NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-IPG10405 In-situ normothermic regional perfusion of the abdomen for livers donated after controlled circulatory death

Final scope

1 Introduction

The procedure included in this NICE HealthTech evaluation is in-situ normothermic regional perfusion (NRP) of the abdomen for livers donated after controlled circulatory death. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This is the first time that this procedure is being assessed by NICE interventional procedures. This document describes the context and the scope of the assessment. The methods and process for the assessment follow the Interventional procedures programme manual and the NICE HealthTech programme manual.

2 Lay description

When a liver is donated after the donor's heartbeat stops after the withdrawal of care because they are too sick to recover (donation after controlled circulatory death), the liver can be damaged because it does not receive blood for a period of time. In this procedure a machine pumps the donor's own blood through the organs in their abdomen (regional perfusion) at normal body temperature (normothermic). The aim is to reduce damage to the liver and allow assessment of how well the liver works while it is still in the donor's body (in situ).

3 The condition

Liver transplant is a treatment option for people with end-stage liver disease (for example, because of alcohol-related liver disease, metabolic, autoimmune or infectious conditions), liver cancer or acute liver failure. A total of 785 whole liver transplants were done in the UK between April 2024 and March 2025. At the end of March 2025 there were 584 adults still on the UK active liver transplant list (NHS Blood and Transplant, 2025a). Most livers are donated as whole organs and come from donors who have died from circulatory or brain death. In April 2024 to March 2025, in the UK 433 adult livers were donated from donors who died from circulatory death and 602 from donors who died from brain death (NHS Blood and Transplant, 2025a). Not all of these livers were able to be used for transplants. This assessment will focus on livers donated after controlled circulatory death. Donation after controlled circulatory death is where a person's organs are retrieved for transplant following planned withdrawal of life-sustaining treatments (NHS Blood and Transplant).

4 Current practice

A donor liver for transplant 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. After removal, the liver is transferred to the selected hospital for transplant as soon as possible. Before livers are transplanted they can be stored for about 8 to 12 hours in an icebox, depending on a variety of factors including the time taken to retrieve them (British Liver Trust 2022, British Transplantation Society 2023, NHS Blood and Transplant 2025b) .

5 Unmet need

There is a shortage of organs available that are suitable for transplant in the UK and a high demand for donor livers (NHS Blood and Transplant, 2025a). This demand is rising because of an increasing prevalence of chronic liver diseases in the general population (British Liver Trust, 2024). The shortage of suitable donor livers can result in longer waiting times for people on the waiting list for a liver transplant which 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, 2025a).

Livers from donors who have died from controlled circulatory death are at risk of ischaemic damage. This damage occurs because of interrupted blood flow to the liver when the donor dies. Further ischaemic damage can occur when the liver undergoes a period of static cold storage prior to 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 (Mastrovengalis, 2024). In the UK, many donor livers with ischaemic damage are not used in transplants due to the risk of worse transplant outcomes and uncertainty about liver viability (Eden, 2023). This includes livers that are declined either before retrieval or after they have been retrieved. Between April 2024 to March 2025, out of 727 livers donated after controlled circulatory death, 309 were transplanted, which

means that 58% of the donated livers were not used for transplant (NHS Blood and Transplant 2025a).

6 The procedure

In-situ NRP of the abdomen is a procedure that restores circulation to the abdominal organs of a donor after they have died from controlled circulatory death and before their liver is removed. During in-situ NRP, instead of immediately cold flushing the organ, the donor is first connected to a machine establishing 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 donor death. A clamp is placed across the descending thoracic aorta to prevent blood flow to the brain (UK NRP National Protocol, 2025). 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 (Oniscu, 2014). After removal of the liver, the process follows current practice prior to transplantation. The aim of in-situ NRP is to reverse 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 is recovered from ischaemic damage to its best possible condition before storage, ready for transplantation.

6.1 Innovative aspects of the procedure

The proposed innovative aspect of in-situ NRP is that it allows the liver to recover from existing ischaemic damage inside the donor's body before it is cooled down and stored for transport and prevent further ischaemic damage during the storage process. The procedure may help to improve the quality of livers retrieved from donors who have died from controlled circulatory death and subsequently increase the number of them that are suitable for transplant.

6.2 Current known use of the procedure

In-situ NRP of the abdomen is part of the NHS Blood and Transplant framework which recommends it for use alongside static cold storage for retrieving livers after controlled circulatory death of the donor (UK NRP National Protocol, 2025). Currently 6 out of the 10 organ retrieval centres in the UK can do this procedure, and it is regular practice in at least 3.

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

- End-stage liver disease can significantly affect people's daily living. 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. Disease severity is an important factor in determining the allocation of liver transplants as people with end stage liver disease may be classed as disabled. People with more severe liver disease and higher risk of mortality are more likely to be prioritised for liver transplantation ahead of people with less severe liver disease and lower risk of mortality, although other factors may also be considered.

- Adults from White or Asian backgrounds tend to wait less time for a liver transplant than other ethnic backgrounds (NHS Blood and Transplant, 2025a).

- All of 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).

- There are different types of liver diseases that can be associated with alcohol, obesity, viral infection, and genetic factors. Overall, men are more likely to die from liver disease than women (British Liver Trust, 2024).

- Between April 2024 to March 2025, most livers donated came from adults from White backgrounds. 91% of liver donors were White adults (NHS Blood and Transplant, 2025a).

- Between April 2024 to March 2025 males received more liver transplants than females. Males represented 63% of transplant recipients and 52% of active waiting list patients (NHS Blood and Transplant, 2025a).

- Between April 2024 to March 2025 older people received more transplants than younger people. People aged 50-59 years represented 28% of transplant recipients and adults aged 60-69 years represented 32% of transplant recipients (NHS Blood and Transplant, 2025a).

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

Additional considerations include:

- People living in more deprived areas are more likely to develop liver diseases, including liver cancer. In areas experiencing the greatest levels of deprivation the rate of premature deaths from liver disease is almost four times higher than in the least deprived areas (British Liver Trust, 2024)

- In the UK currently in-situ NRP can be carried out by 8 out of 10 of the organ retrieval centres and it is regular practice in at least 3 organ retrieval centres for controlled circulatory death cases. This means

there may be geographical variation in access to donor livers that have been retrieved using in-situ NRP.

8 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of in-situ NRP of the abdomen for the recovery of donor livers from controlled circulatory death to determine whether it works well enough and is safe enough for use in the NHS.

Table 1: Decision problem

Population	People receiving a liver transplant from donors who have died from controlled circulatory death.
Intervention	In-situ NRP of the abdomen to retrieve the liver after the donor has died from controlled circulatory death
Key efficacy outcomes (may include but are not limited to)	• Transplant utilisation (use of livers or proportion not discarded) • Post-transplant liver function (serum aspartate aminotransferase AST, alanine aminotransferase, serum creatinine, total bilirubin, prothrombin time) • Long term (6-12 months post-transplant) liver function (e.g. ALP measurement to assess biliary damage) • Acute rejection of the donor liver by the recipient • Graft survival • Primary non-function of the graft • Early allograft dysfunction • Recipient mortality 7 days and 1 year after transplantation • Recipient mortality without relisting or retransplantation, recipient mortality after relisting and re-transplantation • Recipient re-listing • Recipient re-transplantation

	• Recipient time to recovery to normal functional status post-transplantation • Circuit failure during in-situ NRP (loss of blood volume, air or clots in the circuit) • NRP procedure-related failure that impacts the donor liver (failed cannulation of the donor, mechanical failure of the device)
Key safety outcomes (may include but are not limited to)	• NRP procedure-related adverse events that impact the recipient (e.g. infections, bleeding, cardiovascular complications, and thromboembolic complications related to the graft) • Biliary complications (e.g. ischaemic cholangiopathy, non-anastomotic strictures) • Recipient hospitalisation (total hospital admissions) after 1st year of transplantation • Renal complications

9 Other issues for information

There is currently 1 device (CardioHelp from GETINGE Ltd) available to do this procedure in the UK. This device is mentioned in the UK in-situ NRP procedure protocol for retrieving livers from donors after controlled circulatory death and the British Transplantation Society's guidelines on transplantations from donors who have died from circulatory death. The instructions for use state that the intended population for CardioHelp is all people irrespective of age, size and weight. They also state the intended use is to drive, to control, to monitor and to protocol an extracorporeal circulation.

10 NICE team

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Appendix A: Related evidence or guidance

Relevant registries or emerging key trials

NRP vs DHOPE v COR-NMP in ECD-DCD Donation: observational study, adult liver transplant recipients, adult livers donated after circulatory death from people aged between 50 to 75 years old, in-situ NRP compared with other retrieval methods, predicted sample size of 150, Netherlands. The primary outcomes are organ utilisation rates and patient and graft survival. The expected completion date is May 2029.

Immunometabolism of Machine Perfusion Strategies (iMaps): randomised controlled trial with parallel assignment, adult liver transplant recipient, adult livers donated after circulatory death from donors aged 18 and over, in-situ NRP compared with other retrieval methods, predicted sample size of 36, England. The primary outcome is determining the mechanism of ischaemic-reperfusion injury in humans using static cold storage, NRP and hypothermic machine perfusion methods that are followed by machine perfusion. The expected completion date is May 2026.

Related NICE guidance, standards or indicators

NICE interventional procedures guidance

- Ex-situ machine perfusion for extracorporeal preservation of lungs (ex-vivo lung perfusion) for transplant (2021), NICE interventional procedure guidance 695 [IP695] (Recommendation: standard arrangements)
- Ex-situ machine perfusion for extracorporeal preservation of livers for transplantation (2019), NICE interventional procedure guidance 636 [IPG636] (Recommendation: special arrangements)
- Extracorporeal whole liver perfusion for acute liver failure (2021), NICE interventional procedure guidance 690 [IPG690] (Recommendation: research only)
- Normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death (2016), NICE interventional

procedure guidance 548 [IPG548] (Recommendation: standard arrangements)

- Living-donor liver transplantation (2015) NICE interventional procedure guidance 535 [IPG535] (Recommendation: standard arrangements)

NICE HealthTech guidance

- Ex-situ machine perfusion devices for deceased donor liver transplants
- (In progress due to complete August 2026) NICE HealthTech guidance in development HTE10066
- Machine perfusion devices for lung transplants (scoping in progress)

NICE technology appraisal guidance

- Machine perfusion systems and cold static storage of kidneys from deceased donors (2009), NICE technology appraisal guidance 165 [TA165]

NICE clinical guidelines

- Alcohol-use disorders: diagnosis and management of physical complications (2017), NICE clinical guideline 100 [CG100]
- Organ donation for transplantation: improving donor identification and consent rates for decreased organ donation (2011; last updated 2016) NICE clinical guideline 135 [CG135]
- Hepatitis B (chronic): diagnosis and management (2013; last updated 2017), NICE clinical guideline 165 [CG165]

NICE quality standards

- Hepatitis B (2014), NICE quality standard 65 [QS65]
- Liver disease (2017), NICE quality standard 152 [QS152]

Other related documents

National policy documents

NHS Blood and Transplant UK national protocol for normothermic regional perfusion (NRP) in controlled Donation after Circulatory determination of Death (2025)

NHS Blood and Transplant policy on liver transplantation: selection criteria and recipient registration (2024)

NHS Blood and Transplant policy on decreased donor liver distribution and allocation (2025)

NHS Blood and Transplant policy on the registration process for liver indications requiring additional waiting time (2025)

NHS Blood and Transplant policy on living donor liver transplant (2025)

Other national guidelines

Milson C, Considine A, Cramp M et al. (2020) Adult liver transplantation: a UK clinical guideline – part 1: pre-operation. Frontline Gastroenterology 11(5): 375-384.

Milson C, Considine A, Cramp M et al. (2020) Adult liver transplantation: UK clinical guideline- part 2: summary and post-operation. Frontline Gastroenterology 11(5): 385-396.

British Transplantation Society's UK guidelines on transplantation from deceased donors after circulatory death (2023)