

National Institute for Health and Care Excellence
IP2083 VA ECMO for postcardiotomy cardiogenic shock in adults

IPAC date: 14/08/2025

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 1 British Cardiovascular Society	1	The British Cardiovascular Society supports the recommendations made.	Thank you for your comment.
2.	Consultee 7 Clinical	1	No comments but I agree with the recommendations	Thank you for your comment.
3.	Consultee 8 Clinical	1	No comments but I agree with the recommendations	Thank you for your comment.
4.	Consultee 9 Clinical	1	No comments but I agree with the recommendations	Thank you for your comment.
5.	Consultee 3 Company Medtronic	1	Medtronic Limited disagrees that the following draft recommendations represent a reasonable interpretation of the evidence or a sound and suitable basis for guidance to the NHS:	Thank you for your comment. The recommendation has been changed to 'can be used during the evidence generation period'. Kowalewski (2021), Alba (2021), Biancari (2018), Chen (2017),

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			<p>'More research is needed on venoarterial extracorporeal membrane oxygenation (VA ECMO) to manage postcardiotomy cardiogenic shock (PCS) before it can be used in the NHS.'</p> <p>'This procedure should only be done as part of formal research and an NHS research ethics committee needs to have approved its use.'</p> <p>We are aware that ECMO centres in NHS hospitals across the UK currently provide VA ECMO for PCS; within these hospitals, VA ECMO is considered rescue therapy for patients who have not responded to standard treatments. The draft recommendations are therefore inconsistent with clinical practice in the UK and risk restricting access to a procedure that has demonstrated life-saving potential in appropriately selected patients.</p> <p>There is a substantial evidence-base supporting the efficacy of VA ECMO in this patient population. An analysis of the Extracorporeal Life Support Organisation (ELSO) registry[1] using a data cut from January 2010 to December 2018 noted that 7,185 patients with PCS were supported with VA ECMO during this time-period with an overall survival to hospital</p>	<p>Bonacchi (2020), Chen (2020), Danial (2023) and Loungani (2021) are included in the main evidence tables in the overview.</p> <p>Inoue (2022) and Suverein (2023) refer to ECPR, which is covered by a separate IPG (please see consultation comments and responses for IP2083).</p>

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			<p>discharge of 41.7%. This finding has been corroborated by multiple large meta-analyses; Alba et al.[2] (n=8,231) reported that 30-day mortality/mortality at discharge was 59% (95% Confidence Interval [CI]: 56%-63%) while Biancari et al.[3] (n=2,986) reported that hospital survival was 36.1% (95% CI: 31.5%-40.8%).</p> <p>Survival outcomes for this patient population appear to be comparable to those reported for other high-risk populations such as refractory cardiac arrest where VA ECMO is generally indicated worldwide (e.g., survival to discharge is ~30%).[4, 5]</p> <p>While early mortality is high, it is important to contextualise this within the life-threatening situation of PCS and the potential of VA ECMO to provide meaningful recovery for survivors. Chen et al. (2017)[6] reported that, among patients who survived at least 1-year post-ECMO, subsequent mortality, readmission rates, and healthcare costs were similar to non-ECMO patients. This finding is supported by survival data at other time points: the prospective multi-centre analysis by Bonacchi et al.[7] reported overall survival at 1-year to be 32.1%; Chen et al. (2020)[8] found that 34% of patients survived at least 3-years; while Bonacchi et al.[7] and Danial et al.[9] reported survival at 5-years to be 25.2% and 22.8%, respectively.</p>	

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			<p>Moreover, findings from the ELSO registry[1] show a reduction in the rate of complications over time; this is likely due to increased centre experience, improved multidisciplinary coordination, and the development of institutional weaning protocols.[10]</p> <p>Medtronic requests that a recommendation of ‘can be used as an option/can be used during the evidence generation period’ is adopted; such a recommendation would align the recommendations with clinical practice in the UK, ensure continued access for patients to this procedure, and allow further data collection via the ELSO registry.</p> <p>References</p> <p>1. Kowalewski M, Zieliński K, Brodie D, MacLaren G, Whitman G, Raffa GM, Boeken U, Shekar K, Chen YS, Bermudez C, D’Alessandro D. Venoarterial extracorporeal membrane oxygenation for postcardiotomy shock—analysis of the extracorporeal life support organization registry. Critical care medicine. 2021 Jul 1;49(7):1107-17.</p>	

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			<p>2. Alba AC, Foroutan F, Buchan TA, Alvarez J, Kinsella A, Clark K, Zhu A, Lau K, McGuinty C, Aleksova N, Francis T. Mortality in patients with cardiogenic shock supported with VA ECMO: A systematic review and meta-analysis evaluating the impact of etiology on 29,289 patients. The Journal of Heart and Lung Transplantation. 2021 Apr 1;40(4):260-8.</p> <p>3. Biancari F, Perrotti A, Dalén M, Guerrieri M, Fiore A, Reichart D, Dell'Aquila AM, Gatti G, Ala-Kokko T, Kinnunen EM, Tauriainen T. Meta-analysis of the outcome after postcardiotomy venoarterial extracorporeal membrane oxygenation in adult patients. Journal of cardiothoracic and vascular anesthesia. 2018 Jun 1;32(3):1175-82.</p> <p>4. Inoue A, Hifumi T, Sakamoto T, Okamoto H, Kunikata J, Yokoi H, Sawano H, Egawa Y, Kato S, Sugiyama K, Bunya N. Extracorporeal cardiopulmonary resuscitation in adult patients with out-of-hospital cardiac arrest: a retrospective large cohort multicenter study in Japan. Critical Care. 2022 May 9;26(1):129.</p> <p>5. Suverein MM, Delnoij TS, Lorusso R, Brandon Bravo Bruinsma GJ, Otterspoor L, Elzo Kraemer CV, Vlaar AP, Van Der Heijden JJ, Scholten E, Den Uil C, Jansen T. Early</p>	

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			<p>extracorporeal CPR for refractory out-of-hospital cardiac arrest. New England Journal of Medicine. 2023 Jan 26;388(4):299-309.</p> <p>6. Chen SW, Tsai FC, Lin YS, Chang CH, Chen DY, Chou AH, Chen TH. Long-term outcomes of extracorporeal membrane oxygenation support for postcardiotomy shock. The Journal of Thoracic and Cardiovascular Surgery. 2017 Aug 1;154(2):469-77.</p> <p>7. Bonacchi M, Cabrucci F, Bugetti M, Dokollari A, Parise O, Sani G, Prifti E, Gelsomino S. Outcomes' predictors in post-cardiac surgery extracorporeal life support. An observational prospective cohort study. International Journal of Surgery. 2020 Oct 1;82:56-63.</p> <p>8. Chen F, Wang L, Shao J, Wang H, Hou X, Jia M. Survival following venoarterial extracorporeal membrane oxygenation in postcardiotomy cardiogenic shock adults. Perfusion. 2020 Nov;35(8):747-55.</p> <p>9. Danial P, Olivier ME, Bréchet N, Ponnaiah M, Schoell T, D'Alessandro C, Demondion P, Clément M, Juvin C, Carillion A, Bouglé A. Association between shock etiology and</p>	

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			<p>5-year outcomes after venoarterial extracorporeal membrane oxygenation. Journal of the American College of Cardiology. 2023 Mar 7;81(9):897-909.</p> <p>10. Loungani RS, Fudim M, Ranney D, Kochar A, Samsky MD, Bonadonna D, Itoh A, Takayama H, Takeda K, Wojdyla D, DeVore AD. Contemporary use of venoarterial extracorporeal membrane oxygenation: insights from the multicenter RESCUE registry. Journal of cardiac failure. 2021 Mar 1;27(3):327-37.</p>	
6.	Consultee 4 University Hospitals of Leicester NHS Trust	1	<p>In response to the draft guidance on the use of VA ECMO to manage post-cardiotomy cardiogenic shock, we would like to express our concerns on the impact of this guidance on a selected group of patients who would likely benefit from it.</p> <p>As a cardiac surgery centre with expertise and experience in providing ECMO for all age groups, we have developed a process where patients who may benefit from VA ECMO are considered and managed by an experienced multidisciplinary team. This process has been associated with a higher than benchmark outcomes for our VA ECMO patients (62% in the last 3 years). This is especially necessary for our centre with a case mix that includes high risk patients such as Major aortic surgery, adult congenital disease/ grown up congenital heart</p>	<p>Thank you for your comment.</p> <p>The recommendation has been changed to 'can be used during the evidence generation period'.</p> <p>The 3 cited references have been added to the overview (2 in the main evidence and 1 in table 5).</p>

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			<p>disease, high risk constrictive pericarditis and complicated/ multiple valvular heart disease.</p> <p>Refractory post cardiectomy cardiogenic shock is usually fatal. Central or peripherally implanted VA ECMO support can bridge such patients to recovery. transition to more durable mechanical support (such as VAD) or cardiac transplantation. Careful patient selection by an experienced multidisciplinary team and timing of intervention prior to irrecoverable organ failure in addition to management in an experienced centre are crucial for optimizing outcomes.</p> <p>The draft guidance if ratified, stands the risk of not being followed by clinicians as we would not like to disadvantage a selected group of patients by not giving them the best care possible. In addition, we would not benchmark on care delivered to these patients by similar centres around the world.</p> <p>We would recommend that appropriate patients with cardiogenic shock post-cardiectomy can be considered for VA ECMO by a multi-disciplinary team with adequate expertise and experience. Patients should be managed in an ECMO centre and submission of data to a registry should be compulsory (e.g. ELSO) to allow for observational, data driven</p>	

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			<p>research that would potentially improve the care provided to these patients.</p> <p>This approach is supported by published studies some which we have contributed data to as shown below:</p> <p>1. Fausto Biancari, Magnus Dalén, Antonio Fiore et al. Multicenter study on postcardiotomy venoarterial extracorporeal membrane oxygenation, The Journal of Thoracic and Cardiovascular Surgery, Volume 159, Issue 5, 2020, Pages 1844-1854.e6, ISSN 0022-5223, https://doi.org/10.1016/j.jtcvs.2019.06.039.</p> <p>2. Mariscalco G, Fiore A, Ragnarsson S et al. Five-year survival after post-cardiotomy veno-arterial extracorporeal membrane oxygenation, European Heart Journal. Acute Cardiovascular Care, Volume 10, Issue 6, August 2021, Pages 595–601.</p>	

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			<p>4. Mariscalco Giovanni, Dashey Susan, Yusuff Hakeem et al. Peripheral versus central extracorporeal membrane oxygenation for postcardiotomy shock: Multicenter registry, systematic review, and meta-analysis.</p> <p>The Journal of Thoracic and Cardiovascular Surgery, Volume 160, Issue 5, 1207 - 1216.e44</p>	
7.	Consultee 5 Professional expert	1 Recommendations	<p>This is not an accurate statement. We have used VA ECMO in post cardiotomy patients in the NHS for over twenty years! In fact i would go as far as saying that it has now become a primary VAD of choice post cardiotomy in our specialist transplant centre unless their comorbidities or post op biochemical profile is such that it is obvious they will not survive regardless of this potential treatment option.</p>	<p>Thank you for your comment.</p> <p>The recommendation has been changed to 'can be used during the evidence generation period'.</p>
8.	Consultee 6 Professional expert	1 Recommendations	<p>This treatment is frequently used in all 6 UK heart transplant centres to treat severe primary graft dysfunction of newly transplanted hearts. It would be problematic if NICE produced guidance that was not compatible with continuation of this practice.</p> <p>Around 20-25% of transplanted hearts will not support the circulation immediately after implant. The UK does around 200 heart transplants per year, so this affects 40-50 patients per year. These patients are typically brought out of theatre on central VA ECMO. The vast majority of patients recover and</p>	<p>Thank you for your comment.</p> <p>Please see response to comment 7. Section 3.12 has been added to the guidance, noting that this procedure could have a better outcome if it is used for post-transplant support because of primary graft dysfunction.</p>

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			<p>are weaned from VA ECMO in 4-5 days. They have excellent long term outcomes.</p> <p>If the committee is interested, this activity is described in the annual NHS BT reports on mechanical circulatory support related to heart transplantation.</p>	
9.	Consultee 2 Clinical	1	<p>I am a consultant cardiologist specialising in adult congenital heart disease and have been leading a UK Level 1 ACHD centre for the last 15 years. I am regularly involved in the work up of patients for cardiac surgery and in their post surgical care.</p> <p>Audit of our own data (historically the largest ECMO centre by volume in the country) has shown that post cardotomy VA ECMO in patients with adult congenital heart disease improves survival significantly above that in older cohorts undergoing surgery for acquired cardiac conditions who also receive this treatment. For this reason, analysis of outcomes associated with post cardotomy VA ECMO should be determined separately for these two cohorts.</p> <p>In addition, as the number of ACHD patients undergoing surgery in the UK is small in comparison to those having surgery for acquired conditions, adjustments should be made</p>	<p>Thank you for your comment.</p> <p>The recommendation has been changed to 'can be used during the evidence generation period'. The data needed is detailed in 'what evidence generation is needed'.</p>

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			<p>to the length of time that data is acquired for the ACHD group in order to draw valid statistical conclusions.</p> <p>Account should also be made of the potential life years saved in this much younger cohort and the fact that many patients require repeated cardiac surgery through their lifetimes, making it essential that the myocardium is preserved as much as possible for each surgical episode including the immediate recovery period on the ICU. The use of VA ECMO as a bridge to recovery from the assault of elective surgery can be vital in this group of patient with complex cardiac anatomy facing a potential long lifetime of procedures.</p> <p>Finally, patients with congenital heart disease very often undergo surgery for right sided cardiac lesions i.e. tricuspid and pulmonary valve operations. In this context, we have found that VA ECMO can be even more vital in supporting the heart to recovery after surgery, especially in the context of pre-operative right ventricular impairment, an additional risk factor to early surgical mortality in this group. Those undergoing tricuspid valve repair for Ebstein anomaly are often at particularly high risk and may have the most to gain from post cardotomy VA ECMO support. Any analysis of the efficacy of post cardotomy VA ECMO should therefore also involve subgroup analysis of patients undergoing surgery for right</p>	

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			sided lesions. Again numbers will be relatively small and as with the ACHD group as a whole, sufficient time should be given to build up a large enough cohort to allow valid conclusions to be drawn.	
10	Consultee 5 Professional expert	1	This document does not reflect the reality of working in cardiac surgery in 2025. So many cardiac centres, even those that do not specialise in transplantation or heart failure will use VA ECMO in a post cardiectomy scenario as a bridge to decision. I personally have performed mobile retrieval of patients that have been established on VA ECMO in another centre, post cardiectomy, to bring them to Wythenshawe for assessment and optimisation and consideration of further long term mechanical support options.	Thank you for your comment. Please see response to comment 7. The committee considered the potential for people to be transferred on VA ECMO, but this is rare and so not included in the guidance.
11	Consultee 6 Professional expert	Why the committee made these recommendations	It is hard to imagine that a randomised controlled trial will ever be performed. Where a patient simply cannot be weaned from cardio-pulmonary bypass at the end of conventional cardiac surgery, then the options in simple terms are (a) allow the patient to die or (b) support with VA ECMO.	Thank you for your comment. The guidance does not state that research should be in the form of randomised controlled trials. Section 3.10 states 'It would be difficult to do randomised controlled trials in people with PCS. So, other types of data collection such as registries could be useful.'

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12	Consultee 6 Professional expert	3.10 Committee comments	Agree	Thank you for your comment.
13	Consultee 10 Royal Papworth Hospital	Not specified	<p>1. Patient and Disease Selection:</p> <ul style="list-style-type: none"> o Criteria for patient selection: Patient age and comorbidities have a significant impact on survival, we have seen very limited survival in patients over the age of 70. o Types of diseases/conditions we believe could be suitable for treatment: In our centre we have seen good outcomes for post Pulmonary Thromboendarterectomy (PTE) and post-transplant patients, however our outcomes for patients outside this group are much poorer (10% survival).¹ If desired can provide data from the last 7 years, this follows a similar pattern, with some improvement in the general group (30% survival) 	<p>Thank you for your comment.</p> <p>The guidance states, 'patient selection should be done by a multidisciplinary team...'</p>
14	Consultee 10 Royal Papworth Hospital	Not specified	<p>2. Decision Making:</p> <ul style="list-style-type: none"> o Decision-making process: We would advocate for a multidisciplinary team approach involving the primary operating surgeon a neutral Cardiac Surgeon not directly involved in the case, a Cardiac Anaesthetist and Intensivist/ECMO consultant. o We have seen better outcomes the earlier this decision making occurred. Pre-op discussion is the ideal, or just prior to 	<p>Thank you for your comment.</p> <p>The guidance states, 'patient selection should be done by a multidisciplinary team...'. Section 3.14 has been added, citing that reducing the time to starting VA ECMO to manage PCS is of high importance for better outcomes.</p>

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			coming off bypass. Outcomes are much worse when used in a rescue context either after multiple failed attempts to come off bypass or in ICU after the patient has deteriorated.	
15	Consultee 10 Royal Papworth Hospital	Not specified	<p>3. Training and Expertise:</p> <ul style="list-style-type: none"> o There is a learning curve for initiation and management of VA-ECMO patients and therefore we would advocate for the care of these patients in expert high volume centre. We would highlight the high level of nursing expertise required to manage these patients and the high risk of limb ischaemia where a peripheral VA approach is used. o While high risk patients should be managed in centres with the capability and expertise to deliver post cardiectomy ECMO, there is still a need for these centres to support and retrieve patients from other centres, again early recognition and discussion with 	<p>Thank you for your comment.</p> <p>'What this means in practice' (who should be involved with the procedure) has been changed and section 3.15 has been added in response to the comment.</p>
16	Consultee 10 Royal Papworth Hospital	Not specified	<p>4. Research:</p> <ul style="list-style-type: none"> o Evolving evidence supports early decision making, and considered patient selection o Less invasive approaches where the chest can be closed to reduce bleeding and potential infection problems are showing promise and improved outcomes. o Ongoing research should focus on good data collection, adoption of a UK network approach and registry and application of adaptive and novel trials methodologies to 	<p>Thank you for your comment.</p> <p>The guidance states, 'patient selection should be done by a multidisciplinary team...'. Section 3.14 has been added to the guidance.</p> <p>The recommendation has been changed to 'can be used during the evidence generation period'.</p>

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			<p>look at evolution and evaluation of different approaches and management strategies.</p> <p>References</p> <p>1. Rubino, A., Costanzo, D., Stanszus, D., Valchanov, K., Jenkins, D., Sertic, F., Fowles, J.A. and Vuylsteke, A., 2018. Central veno-arterial extracorporeal membrane oxygenation (C-VA-ECMO) after cardiothoracic surgery: a single-center experience. Journal of Cardiothoracic and Vascular Anesthesia, 32(3), pp.1169-1174.</p>	<p>The data needed is detailed in 'what evidence generation is needed'.</p> <p>Rubino (2018) has been added to the main evidence in the overview.</p>
17	Consultee 3 Company Medtronic	General	<p>While not within the remit of the Interventional Procedures Guidance programme, we would also like to highlight the potential benefits of VA ECMO for organ donation. There is a growing evidence base suggesting that organs from donors after ECMO can be successfully utilised, expanding the organ pool with high graft and recipient survival; a systematic review by Rajsic et al. identified 20 studies comprising 147 donors and 360 organ donations.[1] The most frequently donated organs were kidneys (68%, n=244/360) and livers (24%, n=85/360). In total, 98% (n=292/299) of recipients survived with preserved graft function (92%, n=319/347) until follow-up within a variable period of up to 3-years.</p> <p>References</p>	<p>Thank you for your comment.</p> <p>Section 3.13 has been added to the guidance in response to the comment.</p>

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			1. Rajsic S, Tremi B, Innerhofer N, Eckhardt C, Spurnic AR, Breitkopf R. Organ Donation from Patients Receiving Extracorporeal Membrane Oxygenation: A Systematic Review. Journal of cardiothoracic and vascular anesthesia. 2024 Mar 20.	

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