NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

In-situ abdominal normothermic regional perfusion to preserve donor livers during retrieval for transplantation after controlled circulatory death

Summary of the procedure

When a liver is donated after treatment has been withdrawn and the donor's heart stops beating (controlled circulatory death), the liver may be damaged. This is because it does not receive blood with oxygen for a short period. In this procedure, a machine puts oxygen into the donor's blood and pumps it through the organs in their abdomen (regional perfusion) at normal body temperature (normothermic). The aim is to keep supplying the liver with oxygen while it is still in the donor's body (in situ) to reduce damage before transplantation.

NICE interventional procedures guidance applies to the NHS in England, Wales and Northern Ireland.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations on the safety and efficacy of these procedures. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on in-situ abdominal normothermic regional perfusion to preserve donor livers during retrieval for transplantation after controlled circulatory death in the NHS. The interventional procedures 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 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 safety and efficacy 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 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 in-situ abdominal normothermic regional perfusion to preserve donor livers during retrieval for transplantation after controlled circulatory death. The recommendations in section 1 may change after consultation.

More details are available in NICE's interventional procedures programme manual and NICE's HealthTech programme manual.

Key dates:

Closing date for comments: 28 July 2026

Second committee meeting (if needed): 10 September 2026

1 Recommendation

1.1 In-situ abdominal normothermic regional perfusion can be used as an option to preserve donor livers during retrieval for transplantation after controlled circulatory death.

What this means in practice

There is enough evidence on the safety and efficacy of this procedure for healthcare professionals to consider in-situ abdominal normothermic regional perfusion as an option to preserve donor livers during retrieval for transplantation after controlled circulatory death.

Healthcare professionals and centres doing this procedure should follow the relevant Human Tissue Authority's regulatory and legal requirements and the NHS Blood and Transplant Organ Donation and Transplantation's national protocols and guidance for consent.

NHS England may have policies on funding of procedures.

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Details about everyone having this

procedure should be entered into the NHS Blood and Transplant Organ Donation and Transplantation registry. Healthcare professionals should regularly review the data on outcomes and safety.

Who should be involved in the procedure

Healthcare professionals and centres should have specific training and expertise in this procedure. The procedure should be done in line with NHS Blood and Transplant Organ Donation and Transplantation policies and protocols.

Why the committee made this recommendation

Comparative observational studies show that this procedure works as well as, or better than, other methods used to preserve donor livers during retrieval for transplantation after controlled circulatory death. There is no data from randomised controlled trials. But the observational studies use methods that reduce potential bias and the results are consistent between them. Evidence also shows that the procedure could increase how many donated livers are accepted for transplantation. There are no concerns about the procedure's safety. So, it can be used.

2 Information about the procedure

2.1 In-situ abdominal normothermic regional perfusion is a procedure that restores circulation to the abdominal organs of a donor after controlled circulatory death and before their liver is removed. During in-situ abdominal normothermic regional perfusion, instead of immediately cold flushing the organ, the donor is first connected to a machine to establish an extracorporeal membrane oxygenation circuit. This machine is made up of a pump, oxygenator and heater. It perfuses the abdominal organs with an oxygenated blood supply at body temperature for about 2 hours after the donor's death. A

clamp is placed across the descending thoracic aorta to prevent blood flow to the brain. During the procedure, blood gas and biochemistry tests can be done to assess the function of the liver in real time before it is retrieved. Once the liver is removed, current practice is followed before transplantation.

2.2 The aim of in-situ abdominal normothermic regional perfusion is to reduce the ischaemic damage that occurs during the liver retrieval process and stop this damage becoming irreversible during the subsequent cold-storage process. This means that the liver can recover to its best possible condition before storage, so that it is suitable for transplantation.

3 Committee discussion

The interventional procedures advisory committee considered evidence on in-situ abdominal normothermic regional perfusion to preserve donor livers during retrieval for transplantation after controlled circulatory death from several sources. This included evidence submitted by Getinge Ltd, a review of efficacy and safety evidence, and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Liver transplant is a treatment option for people with end-stage liver disease (for example, because of alcohol-related liver disease or metabolic, autoimmune or infectious conditions), liver cancer or acute liver failure. Between April 2024 and March 2025, 785 whole-liver transplants were done in the UK. At the end of March 2025 there were 584 adults on the UK's active liver transplant list (NHS Blood and Transplant annual report on liver transplantation, 2025).

3.2 Most livers are donated as whole organs and come from donors who have died from circulatory or brain death. Between April 2024 and March 2025, in the UK 433 adult livers were donated from

donors who died from circulatory death (NHS Blood and Transplant annual report on liver transplantation, 2025). Not all these livers were able to be used for transplants.

3.3 This guidance focuses on livers donated after controlled circulatory death. This is when a person's organs are retrieved for transplantation following planned withdrawal of life sustaining treatments.

Current practice

3.4 A donor liver for transplantation is usually preserved using static cold storage. This involves immediately flushing the donor liver with cold organ-preservation solution and then placing it in a sterile bag in a cold-storage icebox for transport. This process is done by a specially trained team and aims to minimise ischaemic damage to the donor liver. Before a liver is transplanted it can be stored in an icebox for about 8 to 12 hours. The storage time depends on a number of factors, including the time taken for retrieval.

3.5 Normothermic machine perfusion is an ex-situ preservation technique. The recovered liver is placed on a mechanical circuit that circulates oxygenated, blood-based perfusate at body temperature. NICE HealthTech guidance on ex-situ machine perfusion for extracorporeal preservation of livers for transplantation recommends it for use with special arrangements. The procedure is a recognised clinical option within the NHS to preserve livers donated after controlled circulatory death.

Unmet need

3.6 There is a shortage of organs available that are suitable for transplantation in the UK. There is also a high demand for donor livers. This demand is rising because of an increasing prevalence of chronic liver diseases in the general population. The shortage of suitable donor livers can result in longer waiting times for people on

the waiting list for a liver transplant. This is associated with complications, worsening symptoms and death. Two-year follow-up data of people registered on the waiting list between April 2022 and March 2023 indicated that 11% died before receiving a liver transplant and a further 11% were still waiting (NHS Blood and Transplant annual report on liver transplantation, 2025).

3.7 Livers from donors who have died from controlled circulatory death are at risk of ischaemic damage. This damage occurs because blood flow to the liver is interrupted when the donor dies. Further ischaemic damage can occur when the liver undergoes a period of static cold storage before transplantation. The damage becomes irreversible during the cold-storage process. As a result, livers retrieved from donors who have died from controlled circulatory death can be unsuitable for transplantation. In the UK, many donor livers with ischaemic damage are not used in transplants because of the risk of worse transplant outcomes and uncertainty about liver viability. This includes livers that are declined either before or after retrieval. Between April 2024 and March 2025, out of 727 livers donated after controlled circulatory death, 309 were transplanted. Therefore, 58% of the donated livers were not used for transplantation (NHS Blood and Transplant annual report on liver transplantation, 2025).

Innovative aspects

3.8 In-situ abdominal normothermic regional perfusion can allow the liver to recover from existing ischaemic damage inside the donor's body before the liver is retrieved, cooled down and stored for transport. This prevents further ischaemic damage during the storage process. The procedure can improve the quality of livers retrieved from donors who have died from controlled circulatory death and increase the number of livers suitable for transplantation.

The evidence

3.9 NICE did a rapid review of the literature on the efficacy and safety of this procedure. The evidence included 3 systematic review and meta-analyses and 5 observational comparative studies. It is presented in the summary of key evidence section in the interventional procedures assessment report. Other relevant literature is in the appendix of the assessment report.

3.10 The professional experts, patient experts and the committee considered the key efficacy outcomes to be:

- primary non-function
- early allograft dysfunction
- graft survival and graft loss
- transplant utilisation and discard rate
- recipient survival.

3.11 The professional experts, patient experts and the committee considered the key safety outcomes to be:

- recipient hospitalisation
- biliary complications
- ischaemic cholangiopathy
- hepatic artery thrombosis
- renal complications
- procedure-related adverse events.

3.12 Four commentaries from people who received livers that were preserved during retrieval using in-situ abdominal normothermic regional perfusion, and 121 commentaries from people who have had or are waiting for a liver transplant, or their carers, were discussed by the committee.

Committee comments

3.13 The committee heard that the procedure would not negatively affect retrieval of other abdominal organs for donation. Experts said there is less evidence available, but they would expect some benefits to be seen for other abdominal organs retrieved using in-situ abdominal normothermic regional perfusion than with conventional static cold storage.

3.14 The procedure gives the retrieval team more time to retrieve the liver than conventional static cold storage does. During this time, the team can also test liver function, which would not usually be possible.

3.15 The procedure can be used to complement ex-situ machine perfusion. This is sometimes used when the liver is transported to the recipient.

3.16 The retrieval team for in-situ abdominal normothermic regional perfusion needs more clinical team members than the team for standard abdominal retrieval.

Equality considerations

3.17 In-situ abdominal normothermic regional perfusion should be done by teams with specific training and specialist equipment. Not all centres currently have access to this, so there could be regional differences in services.

3.18 The procedure enables transplant teams to objectively assess liver function before they retrieve the donor liver. This means that acceptance of the liver is not based on subjective assessment alone. It also means that livers that would not previously have been considered suitable for donation could be considered suitable based on objective liver function tests. So, the procedure could reduce variation in practice and improve equity of access to donor livers.

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures 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

Rick Body

Chair, interventional procedures 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 consultant clinical adviser, a project manager and an associate director.

Sarah Abraham and Louisa Robinson

Technical leads

Evan Campbell

Technical adviser

Anthony Akobeng

Consultant clinical adviser

Corrina Purdue

Project manager

Lizzy Latimer

Associate director

ISBN: [to be added at publication]