preservation solution and then placing it in a sterile bag in a cold storage icebox for transport to the selected hospital for transplant as soon as possible. The aim is to minimise ischaemic damage to the organ. The clinical experts explained that organ retrieval teams increasingly do in-situ normothermic regional perfusion (NRP) before abdominal organs are removed from donors after circulatory death. During NRP, the function of the liver can be assessed. NRP and ex-situ machine perfusion can be used sequentially in the same pathway.
- 3.7 According to [NICE HealthTech guidance 496](#), ex-situ machine perfusion should only be used with special arrangements for clinical governance, consent, and audit or research. The clinical experts reported that most UK liver transplant centres use ex-situ machine perfusion devices. But that practices and funding arrangements differ across centres, leading to variation in

provision. In the UK, ex-situ machine perfusion devices are used only at the hospital of the person having the transplant, after the liver has been transported using SCS.

Unmet need

- 3.8 There is a shortage of high-quality donor livers available for transplant in the UK and demand is rising because of the increasing prevalence of chronic liver diseases in the general population. This shortfall results in significant mortality and morbidity for people on the waiting list for a liver transplant.
- 3.9 In the UK, many donated livers do not proceed to transplant, particularly organs from people who were older, who had a condition that affected liver function or who donated their liver after circulatory death. These organs are at higher risk of worse outcomes if they are preserved using SCS only. Because it is not possible to assess how well donor livers are functioning during SCS, decisions about whether an organ is suitable for transplantation are based on characteristics of the donor and liver appearance. This uncertainty may lead to some healthcare professionals declining organs that could potentially be used.
- 3.10 The committee heard that ex-situ machine perfusion devices were most likely to improve outcomes in high-risk transplants, such as those involving extended criteria donors, complex recipients or logistical challenges, such as the use of split livers.
- 3.11 The committee concluded that there is a large unmet need for people on the liver transplant waiting list. Increasing utilisation of available organs is likely to benefit people who need a liver transplant.

Patient considerations

- 3.12 The committee considered evidence from lived experience experts, and a survey of people who have had or are awaiting liver transplant surgery, or are supporting someone who is. People with conditions requiring a liver transplant described substantial and wide-ranging impacts across all aspects of daily life because of severe symptoms. Waiting for a transplant is associated with considerable emotional strain, marked by persistent uncertainty, anxiety and disruption to normal activities. Restrictions to travel also affect social contact and personal relationships. Not all organ retrievals lead to transplants, and some surgeries are cancelled because of medical issues, logistical challenges or last-minute clinical decisions. Preparing for and attending transplantation surgeries that do not proceed is particularly distressing. It is also upsetting for the families of donors when donated organs are not used in transplantation procedures. Barriers affecting access to liver transplantation services include geographical distance from transplant centres.
- 3.13 According to lived experience experts and the survey results, most people having liver transplants are supportive of ex-situ machine perfusion devices and are happy to accept a liver preserved using these devices.
- 3.14 The committee acknowledged that people who need a liver transplant face substantial and wide-ranging challenges to their daily lives because of severe symptoms, as well as the stress and limitations of waiting for a suitable donor liver.

Clinical effectiveness

Identified evidence

- 3.15 Literature searches identified 168 studies, which were prioritised based on the quality of evidence and applicability to UK practice,

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for each device and perfusion method. Fifteen studies were prioritised for review: 7 randomised controlled trials (RCTs) on Liver Assist, 2 RCTs on VitaSmart and 6 non-randomised comparative studies on metra. No suitable studies on PerLife Pro were identified. All studies assessed ex-situ machine perfusion used at the hospital of the person having the transplant, after the liver has been transported using SCS, compared with SCS alone. One study on metra included a third arm, NRP then SCS.

- 3.16 No evidence on ex-situ machine perfusion in children and young people or on the sequential use of NRP followed by ex-situ machine perfusion was identified in the prioritised studies, or results were not reported separately. The deprioritised studies were then checked, but only limited evidence was found on these 2 groups.
- 3.17 The clinical experts advised that it is reasonable to generalise clinical results obtained from one device to other devices using the same perfusion method. Clinical experts advised that it is not possible to make overarching conclusions on whether findings from one perfusion method can be generalised to other perfusion methods. This is because of a lack of large studies directly comparing normothermic and hypothermic oxygenated machine perfusion.

Transplant utilisation

- 3.18 None of the prioritised studies reported comparative evidence on transplant utilisation (proportion of donor livers that proceed to transplant).
- 3.19 The clinical experts noted that it is challenging to design clinical trials that can robustly demonstrate increased organ utilisation with ex-situ machine perfusion devices. When donor livers are randomised to ex-situ machine perfusion or SCS after they have

already been accepted for transplantation, machine perfusion devices cannot rescue organs that would otherwise have not proceeded to transplantation. Conversely, when randomisation occurs before organ acceptance, healthcare professionals cannot be blinded to the organ preservation method. This introduces the potential for investigator bias, because the availability of machine perfusion may influence acceptance decisions.

3.20 The clinical experts reported that ex-situ machine perfusion devices have increased the number of donated livers that can be used in clinical practice. But they noted that the extent of this benefit is challenging to quantify in real-world settings. This is because of variation in practice across the UK and because NHSBT registry data does not report outcomes by the organ preservation method.

3.21 The committee recognised the difficulties in generating evidence to demonstrate the impact of ex-situ machine perfusion on transplant utilisation. The committee concluded that it is likely that ex-situ machine perfusion devices increase the number of donated livers that can be used in clinical practice, although direct evidence is lacking.

Overall survival

3.22 None of the ex-situ machine perfusion technologies were shown to reduce death compared with SCS in the prioritised studies. The clinical experts explained that it is challenging to demonstrate a mortality benefit for ex-situ machine perfusion devices compared with SCS. This is because death due to graft failures can usually be avoided through the use of super-urgent pathways for liver re-transplantation.

3.23 The clinical experts noted that a reduction in mortality associated with machine perfusion is highly plausible. This is because of

reductions in complication-related mortality, and improved graft viability and longer-term transplant outcomes.

- 3.24 The committee accepted that it is challenging to generate evidence to demonstrate a mortality benefit for ex-situ machine perfusion devices compared with SCS, but that a benefit is plausible.

Other clinical outcomes

- 3.25 The committee noted that none of the prioritised studies reported comparative evidence on waiting list outcomes (size, duration and mortality), device-related adverse events, healthcare professional satisfaction or wellbeing, or patient or carer health-related quality of life.
- 3.26 In the prioritised evidence, hypothermic oxygenated machine perfusion was associated with improved graft survival and fewer non-anastomotic biliary strictures compared with SCS. Normothermic machine perfusion was not associated with these benefits in the prioritised evidence.
- 3.27 The committee heard that ex-situ machine perfusion is not associated with more adverse events than SCS.
- 3.28 The committee considered that, while direct evidence is lacking in some cases, overall, ex-situ machine perfusion devices are likely to improve clinical outcomes for transplant recipients compared with SCS.

Children and young people

- 3.29 The committee heard that ex-situ machine perfusion devices are being used in liver transplant centres for children and young people, based on the benefits observed in adults. The committee noted that funding of ex-situ machine perfusion devices is also an issue in liver transplant centres for children and young people.

- 3.30 The clinical experts advised that ex-situ machine perfusion devices offer benefits for all donor livers used in children and young people, including split or reduced livers from adult donors as well as whole livers from paediatric donors.
- 3.31 The clinical experts explained that using ex-situ machine perfusion devices in paediatric liver transplantation has led to increased organ utilisation across the healthcare system. It has also reduced time pressures across the national liver transplantation pathway, particularly in complex cases. They explained that liver transplantation in children and young people comes with additional time constraints compared with transplantation in adults because of the need to use split or reduced livers from adult donors. Using ex-situ machine perfusion devices during liver splitting may help reduce ischaemic damage to the donor liver. By shortening the duration of ischaemia, these devices may also increase the likelihood that the right lobe of the split liver can be transported to an adult liver transplant centre and used.
- 3.32 The committee concluded that ex-situ machine perfusion devices are likely to benefit children and young people and small adults who require a liver transplant from a deceased donor. They may also increase the number of split livers available for transplantation in adults.

Pathway considerations

- 3.33 The committee heard from clinical experts that changes to the national liver transplantation pathway are in progress. This includes the routine use of NRP in livers donated after circulatory death and the introduction of a national network of assessment and recovery centres, which aims to help address the variation in waiting times across liver transplant centres. Clinical experts noted that achieving this aim is likely to take time, and that the ongoing use of ex-situ

machine perfusion devices at liver transplant centres will continue to play an important role in reducing variation in waiting times across centres.

- 3.34 Because of data limitations, it was not possible to consider potential changes to the national liver transplantation pathway in scenario analyses.
- 3.35 The committee noted planned changes to the liver transplantation pathway. But, it agreed that the routine use of ex-situ machine perfusion devices at liver transplant centres will likely be of continued benefit to people waiting for a liver transplant. It also agreed that more standardised practice will help address the current variation in service provision.

Cost effectiveness

Model structure and inputs

- 3.36 The committee considered a health economic model developed by the EAG to assess the cost effectiveness of ex-situ machine perfusion devices used at the hospital of the transplant recipient, compared with SCS alone.
- 3.37 The model is composed of a decision tree that captures the impact of ex-situ machine perfusion on waiting list outcomes and short-term post-transplant complications, followed by a Markov model to estimate lifetime costs and benefits. One year after having a transplant, people enter the long-term component of the model, which is structured as a Markov model with 3 health states (post-transplantation, post-re-transplantation, and death) and yearly cycles. An additional tunnel state is included to capture re-transplants, and all outcomes within the first year of having a re-transplant (including death).

- 3.38 Clinical inputs were mostly sourced from published evidence included in the clinical review and NHSBT registry data. Where clinical evidence on a specific machine perfusion device was lacking, it was assumed that it was the same as another device. For some key drivers of model results, this meant generalising data across different perfusion methods and using clinical inputs that were not statistically significant. The committee heard that because NHSBT registry data does not report outcomes by preservation method, and NRP and ex-situ machine perfusion are already used in UK practice, the model may underestimate the true incremental benefit of ex-situ machine perfusion. Conversely, there is also a risk that incremental benefits have been applied in the model to a baseline that already includes these gains.
- 3.39 The committee concluded that the economic model structure, assumptions and clinical and cost parameters were suitable to answer the decision question for this assessment.

Model results

- 3.40 In the base-case deterministic analysis, all ex-situ machine perfusion devices were more costly and more effective compared with SCS alone. In adults, the incremental cost-effectiveness ratios (ICERs) ranged from around £5,600 to £19,400 per quality-adjusted life year (QALY) gained. Results from probabilistic sensitivity analyses were consistent with the deterministic findings. The committee understood that this analysis should not be used to compare cost effectiveness between devices because of data limitations.
- 3.41 Total costs were higher with ex-situ machine perfusion because of the additional costs associated with the devices and increased number of people who have a transplant. These increased costs are partially offset by cost savings associated with fewer re-

transplants and reduced time spent on the waiting list. The committee heard that the estimate of waiting-list costs was based on published evidence. When more recent data from an NHSBT-linked analysis published after the evidence cut-off date were explored, this made little difference to the results because waiting-list costs were not a key driver of the model.

- 3.42 Ex-situ machine perfusion devices led to incremental QALY gains, driven primarily by the increased numbers of transplants, reductions in primary non-function of the donated liver (and associated mortality) and improvements in long-term survival. The EAG explained that the same organ utilisation rate (1.1; favouring machine perfusion) was applied to all ex-situ machine perfusion devices in the base-case analysis, obtained from studies on normothermic ex-situ machine perfusion started at the donor hospital, rather than only being used at the recipient hospital. The clinical experts explained that it is likely that both normothermic and hypothermic oxygenated machine perfusion devices increase the number of organs that can be transplanted, even though evidence on the latter is lacking.
- 3.43 Two subpopulations were also explored: children and young people, and recipients of livers from extended criteria donors. Because of limited subgroup-specific evidence, scenarios were explored assuming that base-case population data is applicable for these groups. Therefore, the results were broadly consistent with the base case, but further evidence is needed to confirm this.
- 3.44 Sensitivity and scenario analyses testing key structural and parameter assumptions suggested that the results were broadly robust to uncertainty within the model. If it is assumed that machine perfusion has no impact on long-term mortality and that improvements in organ utilisation reduce time to transplant but does not increase the number of organs utilised, the resulting

ICERs were above the range that NICE would typically consider to be a cost-effective use of NHS resources. But, clinical experts suggested that the assumptions underpinning this scenario were unlikely to be plausible.

- 3.45 The committee concluded that LiverAssist, metra, PerLife Pro and VitaSmart were likely to be a cost-effective use of NHS resources.

Additional benefits not captured in health economic model

- 3.46 Several additional potential benefits of ex-situ machine perfusion devices may not be captured in the economic model because of data limitations. By extending the safe preservation time of donor livers beyond what is possible with SCS, ex-situ machine perfusion may reduce logistical pressures and support staff wellbeing and workforce sustainability. In addition, viability testing of higher-risk organs may reduce anxiety among people on the transplant waiting list by lowering the likelihood of cancelled procedures.

Equality considerations

- 3.47 The committee considered the potential equality issues for this assessment, described in the [final scope and the equality impact assessment](#). The EAG did not identify any additional equality issues.
- 3.48 The committee considered the health inequality issues identified during the scoping process. The committee understood that different clinical practices and funding arrangements for ex-situ machine perfusion devices have emerged across liver transplant centres, leading to unequal access to these devices across the UK. Funding of these devices typically comes from local charitable sources rather than core NHS funding.
- 3.49 The clinical experts explained that some people living in rural locations may have experienced reduced access to donor organs

before the introduction of ex-situ machine perfusion devices, because of logistical challenges.

- 3.50 The committee concluded that guidance on the routine use of ex-situ machine perfusion devices will help address regional inequalities.

4 Committee members and NICE project team

This topic was considered by [NICE's medical technologies advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of each committee meeting](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Jacob Brown

Chair, medical technologies advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Samantha Baskerville and Robbie Pitcher

Technical leads

Rebecca Owens

Technical adviser

Toni Gasse

Project manager

Lizzy Latimer (May 2025 to February 2026), Janet Robertson (February 2026 onward)

Associate directors

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