National Institute for Health and Care Excellence

IP1289 – Normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death
Consultation Comments table
IPAC date: Friday 18th December 2015

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 on behalf of the Directorate of Organ Donation and Transplant NHS Blood and Transplant	**1**	We welcome the review by NICE and broadly agree with the conclusions. The heart transplant rates in the UK are low and we would be keen to support any development that increases the number and safety of heart transplantation in the UK. Assessment of donor hearts is complex and there is little room for error in the balance of risks. Machine perfusion would allow for a more functional assessment of cardiac function and its suitability for use as well as making a 'marginal' heart but suitable for clinical use. We would welcome a comment that NICE recognises the need for more service evaluation of this approach so the role, effectiveness and costs of normothermic extracorporeal preservation can be fully evaluated.	Thank you for your comments. Consultee agrees with the IP recommendations. Cost-effectiveness is not part of the remit of the IP Programme.

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2	Consultee 2 TransMedics, Inc		1. Introduction Heart transplantation is the therapy of choice for select patients with end-stage heart disease (Hunt, 2006 [7]; Hunt and Haddad 2008 [8]; and Lund et al., 2014 [14]). Despite significant progress in most aspects of heart transplantation (i.e., donor management, operative technique, post-operative care and immunosuppressive regimens), the technique for donor heart preservation has remained cold ischemic storage for over 30 years. Cold storage subjects the donor heart to time-dependent ischemic and subsequent reperfusion injuries that have the potential to impair heart function post-transplantation (Parolari, et al., 2002 [17]). Prolonged ischemia time has been shown to be an important risk factor for early donor heart dysfunction and recipient death (Banner et al., 2008 [2]; and Russo et al., 2010 [14]). Limitations of cold storage time also adversely affect donor heart utilization and possible organ sharing (Russo et al., 2007 [15]; Krakauer et al., 2005 [11]; Yeen et al., 2013 [17]; and Kobashigawa et al., 2015 [9]).	Thank you for your submission. This literature review submitted by the consultee broadly discusses cold ischaemia, donation after brainstem death (DBD) and donation after circulatory death (DCD) and makes no specific references to the recommendations or contents of the overview. The consultee identifies limitations of cold storage which were discussed by the committee when drafting the guidance. The consultee describes how one ex-vivo perfusion system works. Again, the committee discussed the mechanism of ex-vivo perfusion when drafting guidance.

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	Consultee 2 TransMedics, Inc		The current technique of cold static storage imposes significant limitations: • It subjects the donor hearts to time-dependent ischemic injuries and subsequent reperfusion injuries that impair heart function post-transplant. This causes transplanting physicians to only select donor hearts that they deem to be most likely to withstand the potential damage associated with cold storage preservation, leaving significant number of donor hearts un-utilized annually. It also imposes significant time and geographical limitations on the heart retrieval process, which further adversely impacts the utilization of available donor hearts. These time-dependent ischemic injuries have been directly correlated to post-transplant complications, such as primary graft dysfunction and death (Stehlik et al., 2010 [16]). • It lacks any perfusion capabilities to maintain the heart in a near-physiologic (in vivo like) environment after the donor heart is retrieved from the body of the donor. This limits utilization of certain donor hearts that have been subjected to the harsh and untoward physiological conditions of brain death in the donor body prior to procurement as well as the harsh conditions of cold storage. • Due to the time limitation of the current technique of cold storage, the transplant team has limited time to perform assessments of the donor and graft condition. The limitations of cold storage have been well established and have had led to the recommended preservation time of no longer than 4 hours (Costanzo et al, 2010 - ISHLT Guidelines for the Care of Heart Transplant Recipients, 2010 [3]). This recommendation is based upon the published literature that has established the risks associated with long ischemic time by numerous researchers. Data from the ISHLT Registry have shown that the risk of mortality at one year increases steadily with every minute of ischemic time in excess of 3 hours (Stehlik et al., 2010 [16]). For the past several decades there has been scientific and clinical interest in the development of ex-vivo heart perfusion (EVHP) with oxygenated and nutrient enriched blood to reduce ischemic injury to the donor heart and potentially enable ex-vivo assessment of metabolic and mechanical function.	The consultee also summarises some studies of ex-vivo perfusion. Ardehali 2015, Koerner et al 2014, Saez G 2014 have been included in table 2 in the overview and were discussed by the Committee. Hamed A, Tsuer et al (2009) referenced by the consultee (in page 6) is a supplement and not published/indexed paper. Therefore will not be included in the guidance. Donor Heart Transplantation from Donors after Circulatory death (DCD) falls outside the scope of this guidance.

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	Consultee 2 TransMedics, Inc		2. technology overview The OCS Heart is an ex-vivo, portable, pulsatile blood perfusion system intended to maintain a donated heart in a beating, near-physiological state prior to the transplantation into a recipient. The OCS maintains heart viability by providing a controlled environment, continuously perfusing the donated heart with warm, oxygenated blood obtained from the donor, supplemented with the TransMedics® Heart Solution Set. The blood that is used in the system is collected from the donor immediately prior to retrieval of the donor heart. It is combined with the Heart Solution Set and is continuously circulated to the heart throughout the preservation time in a closed circuit. The system it incorporates a number of monitors to assess preservation conditions, such as fluid flow rates, pressures, temperature, oxygen saturation, and hematocrit. In addition, venous and arterial lactate levels from the donor heart can be sampled through ports in this system. The OCS consists of the following major components: 1. OCS Heart Console (Console): The Console is the non-sterile, reusable portable enclosure that houses the infusion and circulatory pumps, the batteries, electronics, gas delivery devices, monitoring systems, and Wireless Monitor. The Wireless Monitor allows the user to adjust various settings and displays information. The OCS connects to its mobile base for transport. 2. Heart Perfusion Set (HPS): The sterile, single-use, disposable Heart Perfusion Set contains all the components and mechanisms that directly contact blood or the heart during preservation. The Heart Perfusion Set consists of the sterile, single-use Heart Perfusion Module (HPM), connectors, lines and other tools required for connection to a heart and for use during a preservation session. The HPM mounts to the OCS Heart Console and provides the sterile blood circuit and protected environment for a heart within the OCS. The heart is instrumented within the heart chamber of the Heart Perfusion Module. The remaining components of the HPS are used to instrument the donor heart, or are used to initiate/terminate perfusion.	

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	Consultee 2 TransMedics, Inc		3. Heart Solution Set (HSS): The Heart Solution Set is a sterile, single-use, solution set used to prime the system and maintain the circulating blood and heart during transport. It consists of a Priming Solution and a Maintenance Solution. The OCS is compact and portable, and it operates from an external alternating current power source or from its own batteries. The device can be used in a variety of physical settings, such as an operating room, ambulance, helicopter, airplane or sports utility vehicle. • PROTECT European Experience: Koerner et al.[12] reported on 2 year survival data of OCS heart transplant recipients as compared to prospective, non-randomized, concurrent control patients transplanted with hearts preserved by cold static storage (CSS) in the same German institution. This study compared the long term results of 29 heart transplant recipients who received OCS-preserved hearts to 130 heart transplant recipients who received hearts preserved using CSS at the same institution over the same period of time. All recipients received standard criteria donor hearts. In this article, the authors summarized the key clinical outcomes at 30 days, 1 year and 2 years following heart transplantation The results show 1 and 2 year survival for OCS patients of 89%, compared to 1 and 2 year survival of 81% and 79% for the control patients.	

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	Consultee 2 TransMedics, Inc		• Ex-Vivo Metabolic Assessment of Donor Heart on OCS System. Hamed, et al.[6]: During European clinical experience with the OCS Heart technology, it was shown that circulating lactate level – estimated by the arterial lactate level - during OCS perfusion of donor hearts was a sensitive predictor for post-transplant outcomes. This relation was established in a prospective analysis of the early global OCS experience (n=49 patients transplanted with OCS-perfused donor hearts). Post-transplant outcomes were categorized into Group A (graft failure within 30 days) and Group B (absence of graft failure at 30 days). A logistic regression analysis was constructed (1 variable, 2 variable, Best 2) using Group A as the outcome variable. The results demonstrated that ending arterial lactate level on OCS was statistically significant in all models (p=0.004) and using a cutoff of end of perfusion lactate of 4.96 mmol/L, lactate had a 0.625 sensitivity and 0.975 specificity. This work provided the foundation for ex-vivo OCS Lactate levels of donor hearts perfusion to assess their viability for transplantation. • UK Experience with Extended Criteria Donor Hearts in High Risk Recipients: Garcia Saez, et al. [5] reported on the survival of a series of 26 heart transplant recipients in which the OCS was used to preserve the donor hearts from standard and extended criteria donors and transplanted in high risk recipients. Most notable about this case series was the inclusion of both “high-risk recipients” (e.g., recipients on VADs with complications, elevated PVR, etc.) and “high-risk donors” donors (e.g., Left Ventricular Hypertrophy (LVH), expected prolonged ischemic time >4 hours, Ejection Fraction (EF) <50%, non-specific CAD, alcohol and drug abuse, etc.). In this published series, a 96% survival has been reported at 257 ± 116 days. • International Successful Clinical Experience with Donor Heart Transplantation from Donors after Circulatory death (DCD): Dhital et al. [4] in Sydney, Australia reported on a successful cohort of heart transplantation with donor hearts maintained on OCS from donors after circulatory death (DCD). In this published series, all patients survived beyond 30 days and were reported to be alive at 77, 91 and 176 days post-transplant at time of publication. Since the publication date, there have been 3 additional successful transplants from DCD donors using the OCS heart at the same institution. All 6 transplanted recipients are alive to-date.	

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<tr><td></td><td>Consultee 2
TransMedics, Inc</td><td></td><td>Summary long term data from all 6 recipients are listed in Table below
Long Term Follow-Up Data on All Sydney DCD Heart Transplant Recipients All Patients Are Alive as of October 13, 2015
<table>
<tr><th>No.</th><th>Post-operative mechanical support</th><th>Postoperative length of stay</th><th>Survival Days since Transplant</th></tr>
<tr><td>1</td><td>ECMO</td><td>26 days</td><td>456 days</td></tr>
<tr><td>2</td><td>No</td><td>28 days</td><td>371 days</td></tr>
<tr><td>3</td><td>IABP</td><td>21 days</td><td>355 days</td></tr>
<tr><td>4</td><td>No</td><td>23 days</td><td>292 days</td></tr>
<tr><td>5</td><td>No</td><td>32 days</td><td>165 days</td></tr>
<tr><td>6</td><td>No</td><td>7 days</td><td>151 days</td></tr>
</table>
• The PROCEED II International Clinical Trial. Ardehali, et al.[1]: The study demonstrated that OCS use was easily implemented by the trial sites' organ retrieval staff, and the OCS was successfully used for donor heart preservation. The device itself performed as intended as evidenced by the stable perfusion parameters and metabolic status of donor hearts during use.
The study met its primary effectiveness endpoint and achieved study success, demonstrating that the OCS is effective. Study success was achieved regardless of the study population analyzed –including the PP, ITT and AT populations.
In addition, the primary safety analysis for the study was met; that is, the incidence of cardiac- graft related serious adverse events (Cardiac Graft SAEs). The use of cardiac-graft related SAEs is a strong measure of post-transplantation graft function and directly reflects the quality of the preservation of the donor heart. In the PROCEED II Trial, the OCS met this important endpoint.</td><td></td></tr>
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	Consultee 2 TransMedics, Inc		In addition, analysis of AEs, SAEs and cause of death in the first 30-days did not raise safety concerns and the results were statistically comparable in both study arms. During the conduct of the PROCEED II trial, five donor hearts designated for four randomized patients (1 patient with 2 donor hearts offered) were deemed not acceptable for transplantation while on the OCS and were declined for transplantation. The four patients (that these hearts were assigned to) were subsequently transplanted with another donor heart offer and their outcomes were included in the analysis of this trial. Four (4) of the 5 donor hearts were declined due to rising perfusate lactate levels during the OCS preservation session, indicating persistent myocardial ischemia despite attempts of optimization of myocardial perfusion, and 1 heart was declined due to friable aortic tissue that was difficult to support the aorta cannula for OCS perfusion. The ex-vivo metabolic assessment afforded by OCS is a new capability that enables some biomarker data to be assessed by the transplant team up to the point of transplantation. The same is not afforded by cold storage. The turn down of these 5 donor hearts is a reflection of this new capability. It is important to note that the PROCEED II Trial successfully met its primary effectiveness and safety endpoints despite the OCS arm having significantly longer out-of-body time as compared to control (324 minutes vs. 196 minutes), while limiting ischemic time to 113 minutes on OCS vs. 196 minutes in the control group. This is a clinically relevant finding, since it may enable distant procurement of donor hearts for transplantation.	

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	Consultee 2 TransMedics, Inc		4. Bibliography 1. Ardehali A, Esmailian F, Deng M, et al. Ex-vivo perfusion of donor hearts for human heart transplantation (PROCEED II): a prospective, open-label, multicenter, randomized non-inferiority trial. Lancet. 2015; 385: 2577-2584. 2. Banner NR, Thomas HL, Curnow E, et al. The importance of cold and warm ischemia for survival after heart transplantation. Steering Group of the United Kingdom Cardiothoracic Transplant Audit. Transplantation 2008; 86: 542-7. 3. Costanzo MR, Dipchand A, Starling R, et al. The International Society of Heart and Lung Transplantation Guidelines for the Care of Heart Transplant Recipients. The Journal of Heart and Lung Transplantation; 2010; 29: 914-56. 4. Dhital KK, Iyer A, Connellan M, et al. Adult heart transplantation with distant procurement and ex-vivo preservation of donor hearts after circulatory death: a case series. Lancet. 2015; 385: 2585-91. 5. Garcia Saez D, Zych B, Sabashnikov A, et al. Evaluation of the organ care system in heart transplantation with an adverse donor/recipient profile. Ann Thorac Surg. 2014; 98:2099-105. 6. Hamed A TS, Huber J, Lin R, Pogglo EC, Ardehalt A (2009) J Heart Lung Transplant 28 (2): S71 7. Hunt SA. Taking heart: Cardiac transplantation past, present, and future. N Engl J Med 2006; 355: 231–5. 8. Hunt SA, Haddad F. The changing face of heart transplantation. J Am Coll Cardiol 2008; 52: 587–98. 9. Kobashigawa J, Johnson M, Rogers J, et al. Report from a Forum on US Heart Allocation Policy. Am J Transplant. 2015; 15:55-63. 10. Koerner JJ, Ghodsizad A, Schulz U, et al. Normothermic ex vivo allograft blood perfusion in clinical heart transplantation. The Heart Surgery Forum. 2014: 17: 141-145.	

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	Consultee 2 TransMedics, Inc		11. Krakauer H, Lin MJ, Bailey RC. Projected survival benefit as criterion for listing and organ allocation in heart transplantation. J Heart Lung Transplant. 2005;24(6):680-9 12. Lund LH, Edwards LB, Kucheryavaya AY, et al. The Registry of the International Society for Heart and Lung Transplantation: thirty-first official adult heart transplant report-2014; focus theme: retransplantation. J Heart Lung Transplant 2014; 33: 996-1008. 13. Parolari A, Rubini P, Cannata A, et al. Endothelial damage during myocardial preservation and storage. Ann Thorac Surg 2002; 73: 682–90. 14. Russo MJ, Iribarne A, Hong KN, et al. Factors associated with primary allograft failure after heart transplantation. Transplantation 2010: 90: 444-50. 15. Russo MJ, Chen JM, Sorabella PA, et al. The effect of ischemic time on survival after heart transplantation varies by donor age: an analysis of the United Network for Organ Sharing database. J Thorac Cardiovas Surg 2007; 133: 554-9. 16. Stehlik J, Edwards LB, Kucheryavaya AY, et al. The Registry of the International Society for Heart and Lung Transplantation: 27th Adult Heart Transplant Report – 2010. The Journal of Heart and Lung Transplantation; 2010; 29: 1089-103. 17. Yeen W, Polgar A, Guglin M, et al. Outcomes of adult orthotopic heart transplantation with extended allograft ischemic time. Transplant Proc. 2013;45(6):2399-405.	

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3	Consultee 3 Department of Cardiothoracic Transplantation at Harefield Hospital		1. The Department of Cardiothoracic Transplantation at Harefield Hospital, UK has unparalleled experience of normothermic extracorporeal preservation (NEP) of hearts for transplantation and I would like to share our findings, some of which are not evident from the peer-review literature. 2. In September 2013, Harefield and Papworth Hospitals completed participation in PROCEED II, a European multi-centre RCT of conventional cold retrieval versus Transmedics Heart Organ Care System (OCS) support following donation after brainstem death (DBD). The outcomes of this study have been reported[1]. [redacted] Director of Transplantation at Harefield was Chief Investigator for the PROCEED II UK study centres. In view of early, substantial evidence of clinical benefits associated with the Heart OCS, Harefield determined in February 2013 that it was unethical to withhold beneficial therapy through randomisation to the control group and chose to use Heart OCS outside the study protocol for all transplants. This decision and the resultant low study recruitment were accepted by the study sponsor, Transmedics Inc. and by South Birmingham-West Midlands Ethics Committee chaired by [redacted], which had previously provided ethical approval for the UK trial. 3. We recognise that Harefield's decision to use the heart OCS as "standard of care" for all heart transplants is unprecedented and has been met with scepticism by some within the transplant community. The counterargument to our strategy centres on concern about the incremental cost associated with the capital equipment and disposables required for NEP and the perception that the conventional cold storage method for donor heart preservation is adequate for transplantation in the UK and, by implication, that the status quo is acceptable.	Thank you for your comments. The committee is pleased to hear about the experience of this leading centre. Consultee also outlines data on transplant activity in the UK. The PROCEED II trial (Ardehali 2015) findings and results from Saez G 2014 have been included in table 2 in the overview and were considered by the committee. The committee notes that this centre withdrew from the trial once they were no longer in equipoise and considered it unethical to randomise to a control group. The data presented by the consultee (page 14-15) has not yet been published. The NICE IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee.

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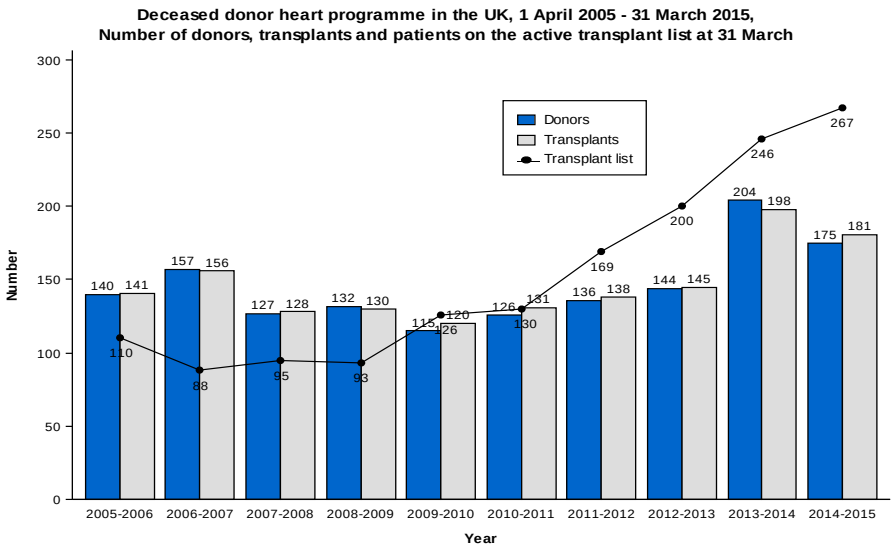
	Consultee 3 Department of Cardiothoracic Transplantation at Harefield Hospital		4. We strongly contest the notion that the status quo in heart transplantation is acceptable for the following reasons: a) There is a growing mismatch between the demand for heart transplantation and donor organ availability:  Source: Transplant activity in the UK, 2014-2015, NHS Blood and Transplant b) Mortality on the heart transplant waiting list is unacceptably high • The 1 year mortality for urgently listed and non-urgently listed transplant candidates is 4 and 10%, respectively[2]. • However, a significant number are suspended from the list (and by implication the majority deteriorate and die thereafter). • The growing mismatch between supply and demand means patients on the waiting list become sicker, making transplantation more risky. • Alternatively, they require mechanical circulatory support, with ongoing risks and increased transplant risk. • The waiting list mortality rate is likely to increase further as the disparity between donor organ demand and supply widens.	

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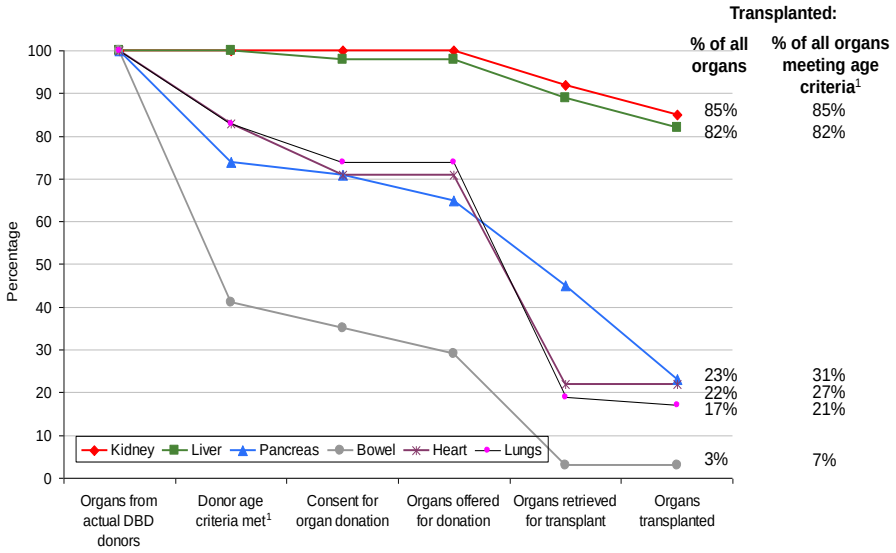
	Consultee 3 Department of Cardiothoracic Transplantation at Harefield Hospital		c) The utilisation rate of hearts from DBD donors is comparatively low An increasing prevalence of donor and recipient risk factors renders transplant teams reluctant to accept many donor organs because of the perceived risk of primary graft dysfunction, the major cause of early recipient mortality. In the UK, only 22 % of DBD donor hearts are transplanted, a comparatively low figure by international standards. **Donation and transplantation rates of organs from DBD organ donors in the UK, 1 April 2014 – 31 March 2015**  [1] Hearts – in addition to age criteria, donors who died due to myocardial infarction are excluded Bowels – in addition to age criteria, donors who weigh >80kg are excluded Source: Transplant activity in the UK, 2014-2015, NHS Blood and Transplant	

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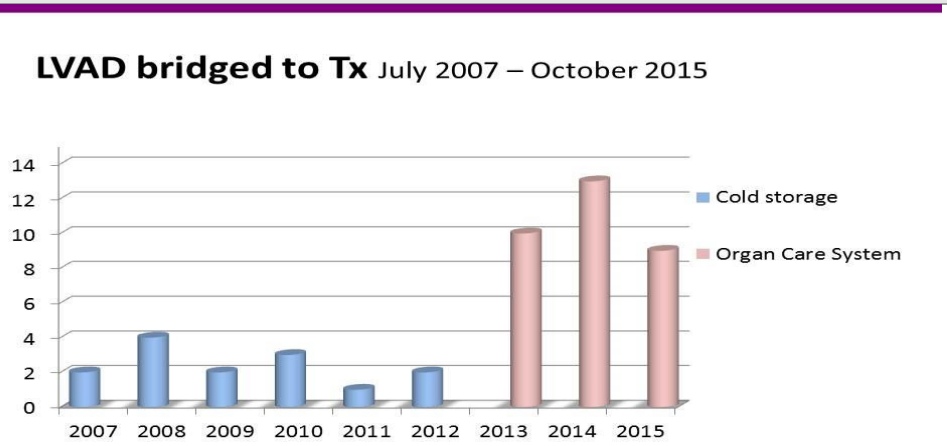
	Consultee 3 Department of Cardiothoracic Transplantation at Harefield Hospital		 **> 50% patients on the Waiting List at Harefield Hospital on LVAD support** - 75% Duration LVAD support > 1 year 7. Logistic benefits of normothermic extracorporeal perfusion NEP allows for longer ischaemic times which facilitates distant heart procurement and allows for greater recipient surgical preparedness, a significant consideration for patients with an implantable LVAD in situ.	

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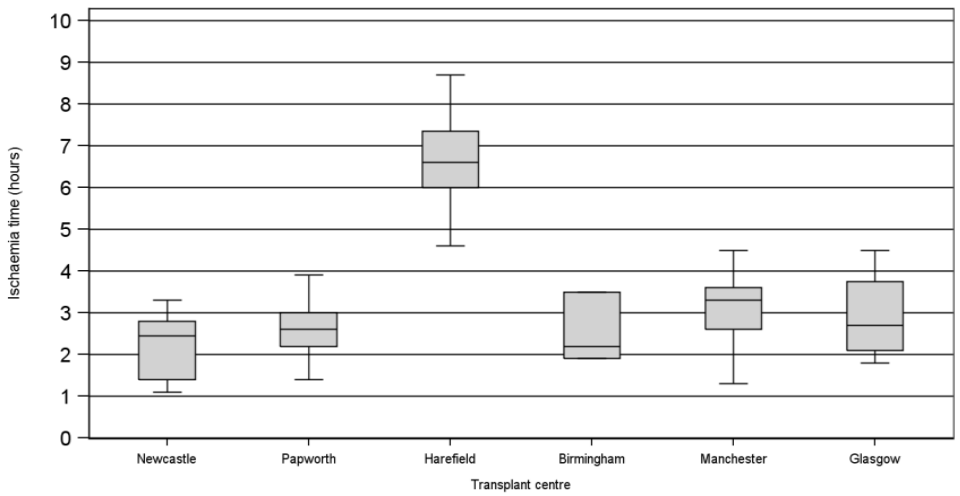
	Consultee 3 Department of Cardiothoracic Transplantation at Harefield Hospital		 **ANNUAL REPORT ON CARDIOTHORACIC TRANSPLANTATION REPORT FOR 2014/2015, NHSBT** Anecdotal benefits of NEP 1. During a DBD ENP heart retrieval, the Harefield retrieval team received late notification of donor adenocarcinoma (a contraindication). The transplant was aborted before the recipient underwent surgery, a situation which could not have been avoided if cold storage had been implemented. 2. A DBD heart appeared to be macroscopically normal on retrieval. On NEP, coronary flow was sub-normal with high perfusion pressures and an adverse blood lactate trend. The heart was rejected and on pathological examination there was non-palpable severe left anterior descending coronary artery disease.	

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	Consultee 3 Department of Cardiothoracic Transplantation at Harefield Hospital		<u>References</u> 1. Ex-vivo perfusion of donor hearts for human heart transplantation (PROCEED II): a prospective, open-label, multicentre, randomised non-inferiority trial Abbas Ardehali, Fardad Esmailian, Mario Deng, Edward Soltesz, Eileen Hsich, Yoshifumi Naka, Donna Mancini, Margarita Camacho, Mark Zucker, Pascal Leprince, Robert Padera, Jon Kobashigawa, for the PROCEED II trial investigators. Lancet 2015;385(9987):2577–2584. 2. NHSBT Annual report – Cardiothoracic transplantation 2014/2015. Published 2015. 3. García Saez D, Zych B, Sabashnikov A, et al. Evaluation of the Organ Care System in heart transplantation with an adverse donor/recipient profile. Ann Thorac Surg 2014; 98: 2099–106. 4. Commissioning for Quality and Innovation meeting. Birmingham UK. June 2015.	

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."