NICE National Institute for Health and Care Excellence

HealthTech Programme

Draft Scope Consultation Comments

HTE10066: Ex-situ machine perfusion devices for deceased donor liver transplants

Comment Number	Section no.	Comment	NICE response
Consultee 1			
1	Are the population and subgroups appropriate and described correctly?	Yes in my opinion	Thank you for your comment.
2	Are the interventions described correctly?	Yes, although I think the LiverAssist device is approved for 24 hours normothermic perfusion and 6 hours hypothermic perfusion rather than the other way around. Section 5.6- at least two published RCT's have shown benefits for the use of NMP devices from the point of donation through to transplantation. I am not sure the current focus of using devices "during transport" accurately captures this specific instance, as livers could be transported to an Assessment and Reconditioning Centre on static cold storage and then be placed on NMP for transport to an implanting centre. The second paragraph suggests that this is in scope but it not absolutely clear.	Thank-you for your comments. According to information provided by the company, the XVIVO Liver Assist is intended for hypothermic perfusion up to 24 hours and normothermic perfusion up to 6 hours. The assessment will consider the use of ex-situ machine perfusion technologies initiated on arrival at the hospital of the person having the transplant, in line with current UK practice. Where possible, the assessment will also consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood

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			and Transplant, including the use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable. This will include the NHSBT ARC pilot programme, provided there is sufficient information to support meaningful analysis. It will exclude the use of ex-situ machine perfusion technologies for transporting donor organs in any manner not trialled under the NHSBT ARC pilot programme.
3	Are there any other technologies that should be included in the assessment?	See above- use of NMP/HMP from donation to implantation, ARC utilisation and use of devices in "Back to Base" (B2B) mode should all be explored in line with the current NHSBT ARC pilot program	Thank-you for your comment. The assessment will consider the use of ex-situ machine perfusion technologies initiated on arrival at the hospital of the person having the transplant, in line with current UK practice. Where possible, the assessment will also consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood and Transplant, including the

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			use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable. This will include the NHSBT ARC pilot programme, provided there is sufficient information to support meaningful analysis. It will exclude the use of ex-situ machine perfusion technologies for transporting donor organs in any manner not trialled under the NHSBT ARC pilot programme.
4	Have the care pathway and comparator been appropriately described?	Yes see above	Thank-you for your comment.
5	Is the place of the technologies in the pathway described appropriately?	Yes see above	Thank-you for your comment.
6	Are livers typically split at paediatric liver transplant centres?	Since 2017 that is my understanding	Thank-you for your comment.
7	Are all of the outcomes suitable for inclusion in the assessment?	Yes	Thank-you for your comment.

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8	Are there any additional outcomes which should be included, particularly for children and young people?	Not my area of expertise	Thank-you for your comment.
9	Which outcomes are most relevant to children and young people?	Not my area of expertise	Thank-you for your comment.
10	Are there any other patient issues that should be considered?	Not my area of expertise	Thank-you for your comment.
11	Are there any other issues for the implementation and adoption of ex-situ machine technologies for liver transplants?	This document captures all the important issues in my opinion	Thank-you for your comment.
12	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	Not that I am aware of	Thank-you for your comment.
13	Are there any additional potential equality or discrimination issues associated with this	Not that I am aware of	Thank-you for your comment.

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	topic that need to be considered?		
Consultee 2			
14	Are the population and subgroups appropriate and described correctly?	Yes	Thank-you for your comment.
15	Are the interventions described correctly?	Yes	Thank-you for your comment.
16	Have the care pathway and comparator been appropriately described?	Broadly, although this does suggest machines used to transport livers happens more frequently than happens in practice.	Thank-you for your comment, the scope has been amended accordingly.
17	Is the place of the technologies in the pathway described appropriately?	Yes, although rarely are machines used to transport livers from the donor hospital to the recipient transplant centre.	Thank-you for your comment, the scope has been amended accordingly.
18	Are livers typically split at paediatric liver transplant centres?	n/k	-
19	Are all of the outcomes suitable for inclusion in the assessment?	n/k	-
20	Are there any additional outcomes which should be included, particularly for children and young people?	n/k	-

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21	Which outcomes are most relevant to children and young people?	n/k	-
22	Are there any other patient issues that should be considered?	n/k	-
23	Are there any other issues for the implementation and adoption of ex-situ machine technologies for liver transplants?	Please see comments in the document regarding the logistical, workforce, governance and financial impacts of using ex-situ liver perfusion machines to transport the organ from donor hospital to recipient transplant centre. Recommending use of machines in transport would also impact upon the transport contract as vehicles are not currently set up to routinely accommodate these machines - this is out of scope of the current contract, and would require re-tendering (likely to take place in 2028), limiting the ability to transport unaccompanied livers.	Thank-you for your comment. The assessment will consider the use of ex-situ machine perfusion technologies initiated on arrival at the hospital of the person having the transplant, in line with current UK practice. Where possible, the assessment will also consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood and Transplant, including the use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable. This will include the NHSBT ARC pilot programme, provided there is sufficient information to support meaningful analysis. It will exclude the use of ex-situ

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			machine perfusion technologies for transporting donor organs in any manner not trialled under the NHSBT ARC pilot programme.
24	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	n/k	-
25	Are there any additional potential equality or discrimination issues associated with this topic that need to be considered?	n/k	-
26	A donor liver for transplant is usually preserved using static cold storage. 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. This is done by a specially trained team	The maximum time a liver is in the icebox is eight hours. I'm not sure where 12 hours has come from.	Thank-you for your comment.

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	before the donor liver is transferred to the selected hospital for transplant as soon as possible, to minimise ischaemic damage to the organ. Livers are usually stored for a maximum of 8 to 12 hours in an icebox before transplantation.		
27	According to experts, this has resulted in the growing use of suboptimal organs from extended criteria donors, who are older and may have conditions that affect liver function such as hepatic steatosis; and those who donated their liver after circulatory death.	NHSBT has received substantive funding for NRP - the roll out of its use to all DCD liver retrievals will increase the utilisation and improve the quality and outcome of DCD livers.	Thank-you for your comment. This information will be considered during the assessment.
28	n 2023/24, 18.5% of livers retrieved from donors after brainstem death (DBD) and 35.5% of livers retrieved from	There has been a change in the mix of DCD and DBD donors, with DCD now representing more than 50% of donors. DCD donation is a complex, time consuming pathway, which has a resource and cost	Thank-you for your comment. This information will be considered during the assessment.

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	donors after circulatory death (DCD) were not transplanted	implication. Minimising livers that are retrieved but not transplanted would potentially improve the cost effectiveness of the donation/retrieval/transplantation pathway.	
29	Some ex-situ machine perfusion technologies can also be initiated at the donor hospital and continued during transportation of the organ to the recipient hospital.	This has happened on occasion, but very rarely. On these occasions, the transplant surgeon will join the NORS team (organ retrieval team) and collect the organ after it has been retrieved, and places the organ on the machine. It's important to note this distinction, as it is NOT a routine part of organ retrieval	Thank-you for your comment. Section 3 on current practice has been amended to clarify that ex-situ machine perfusion technologies are rarely used in the UK to perfuse donor livers during transportation to the recipient transplant centre. This information will be considered during the assessment.
30	extending how long the liver can be preserved to allow more flexibility in the timing of the transplant operation, which may allow more day-time operations, provide more time for challenging cases and help address other organ allocation, transport and in-hospital logistical	NHSBT is currently undertaking a programme of work to implement overnight retrieval of livers - this means the majority of liver transplants will take place in the day time. Changes will commence in 2026/2027	Thank-you for your comment. This information will be considered during the assessment.

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	considerations. It may also support improved staff well-being and workforce sustainability.		
31	Where possible, the assessment will also consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood and Transplant, including the use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable.	I'm not clear what these proposals are as there are currently no plans regarding using machines to transport livers from the donor hospital to the transplant centre. This presents major logistical, financial, governance and workforce challenges, so I suggest this statement is removed.	Thank-you for your comment. The assessment will consider the use of ex-situ machine perfusion technologies initiated on arrival at the hospital of the person having the transplant, in line with current UK practice. Where possible, the assessment will also consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood and Transplant, including the use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable. This will include the NHSBT ARC pilot programme, provided there is sufficient information to support meaningful analysis. It will exclude the use of ex-situ machine perfusion technologies for transporting donor organs in any manner not trialled under

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			the NHSBT ARC pilot programme.
32	Are there any gaps in the evidence base?	Please note comments below related to the proposal to evaluate use of these machines as a transport device. Transport costs and NORS workforce costs/time can be provided by NHSBT Commissioning Team if required.	Thank-you for your comment and offer to provide this information. NICE will be in contact as required.
33	ransportation of organs (including method of transport and whether ex-situ machine perfusion was used)	Cost of an individual (surgeon and/or perfusion preservation practitioner) travelling with the machine from donor hospital to transplant recipient centre. If the proposal is that the individual is a member of the NORS team undertaking the retrieval, additional costs should be considered for the impact of time of NORS team away from base, and the subsequent impact of another team having to cover for them (extended transport times). Using members of the NORS team would also have an impact on transport costs - longer retrieval times results in longer waiting times for vehicles (waiting to collect the organ) which not only has a cost impact but also an impact on driver hours and pilot hours (if a flight is to be used) Vehicles would also need to be upgraded to	Thank-you for your comment. This information will be considered during the assessment.

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		accommodate machines - would need to be costed and a new tender undertaken as this is not within scope of current transport contract.	
34	The commissioning and policy framework for liver donation and transplantation services	Commissioning donation (or retrieval) does not vary across the four nations. The variance is in transplant commissioning.	Thank-you for your comment. The scope has been amended accordingly.
Consultee 3			
35	Are the population and subgroups appropriate and described correctly?	Yes, they are. We would emphasise the importance of including patients on the liver transplant waiting list within the scope, not only those who are called in for a transplant. Machine perfusion provides an opportunity to reduce mortality among patients on the waiting list, which currently exceeds the mortality rate during the first-year post-transplant, even when cold storage is used. In addition, we would like to ensure consensus and alignment that, for the purposes of the UK liver transplant list, an “adult” is defined as an individual aged 16 years or older. It is essential to acknowledge that a considerable number of potentially transplantable donor livers offered to transplant centers are currently being declined and not retrieved, in addition to those declined after being retrieved. The use of machine perfusion technology has the capacity to reduce this rate of decline by providing more	Thank-you for your comments. As set out in the scope, the population to be assessed is people active on the UK waiting list for liver transplantation from deceased donors; outcomes will include size and duration of the liver transplant waiting list and mortality on the liver transplant waiting list. For the purposes of the UK transplant list, adult and child will be defined according to NHSBT policies. The scope has been amended to reference potentially transplantable donor livers that are declined and not retrieved.

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		reliable assessment of organ viability. Data from the NHSBT Annual Activity Report 2024/25 indicate that, of 1,453 organ donors (727 DBD and 626 DCD), only 874 livers (561 DBD and 313 DCD) were transplanted, resulting in 579 livers remaining unused. A substantial proportion of these organs, including many that are not presently retrieved, could potentially have been transplanted to save lives if machine perfusion were more comprehensively implemented and adequately funded.	
36	Are the interventions described correctly?	The descriptions are comprehensive but not completely accurate. The description states that the machines “remove waste products”. This is not strictly true. In fact, the process of circulating perfusate clears the high concentration of waste products that have accumulated during initial organ procurement and then flushes away any new waste products. These waste products get diluted in the total volume of the perfusate. In time they accumulate, but seldom to toxic levels if preservation is under 24 hours. The metra was engineered specifically for extended ex-situ liver preservation (up to 24 hours) and is not adapted from cardiac or general perfusion systems, which require an open perfusion circuit and are designed for short term perfusions (<6hours) during surgeries like	The scope has been amended to state that the circulating perfusion solution clears waste products and prevents their accumulation.

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		cardiopulmonary bypass. The OrganOx metra is the only fully closed perfusion system for ex-situ liver preservation on the market. Closed perfusion circuits minimise the risk of contamination from the external environment and subsequent infection risk as well as contributing to maintaining a sterile environment. They also reduce perfusate loss from the circulation and support consistent metabolic stability. Closed perfusion circuits mimic in vivo perfusion which promote a less inflammatory environment due to reduced blood-air interface, reduced tubing length and reduced surface area of the entire circuit. Closed perfusion circuits also need less priming volume which may contribute to conserving finite resources such as donated RBCs. The OrganOx metra is the only fully automated perfusion device available for ex-situ liver preservation. It autonomously regulates critical parameters, including pressure, gas exchange, temperature, and the delivery of nutrients and medications. By minimizing the need for user intervention, the system reduces the likelihood of human error and enhances the reliability of organ preservation. Furthermore, the metra is one of only two devices with data from randomized controlled trials	

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		(RCTs) in normothermic machine perfusion (NMP).	
37	Are there any other technologies that should be included in the assessment?	Not that we are aware of	Thank-you for your comment.
38	Have the care pathway and comparator been appropriately described?	We reiterate the substantial potential of machine perfusion to influence outcomes related to the liver transplant waiting list. Accordingly, we recommend expanding the assessment of the care pathway to explicitly include this domain. The comparator, static cold storage, is appropriately described.	Thank-you for your comment. As set out in the scope, the population to be assessed is people active on the UK waiting list for liver transplantation from deceased donors; outcomes will include size and duration of the liver transplant waiting list and mortality on the liver transplant waiting list. The assessment will consider the use of ex-situ machine perfusion technologies initiated on arrival at the hospital of the person having the transplant. Where possible, the assessment will also consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood and Transplant, including the use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable.

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39	Is the place of the technologies in the pathway described appropriately?	Yes, they are. An additional consideration is an approach that has not yet been explored in the United Kingdom, but is increasingly adopted in the United States, involves perfusing an organ, assessing its suitability for transplantation, and only then calling in a recipient. This strategy has the potential to reduce the logistical and financial burden of last-minute cancellations. It may be particularly relevant in the context of donation after circulatory death (DCD), where a potential donor may not progress to actual donation. In such cases, the recipient may already have been admitted, allocated a bed, and undergone blood tests and imaging, only to be stood down several hours later. The ability of current normothermic machine perfusion (NMP) devices to preserve livers safely for up to 24 hours creates the opportunity to implement this practice.	Thank-you for your comment.
40	Are all of the outcomes suitable for inclusion in the assessment?	Yes. Note that for hepatic artery thrombosis, if it occurs within 21 days of transplantation the recipient may be listed for a super urgent retransplant; beyond 21 days they must join the elective waiting list. It may assist modelling to use the 21 day time point.	Thank-you for your comment. This information will be considered during the assessment.
41	Are there any additional outcomes which should be included, particularly	In addition to clinical outcomes, several economic and operational outcomes should be considered. First, the costs associated with night-time operating should be evaluated. Procedures	Thank-you for your comment. The scope has been updated accordingly.

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	for children and young people?	performed overnight often require the mobilisation of additional theatre staff, anaesthetists, surgeons, and laboratory personnel, including haematology, biochemistry, and blood transfusion support. These factors contribute to increased expenditure compared with daytime operating and also have implications for staff wellbeing and service sustainability. Second, the potential cost savings associated with reducing the need for air transport of donor livers should be considered. At present, NHSBT spends approximately £3 million annually on transporting livers by air. Advances in organ preservation, including extended preservation times, could enable more organs to be transported by road, thereby reducing reliance on air travel and delivering significant cost efficiencies.	
42	Are there any other patient issues that should be considered?	Two additional patient-related issues warrant consideration. First, the timing of transplantation is of significant importance. The capacity to admit patients in a more planned and less urgent manner, with greater certainty that the transplant will proceed, may reduce psychological stress and improve overall patient experience. In contrast, the current practice often requires patients to present to hospital at very short notice, only for the procedure to be cancelled, which can be both	Thank-you for your comment. The scope has been updated accordingly.

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		distressing and disruptive. Second, in the context of donation after circulatory death (DCD), the need for recipients to be admitted in advance while awaiting confirmation of donor death represents an additional burden. This practice not only contributes to patient anxiety and uncertainty but also increases unnecessary hospital admissions. Advances in organ preservation technologies may mitigate these issues by allowing more predictable scheduling of transplantation procedures.	
43	Are there any other issues for the implementation and adoption of ex-situ machine technologies for liver transplants?	Two key considerations for the implementation and adoption of ex-situ machine perfusion technologies in liver transplantation are workforce requirements and infrastructure needs. Workforce requirements: The level of expertise required to operate perfusion devices varies according to the degree of automation. Fully automated systems require minimal specialist input and supervision, whereas less automated devices necessitate a higher level of expert oversight. This has implications for training, staffing models, and the integration of perfusion specialists within transplant teams. Infrastructure requirements: The facilities needed to accommodate these technologies also differ between devices. Some systems must remain	Thank-you for your comment. This information will be considered during the assessment.

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		within a sterile operating theatre environment throughout perfusion, potentially limiting theatre availability. Others require initial setup in sterile conditions but can subsequently be transferred to non-sterile areas, such as adjacent corridors, thereby optimising operating theatre utilisation.	
44	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	No	Thank-you for your comment.
45	Are there any additional potential equality or discrimination issues associated with this topic that need to be considered?	Variation in the willingness of individual hospital trusts to invest in the infrastructure required to support machine perfusion, such as employing perfusion specialists, has contributed to a postcode-based disparity in liver transplantation services. This variation has led to differing levels of uptake of modern technologies across centres, which is reflected in the substantial differences in median waiting times reported between transplant units. According to the 2025 Annual Liver Report, three centres report median waiting times of less than 80 days, whereas two centres report median waiting times exceeding 200 days. Although the national offering scheme allocates organs to patients irrespective of their location, these discrepancies are largely attributable to differences in the willingness of transplant units to accept offered livers. Centres that have	Thank-you for your comment.

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		implemented modern technologies, including normothermic machine perfusion (NMP), have the potential to evaluate and accept more offers, whereas centres with less investment in these technologies demonstrate lower uptake. Approval by NICE is likely to standardise practice, reduce inter-centre disparities, and create a more equitable allocation landscape.	
Consultee 4			
46	Are there any other technologies that should be included in the assessment?	The current draft scope consultation addresses a critical issue in public health; the need to maximize our ability to provide liver transplantation as a therapy for our population, with equitable distribution, implementing it in a cost-effective manner for the healthcare system. However, we submit that the current scope does not fully capture the breadth of available technologies or the rapidly evolving landscape of liver transplantation practices. In particular, we submit that the Paragonix LIVERguard System should be considered as an additional technology both as an independent solution and in combination with the other machine perfusion technologies. LIVERguard is an advanced static hypothermic preservation system, not a perfusion device. It complements the technologies already in scope, and can be used either on its own or alongside machine perfusion (“back-to-base” model). In multi-centre clinical studies, the LIVERguard system has demonstrated improved clinical	Thank you for your comment. The scope of this assessment is for ex-situ machine perfusion devices. Whilst LiverGuard is a preservation device in this clinical pathway, it is not an ex-situ machine perfusion device and is therefore not considered in scope for this assessment.

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		outcomes, increased acceptable preservation times to support geographic expansion and transplant logistics, and dramatic cost-effectiveness through alternative transport methods. Recently presented at the 2025 World Transplant Congress (WTC), data from the GUARDIAN registry of over 900 subjects show that LIVERguard significantly reduced early allograft dysfunction and acute kidney injury, even in higher-risk livers, while safely extending cold ischemia times. Any near-term guidance document should accommodate the evolving scientific and clinical knowledge being developed on liver preservation. LIVERguard technology aligns with NICE policy goals and NHSBT's strategies surrounding innovation, transport, and equitable access, supporting longer-distance matching and safer preservation across the UK. LIVERguard provides a scalable preservation option for centres without access to perfusion machines, which improves fairness across the system. Paragonix LIVERguard®: Summary for consideration The LIVERguard® system is purpose-built for static hypothermic preservation of donor livers from deceased donors, making it highly relevant for patients on transplant waiting lists. Validated for up to 15 hours of preservation, it enables safe transport across long distances—critical for national organ matching schemes like the UK's	

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		National Liver Offering Scheme (NLOS). Irreversible Damage of Ice Storage Current methods of static hypothermic storage involve burying livers in ice within consumer coolers, exposing hepatic tissue to irreversible cold injury. With this method, donor livers rapidly cool to below 1°C within an hour of preservation, causing irreversible cellular injury including mitochondrial dysfunction and impaired metabolic recovery. In recent years this cellular injury associated with ice storage has been documented across organs using proteomic, metabolomic and clinical outcomes including heart , , lung , kidney and liver . In these studies, they demonstrate that controlled hypothermia using systems like the LIVERguard system avoid cold injury and result in improved outcomes. Even in combination with machine perfusion, these improvements are appreciable and lasting. At the 2025 World Transplant Congress, Dhanireddy et al. presented the effects in liver, concluding "... the injury caused by ice cannot be undone by perfusion." Limitations of Perfusion Systems Machine Perfusion (MP) systems simulate physiological replacement of tissue oxygen delivery and are typically used for preservation of extended criteria donors (ECDs) and donors after cardiac death (DCDs). However, they are complex, costly, and logistically demanding. Due to this most countries have adopted "back-to-	

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		base" strategies where livers are transported in static cold storage back to the recipient centre prior to MP. Unfortunately, this results in very limited transport times due to the risk of cold injury, usually limiting cold ischemia time (CIT) to less than 6 hours. LIVERguard® offers a scalable, cost-effective alternative to ice static cold storage that can be used in combination with “back-to-base" perfusion technologies that are currently in the scope. Furthermore, this allows maximization of the effect of “back-to-base" technologies but also enables more equitable access to improved preservation for centres without access to perfusion technology. Clinical Validation & Performance Recent clinical data from the GUARDIAN-Liver Registry (NCT05082077) presented at the World Transplant Congress in San Francisco by Dhanireddy et al. highlights the evolving clinical impact of controlled hypothermic preservation in liver transplantation. In a population of 898 subjects, investigators found that compared to ice, donor livers preserved in the LIVERguard system represented a higher risk cohort; • Higher proportion of DCD donors (26.3% vs 8.8%, p<0.001) • Longer recovery distances (668 vs 368 km, p<0.001) • Longer cold ischemic times (6.9 vs 5.6 hours, p<0.001) Despite these risk factors, subjects in the	

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		LIVERguard cohort observed less acute kidney injury (AKI) (p=0.019) and less early allograft dysfunction (EAD) (p=0.032). In a subsequent propensity matched analysis of 410 subjects (205 pairs), LIVERguard significantly reduced the incidence of EAD by 51% (p<0.001). On the same propensity matched cohort, a logistic regression model demonstrated that the predicted probability of early allograft dysfunction was attenuated across all cold ischemic times with controlled hypothermic preservation with the LIVERguard System compared to ice (p<0.001). These findings demonstrate that by avoiding ice injury, significantly longer ischemic times are possible without increased risk of complications. Additionally, Dhanireddy et al. presented their single centre experience of 259 liver transplants with LIVERguard preservation in combination with a “back-to-base" NMP model. Compared to traditional ice storage combined with NMP, investigators found LIVERguard with NMP resulted in: • A 122% increase in organ recovery distances (p<0.001) • A 32% increase in CIT (5.7 vs 7.5 hours; p<0.001) Despite significantly longer recovery distances and CITs, a 32% reduction in EAD was observed in favour of LIVERguard preservation over ice static cold storage (p<0.001). The attenuation of EAD risk was independent of donor type, cold	

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		ischemic time and time on NMP. Further numeric (non-significant) reductions in AKI, ICU LOS, and haemodialysis post-transplant were also observed. Alternative Transport, Time-Shifting and Cost-effectiveness Due to the compact, simple to use design, LIVERguard has enabled dramatic cost savings for transplant programs. Subramanian et al. presented how their centre has shifted historic high cost means of transport – private jets and ambulances, to low-cost transport – non-ambulance ground transport for donor livers within 250NM of the transplant centre with the programmatic implementation of LIVERguard preservation. Furthermore, they have become so comfortable with transport times, they have even recovered livers from California and transported them to Florida, using commercial airlines and placing the LIVERguard in economy class seats. They estimate this model of shifting short, chartered flights to ground transportation within 250NM this will save their centre $1.5 million USD in a single year in transportation costs alone, while also improving post-transplant outcomes through advanced preservation. Finally, not every liver requires ex-vivo machine perfusion. Using cost-effective preservation strategies can expand the reach for DCD-NRP procedures and standard DBD donors without the need for expensive ex-vivo technologies and	

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		specialised staffing. Policy Alignment & Global Impact In the UK, where CIT is a key determinant of transplant success, LIVERguard preservation supports: • Expansion of geographic matching • Reduced risk of freezing injury • Real-time monitoring of temperature and location including serialized records With EU MDR approval, it meets Europe's highest regulatory standards and aligns with NHS Blood and Transplant's goals for safety and innovation. Despite the irreplaceable scarcity of liver donation, Potanos et al. first noted in 2013 how government regulations for temperature monitoring and record keeping devices are more advanced in the food industry than what we mandate in the critical field of organ transplantation, "The technique of ice and slush in a cooler is primitive when compared with the refrigerated trucks of the food transportation industry, in which freight routinely undergoes continuous temperature monitoring during shipment." Conclusion LIVERguard® offers a cost-effective, complementary approach, which bridges the gap between traditional ice storage and high-cost ex-vivo perfusion systems. It improves access and enhances outcomes—particularly for deceased	

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		donor transplants, long-distance organ transport, and centres without perfusion infrastructure. With adoption across dozens of transplant centres and validation in over 900 real-world patient cases, LIVERguard® is a scalable and clinically impactful innovation that aligns with NHS priorities. Strategic integration alongside perfusion systems could enhance national transplant outcomes, demonstrate cost-effectiveness, and reduce disparities in organ availability, positioning it as a powerful technology for consideration within the UK's liver transplant framework. References: i. Villa et al., Real-time direct measurement of human liver allograft temperature from recovery to transplantation. Transplantation 2006 ii. Razavi et al., Evaluating the mechanism of action behind controlled hypothermic preservation of donor hearts: A randomized pilot study, Journal of Heart and Lung Transplantation 2025 iii.Sharma et al., Metabolic and transcriptomic insights into temperature controlled hypothermic preservation of human donor hearts. Journal of Heart and Lung Transplantation 2025 iv. Provoost et al., Lung transplantation following controlled hypothermic storage with a portable lung preservation device: first multicentre European experience. Journal of Heart and Lung Transplantation 2024	

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		v. Tingle et al., Normothermic and hypothermic machine perfusion preservation versus static cold storage for deceased donor kidney transplantation. Cochrane Database of Systematic Reviews 2024 vi. Dhanireddy et al. Largest Real-World Multi-Centre Study Outcomes Reported with Controlled Moderate Hypothermic Preservation of Donor Livers. Presented at WTC 2025	
Consultee 5			
47	Are the population and subgroups appropriate and described correctly?	Yes	Thank-you for your comment.
48	Are the interventions described correctly?	Yes, although there could be a mention of sequential and controlled oxygenated rewarming. HOPE can be followed by NMP (including using a period of controlled oxygenated rewarming between the two), to get the reconditioning benefits of HOPE, followed by the viability assessment benefits of NMP. This technique is used in the Netherlands to maximise the recipient outcomes, and utilisation, of highest risk livers.	Thank-you for your comment.
49	Are there any other technologies that should be included in the assessment?	No	Thank-you for your comment.
50	Have the care pathway and	Yes	Thank-you for your comment.

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	comparator been appropriately described?		
51	Is the place of the technologies in the pathway described appropriately?	Yes, although perhaps a clearer distinction should be drawn between the two key potential benefits of improving liver quality and allowing viability assessment. Improving the quality of livers (and therefore improving outcomes), without viability assessment has three advantages for patients waiting for a liver; 1) post-transplant outcome is improved for that patient, 2) reduction in re-transplant means that people are not returning to the waitlist which reduces demand and improves waitlist times, 3) a potentially larger number of livers can be used, as poorer quality grafts are reconditioned, rather than discarded following viability assessment. For livers where it is too high-risk to transplant them without viability assessment, clearly NMP can allow the use of livers that would otherise have been transplanted. Extending preservation is another benefit which is appropriately discussed seperately, and there is increasing evidence for HOPE to prolong preservation and allow daytime operating.	Thank-you for your comment.
52	Are livers typically split at paediatric liver transplant centres?	Yes, or in donor hospitals by retreival teams from paeds centres.	Thank-you for your comment.

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53	Are all of the outcomes suitable for inclusion in the assessment?	The most important measure is all cause mortality for those patients on the waiting list. i.e. does having access to ex situ machine perfusion improve all cause mortality for those waiting for a transplant. This reflects both the ability of ex situ machine perfusion to improve utilisation (with impacts on waitlist mortality), as well as to recondition livers to improve post-transplant outcomes (impacts post-transpant mortality). Whilst this is the most important outcome, evidence for this is lacking (and very difficult to perform/power trials to assess this outcome directly). Transaminase release in the first week post-transplant has significant limitations in the setting of machine perfusion (especially normothermic machine perfusion), as much transaminase is released into the perfusate during NMP, which is then discarded. Recipient transaminases in machine perfused versus SCS livers is therefore not a good measure of damage or function. The same applies for measures of early allograft dysfunction which include transaminase levels in their definitions.	Thank-you for your comment.
54	Are there any additional outcomes which should be included, particularly	No	Thank-you for your comment.

Comment Number	Section no.	Comment	NICE response
	for children and young people?		
55	Which outcomes are most relevant to children and young people?	All cause, long-term, mortality in those on the transplant waiting list.	Thank-you for your comment.
56	Are there any other patient issues that should be considered?	Urgency of transplant is key, regarding level of risk you are willing to accept.	Thank-you for your comments, the scope has been amended accordingly.
57	Are there any other issues for the implementation and adoption of ex-situ machine technologies for liver transplants?	Utilisation and post-transplant outcomes must be considered together, with specific consideration to the cohorts examined. Applying viability assessment in a cohort that would otherwise have been discarded can only increase utilisation. However, applying viability assessment in a cohort that would otherwise have been transplanted can only decrease utilisation; blanket application of a single technique is probably not the correct answer. Given the option to improve recipient outcomes by reconditioning marginal grafts, versus discarding livers that would not function well, the former is preferable. There should also be emphasis on combination of techniques, and the fact that one size does not fit all. For example, marginal but transplantable grafts are probably best served by a technique	Thank-you for your comment. This information will be considered during the assessment.

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		which reconditions them (as reflected by improved post-transplant outcomes). Very high-risk grafts need the most robust viability criteria available. Combining HOPE with NMP (for example using the HOPE-COR-NMP protocol) can allow the reconditioning benefits of HOPE, along with the viability assessment of NMP.	
58	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	No	Thank-you for your comment.
59	Are there any additional potential equality or discrimination issues associated with this topic that need to be considered?	No	Thank-you for your comment.
Consultee 6			
60	Are the population and subgroups appropriate and described correctly?	Update requested, see section 9, Table 2.	Thank-you for your comment. See below for responses to individual comments.
61	Are the interventions described correctly?	Yes; however, please consider including 'small adults' when discussing split-liver transplantation.	Thank-you for your comment. The scope has been amended accordingly.
62	Are there any other technologies that	No	Thank-you for your comment.

Comment Number	Section no.	Comment	NICE response
	should be included in the assessment?		
63	Have the care pathway and comparator been appropriately described?	Yes (to the best of our knowledge)	Thank-you for your comment.
64	Is the place of the technologies in the pathway described appropriately?	Update requested, see section 5.6	Thank you for your comment. See below for responses to individual comments.
65	Are livers typically split at paediatric liver transplant centres?	Yes (to the best of our knowledge)	Thank-you for your comment.
66	Are all of the outcomes suitable for inclusion in the assessment?	Updates requested, see section 9, Table 2.	Thank-you for your comment. See below for responses to individual comments.
67	Are there any additional outcomes which should be included, particularly for children and young people?	Yes, biopsy proven acute rejection and post-reperfusion syndrome (see section 9, Table 2 for details.	Thank-you for your comment See below for responses to individual comments.
68	Which outcomes are most relevant to children and young people?	Not known.	Thank you for your comment.
69	Are there any other patient issues that	No known	Thank you for your comment.

Comment Number	Section no.	Comment	NICE response
	should be considered?		
70	Are there any other issues for the implementation and adoption of ex-situ machine technologies for liver transplants?	No	Thank-you for your comment.
71	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	Not to our knowledge.	Thank-you for your comment.
72	Are there any additional potential equality or discrimination issues associated with this topic that need to be considered?	Not to our knowledge	Thank-you for your comment.
73	'for the preservation and functional assessment of livers'	Please update to: /.../ for the preservation, reconditioning, and/or functional assessment of liver /.../ Rephrasing this section captures that (D)HOPE and NMP serve different purposes and that functional assessment is not a prerequisite for machine perfusion.	Thank-you for your comment.

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		In fact, abundant clinical data has shown that 1-2 h of end-ischemic (D)HOPE is sufficient to recondition / improve the quality of higher risk / marginal grafts (i.e., DCD, ECD) which translates into better outcomes for Tx recipients. By improving preservation, donor organs can be successfully transplanted without the need for viability assessment. Also, combining these complementary techniques allows sequential graft reconditioning and viability assessment [Ref: van Leeuwen et al 2025 doi:10.1038/s41596-024-01130-8]	
74	including the use of ex-situ machine perfusion technologies during transportation of donor organs,	Note that there is currently no evidence indicating that continuous machine perfusion (during transport from donor to recipient hospital) provides any added clinical benefits compared to end-ischemic machine perfusion [e.g., Nasralla et al 2018 (doi: 10.1038/s41586-018-0047-9); Chapman et al 2023 (doi: 10.1097/SLA.0000000000005934)]	Thank-you for your comment.
75	What evidence is available to support the value proposition of ex-situ machine perfusion devices outlined in the scope, i.e.:increasing the number of livers suitable for	Please consider changing the order of the bullets below to reflect the order of prioritization where 'improving clinical outcomes of transplant recipients' should be listed first as it is a prerequisite to achieve the other bullets. i.e.: - improving the clinical outcomes of transplant recipients - increasing the number of livers suitable for	Thank-you for your comment. We have considered this and reordered key value propositions of the technologies to reflect the system need reported to us in expert conversations.

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	transplant?extending preservation time to allow more flexibility in the timing of the transplant operation?improving the clinical outcomes of transplant recipients?	transplant - extending preservation time to allow more flexibility in the timing of the transplant operation.	
76	(particularly with steatotic livers)	Consider removing 'particularly with steatotic livers' as this is only one of many criteria for and ECD. Also, since there is no universal definition of what qualifies as an ECD graft, pooling of data should be done with caution.	Thank you for your comment. This information will be considered during the assessment.
77	use of NRP of livers donated after circulatory death will also be considered.	As the scope of this HTE is 'Ex-situ machine perfusion devices for deceased donor liver transplants' - please clarify that the use of (in-situ) NRP is considered when used in combination with ex-situ machine perfusion protocols. There is compelling evidence in favor of combining NRP and ex-situ MP [e.g., Ghinolfi et al 2021 (doi: 10.1002/LT.25899); Patrono et al 2022 (doi:10.3389/ti.2022.10390); Maroni et al 2021 (doi:10.1111/ctr.14448)]	Thank-you for your comment. NRP is not being considered as a direct comparator to ex-situ machine perfusion in this assessment, but its use earlier in the pathway in a complementary way may be considered.
78	Logistical considerations for adults. These might include complex multi-organ transplants, challenging explant	Please consider updating the description of this sub-group for clarity: Logistical considerations for adults where cold ischemia times are predicted to be extended beyond acceptable limits unless machine perfusion is used. These might include: complex	Thank-you for your comment. The scope has been amended accordingly.

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	surgery, split livers (i.e., transport of right lobe for adult recipient) or other cases where it may be predicted that transport, allocation or in-hospital logistics would lead to cold ischaemia times too long to proceed with transplantation without the use of ex-situ machine perfusion.	multi-organ transplants, challenging hepatectomies, liver splitting (during machine perfusion), and prolonged preservation to and prolonged preservation to allow time for allocation and in-hospital logistics such as enabling day time surgery.	
79	use of NRP of livers donated after circulatory death will also be considered.	In line with the comment above, please clarify that the use of (in-situ) NRP is considered when used in combination with ex-situ machine perfusion protocols.	Thank-you for your comment. NRP is not being considered as a direct comparator to ex-situ machine perfusion in this assessment, but its use earlier in the pathway in a complementary way may be considered.
80	Logistical considerations for CYP recipients. These might include complex multi-organ transplants, challenging explant surgery or other	In line with comment above, please consider updating the description of this sub-group for clarity: Logistical considerations for CYP recipients where cold ischemia times are predicted to be extended beyond acceptable limits unless machine perfusion is used. These might include:	Thank-you for your comment. The scope has been amended accordingly.

Comment Number	Section no.	Comment	NICE response
	cases where it may be predicted that transport, allocation or in-hospital logistics would lead to cold ischaemia times too long to proceed with transplantation without the use of ex-situ machine perfusion	complex multi-organ transplants, challenging hepatectomies, liver splitting (during machine perfusion), and prolonged preservation to and prolonged preservation to allow time for allocation and in-hospital logistics such as enabling day time surgery.	
81	including the use of ex-situ machine perfusion technologies during transportation of donor organs, as applicable.	Note, as per previous comment, there is currently no evidence indicating that continuous machine perfusion (during transport from donor to recipient hospital) provides any added clinical benefits compared to end-ischemic machine perfusion [e.g., Nasralla et al 2018 (doi: 10.1038/s41586-018-0047-9); Chapman et al 2023 (doi: 10.1097/SLA.0000000000005934)]	Thank-you for your comment.
82	Clinical outcomes:	In addition to the recommendations below, please consider including the following clinical outcomes: - Biopsy-proven acute rejection. Acute rejection is a common complication of liver transplantation affecting ~20-30% of transplant recipients. Acute rejection is associated with significantly reduced graft and patient survival. - Post reperfusion syndrome (PRS). PRS affects up to ~50% of liver transplant recipients and involves a reduction in systemic vascular	Thank you for your comment. The scope has been amended to include post-reperfusion syndrome. Given the number of outcomes already included in the assessment, biopsy-proven acute rejection has not been prioritised for inclusion

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		resistance with hypotension and lowered cardiac output. PRS can impact short and long-term graft and patient outcomes.	
83	Transplant utilisation (proportion of donor organs that proceeded to transplant rather than being discarded)Size and duration of liver transplant waiting list Mortality on liver transplant waiting list	Please consider placing these outcomes under a separate heading (e.g., Waitlist outcomes and utilization) as all other clinical outcomes listed are related to post-Tx outcomes in recipients. Also, as per Tingle et al 2023 (doi:10.1002/14651858.CD014685.pub2.), graft utilization should be considered in the context of post-Tx outcomes, and not considered in isolation. Increasing graft utilization is only beneficial if recipient outcomes are improved, or at least maintained.	Thank-you for your comment. The scope has been amended accordingly.
86	Early allograft function, measured with a validated model (7 days) (e.g., Early Allograft Dysfunction or Model for Early Allograft Function criteria)Transaminase release during the first week post-transplant (participant serum) (until 7 days)	In accordance with Tingle et al 2023, we suggest that surrogate endpoints such as EAD and serum ALT/AST post-Tx should be interpreted with caution, and not on its own, as these laboratory values are of questionable clinical relevance in machine perfusion studies due to the 'wash-out effect'. Note. while often used as an endpoint in clinical studies, EAD as defined by Olthoff (2010) was validated in a pre-machine pefusion for its strong correlation with 1 year graft survival. This is, however not be applicable when using machine perfusion, repeatedly demonstrated in studies on machine perfusion [Ref: Nasralla et al 2018 (doi: 10.1038/s41586-018-0047-9); Tingle et al 2023 (doi:10.1002/14651858.CD014685.pub2)]	Thank-you for your comment.

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87	Post-operative requirement for renal replacement therapy (total and if data permits separately for dialysis and kidney transplantation)	Please also include 'duration of dialysis' (days) as this has a large impact on the cost of managing post transplant outcomes.	Thank-you for your comment. The scope has been amended accordingly.
88	Graft survival at 1 year and maximum follow-up	Does this refers to 'Overall Graft survival' (i.e., lack of re-Tx and patient death)? Please specify. Also, please include 'Death-censored Graft Survival' as an outcome measure (i.e., graft survival censored for patients dying with a functioning graft) as this is a commonly reported outcome measure which more accurately describes the fate of the graft as it does not include deaths due to unrelated causes. This allows clinicians to assess the true long-term performance and resilience of the transplanted organ itself and helps distinguish between graft loss due to the organ's failure and graft loss that is a consequence of the patient's death from other causes.	Thank-you for your comment, this information will be considered during the assessment.
89	Biliary complications at 1 year and maximum follow-up (total and if data permits separately for biliary leakage, anastomotic biliary strictures and non-	1) When it comes to biliary complications it is crucial to distinguish between 'surgery-related biliary complications' (e.g., anastomotic biliary strictures)and 'ischemia-related biliary complications' (e.g. non-anastomotic biliary strictures) as only the latter are related to graft preservation. - Please ensure that these outcomes are reported	Thank-you for your comments. 1) This information will be considering during the assessment. 2) This information will be considering during the assessment.

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	anastomotic biliary strictures)	separately. 2) As livers donated after circulatory death (DCD) are significantly more prone to non-anastomotic biliary strictures (NAS), data should be assessed based on donor type (i.e. DCD vs DBD) - Please update accordingly. 3) As a vast majority (~85%) of 'ischemia-related biliary complications' occur within the first 6 months post-Tx and many publications have limited this assessment to 6-months, please change assessment to 6-months and maximum follow-up [Ref: Foley et al 2011 (doi:10.1097/SLA.0b013e3182104784); Tingle et al 2023 (doi:10.1002/14651858.CD014685.pub2).].	3) The scope has been amended accordingly.
90	Hepatic artery thrombosis within 28 days (total and if data permits separately for hepatic artery thrombosis leading to recipient death and emergency retransplant)	Suggest including portal vein thrombosis (PVT) as well as HAT as both can lead to graft failure, but PVT is associated with a higher risk of post-Tx mortality.	Thank-you for your comment. Given the number of outcomes already included in the assessment, PVT has not been prioritised for inclusion.
91	Acute kidney injury post transplantation (defined as stage 2 or 3 on the Acute	1) Suggest including the RIFLE criteria as well. as this criteria is commonly reported in the litertature. 2) Please specify time-frame for the assessment	Thank-you for your comment. Clarification has been added on the use of alternative validated classification systems. No additional detail on the time-

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	Kidney Injury Network classification system)	e.g., 24h post-Tx [Ref: Jochmans et al 2018 (doi:10.1097/SLA.0000000000002593)]	frame has been specified in the scope, but will be considered as part of the assessment.
92	Mechanical failure of machine perfusion technology	Suggest specifying if a mechanical failure has led to the loss of an organ (organ discard), or change i preservation method (e.g., organ to SCS).	Thank-you for your comment. The scope has been amended accordingly.
93	Serious adverse events (e.g., Clavien-Dindo classification, grade III or higher), including bowel perforation, post-transplant lymphoproliferative disorder, bleeding and infections (both donor-related and surgical infections)	Please be cautious when assessing data on adverse events from different study set-ups as adverse events are not uniformly reported. Retrospective trials rarely report adverse events to the same extent, while prospective trials are often more focused on this, leading to a reporting bias that could lead to unjust and skewed comparisons between data sets depending on the evidence level included. I.e. a technology supported with mainly retrospective evidence may seem to have fewer complications reported than a technology with a prospective evidence base.	Thank-you for your comment.
94	hospital length of stay (including ICU)	Suggest assessing ICU separately considering the much higher financial burden.	Thank-you for your comment. The scope has been amended accordingly.
Consultee 7			
95	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	NICE should emphasise the importance of national consistency so that all seven UK transplant centres have access to the same machine perfusion technology. This would ensure patients are not disadvantaged depending on where they are listed, removing the current 'postcode lottery' and promoting equal access to donated livers. The technology should be	Thank-you for your comment. The scope has been amended accordingly.

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		available for all transplants in the UK, regardless of transplant centre, region, or donor location.	
Consultee 8			
96		the key patient benefits are: (i) safety: the ability to test organs before subjecting a patient to the risks of a transplant; (ii) shorter waiting list time: pre-transplant organ assessment results in increased utilisation of higher-risk organs; (iii) improved organ preservation: longer safe organ preservation times increase the time available to admit patients and also enable this complex surgery to be conducted during the day	Thank-you for your comments.
97		Is NICE only considering NRP as a subgroup? This could be as a significant loss to the overall process (ie. We are only considering 'back to base' technologies).	Thank-you for your comment. We can confirm that NRP is not being considered as a direct comparator to ex-situ machine perfusion in this assessment. But the use of NRP earlier in the pathway (before the use of SCS or ex-situ machine perfusion devices) may be considered, where possible.
98		Is it possible to future proof findings by also considering how these technologies can play out in an Assessment and recovery setting, where they are likely to play a major role. It's our understanding that these are being established at the moment. Speak to NHSBT and See this report https://nhsbtdbe.blob.core.windows.net/umbraco-	Thank-you for your comment. Where possible, the assessment will consider potential changes to the national liver transplantation pathway, in line with proposals by NHS Blood and Transplant, including the use of ex-situ machine perfusion technologies during

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		assets-corp/36116/isou-assessment-and-recovery-centre-arc-subgroup.pdf	transportation of donor organs, as applicable. This will include the NHSBT ARC pilot programme, provided there is sufficient information to support meaningful analysis.
99		In outcomes we should also consider ICU length of stay and overall length of stay.	Thank-you for your comment. Hospital length of stay (including ICU) will be considered as part of the assessment.
100		Why do you believe that the OrganOx metra device is not suitable for patients with acute/fulminant liver failure (page 7)?	Thank-you for your comment. This information came from information provided by the company on the use of the metra device.
Consultee 9			
101	Are the population and subgroups appropriate and described correctly?	Yes	Thank-you for your comment.
102	Are the interventions described correctly?	Yes	Thank-you for your comment.
103	Are there any other technologies that should be included in the assessment?	No	Thank-you for your comment.
104	Have the care pathway and comparator been appropriately described?	Yes	Thank-you for your comment.

Comment Number	Section no.	Comment	NICE response
105	Is the place of the technologies in the pathway described appropriately?	Yes	Thank-you for your comment.
106	Are livers typically split at paediatric liver transplant centres?	Yes always.	Thank-you for your comment.
107	Are all of the outcomes suitable for inclusion in the assessment?	Yes	Thank-you for your comment.
108	Are there any additional outcomes which should be included, particularly for children and young people?	No	Thank-you for your comment.
109	Which outcomes are most relevant to children and young people?	Graft survival	Thank-you for your comment.
110	Are there any other patient issues that should be considered?	No	Thank-you for your comment.
111	Are there any other issues for the implementation and adoption of ex-situ	National strategy to improve equity	Thank-you for your comment.

Comment Number	Section no.	Comment	NICE response
	machine technologies for liver transplants?		
112	Are there any changes that need to be made to the scope to eliminate unlawful discrimination and promote equality?	See above.	Thank-you for your comment.
113	Are there any additional potential equality or discrimination issues associated with this topic that need to be considered?	No	Thank-you for your comment.