

ANNUAL REPORT ON MECHANICAL CIRCULATORY SUPPORT RELATED TO HEART TRANSPLANTATION

REPORT FOR 2024/2025 (1 APRIL 2015 – 31 MARCH 2025)

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CONTENTS

Contents

1 2	Intro	cutive summaryduction	7
		ONG-TERM DEVICES USED FOR BRIDGING	
3		tivity	
4	Pa	tient outcomes	
	4.1	Demographic characteristics	23
	4.2	Duration on support	
	4.3	Rate of transplant listing	
	4.4	Competing outcomes	
	4.5	Survival on support	
	4.6	Patient survival from implant	31
	4.7	TAH outcomes	
ADI	JLT S	HORT-TERM DEVICES USED FOR BRIDGING	37
5	Ac	tivity	37
6	Pa	tient outcomes	41
	6.1	Demographic characteristics	42
	6.2	Duration on support	45
	6.3	Rate of transplant listing	46
	6.4	Competing outcomes	47
	6.5	Patient survival from implant	49
ADI	JLT S	HORT-TERM DEVICES USED POST-HEART TRANSPLANT	54
7	Ac	tivity	54
8	Pa	tient outcomes	60
	8.1	Demographics characteristics	61
	8.2	Duration on support	
	8.3	Patient survival from implant	65
	8.4	Patient survival from heart transplant	
PAE	DIAT	RIC DEVICES USED FOR BRIDGING	
9	Ac	tivity	67
10		Patient outcomes	
	10.1	Demographic characteristics	
	10.3	Rate of transplant listing	
	10.4	Competing outcomes	
	10.5	Patient survival from implant	
APF		IX	

A1: Data	80
A3: Glossary of terms	86

EXECUTIVE SUMMARY

1 Executive Summary

This report summarises key information about mechanical circulatory support (MCS) used in patients in the UK as a bridge to heart transplantation or for post-transplant support. MCS in this context includes Long-term ventricular assist devices (VADs), Short-term VADs, total artificial hearts (TAH) and veno-arterial extracorporeal membrane oxygenation (ECMO). The period reported covers 10 years, from 1 April 2015 to 31 March 2025. Data were extracted from the UK MCS Database held by NHS Blood and Transplant on 15 October 2025. Results are generally presented separately for adult and paediatric patients, for long-term and short-term devices and for bridging and post-transplant strategies.

Key findings

Long-term bridging devices in adults:

- During 2024/2025 there were 57 long-term device implants, all long-term VADs. The number of implants was 24% lower than in 2023/2024.
- The most common <u>INTERMACS profile</u> for this patient group was 3 (stable but inotrope dependent) representing 39% of patients.
- The <u>median</u> duration on long-term VAD support was 1,578 days (4.3 years).
- At 3-years post-implant, 62% of patients remained on support, 11% had received a heart transplant, 5% were explanted without transplant and 22% died on support.
- The national 1-year patient <u>survival rate</u> from the point of first long-term VAD implant, irrespective of subsequent intervention (not censored at transplant or explant for recovery) was 87.1%. The 3-year survival rate was 74.0%.

Short-term bridging devices in adults:

- During 2024/2025 there were 166 short-term device implants, comprising 94 VADs and 72 ECMO implants; a 14% increase from the previous financial year.
- The majority (82%) of implants were into <u>INTERMACS profile</u> 1 patients (critical cardiogenic shock).
- The <u>median</u> duration on short-term support was 13 days.
- At 30 days post-implant, 26% of patients remained on short term support, 22% had received a heart transplant, 4% transferred to a long-term device, 20% were explanted without transplant and 28% had died on support.
- The 1-year patient <u>survival rate</u> from the point of first short-term implant (excluding those bridged to long-term support) was 56.9% (not censored at transplant/explant).

Short-term devices used post-heart transplant in adults:

- During 2024/2025 there were 53 adult heart transplants requiring mechanical support within 30 days post-transplant, comprising 46 ECMO only, 7 short-term VAD and ECMO and none involved short-term VAD only. As a percentage of transplants performed, 30% required support.
- The 1-year patient <u>survival rate</u> from the point of implant was 73.3%.
- On average, patients spent 5 days on support.
- Patient survival rates at 90-days and 1-year for transplants requiring support were significantly worse than transplants without support.

Devices used in paediatric patients:

- During 2024/2025, 34 bridging device implants and 3 post-transplant implants were reported, 20 of which were ECMO and 17 were VADs.
- For 61 patients reported as having bridging support between 1 April 2020 and 31 March 2024, the median duration of support was 92 days, 31% of patients received a transplant within 90 days of implant and the 1-year patient <u>survival rate</u> from the point of implant was 88.2%.

Use of the contents of this report should be acknowledged as follows:

Annual Report on Mechanical Circulatory Support Related to Heart Transplantation 2024/2025,

NHS Blood and Transplant

INTRODUCTION

2 Introduction

In the United Kingdom, mechanical circulatory support (MCS) therapy is commissioned as a bridge to heart transplantation or for post-transplant support due to primary graft dysfunction (PGD) or rejection. MCS in this context includes long-term ventricular assist devices (VADs), short-term VADs, total artificial hearts (TAH) and veno-arterial extracorporeal membrane oxygenation (ECMO).

The seven centres that provide this service are those that also perform heart transplantation: Birmingham Queen Elizabeth Hospital, Harefield Hospital, Manchester Wythenshawe Hospital, Newcastle Freeman Hospital, Royal Papworth Hospital, Great Ormond Street Hospital and Glasgow Golden Jubilee Hospital. Great Ormond Street Hospital provide a paediatric service only, Newcastle provide both adult and paediatric services, and the remaining centres provide adult services only. Patients aged less than 16 implanted at Newcastle are reported as paediatric patients, while patients aged 16 or over implanted at Newcastle are reported as adults, otherwise adult centre data are reported in the adult sections and paediatric centre data are reported in the paediatric section, regardless of the age of the patient.

All centres are required to submit data to the national database hosted by NHS Blood and Transplant, known as the MCS Database. The database collects extensive data prior to and at time of device implant, as well as explant, transplant and death along with follow-up at various time points post-implant and post-explant. These data are audited and reported annually herein in order to provide centres, commissioners and patients with relevant and transparent information about the UK MCS service. The report also incorporates data from the UK Transplant Registry on listing for heart transplantation and survival after transplant for patients receiving MCS.

The cohort covered in this report is from 1 April 2015 to 31 March 2025. Data were extracted for this report on 15 October 2025 by which date it was expected that all devices used during the audit period had been reported to the database.

Prior to the introduction of the General Data Protection Regulation (GDPR) in May 2018, consent had to be gained from patients to record their data on the MCS Database. During this time 18 patients refused consent and so these patients are excluded from this report. From May 2018, patient data are recorded lawfully without explicit consent under Section 6(1)e of the GDPR. Use of Section 6(1)e requires a specific exemption, and the patient data is being collected and processed under Section 9(2)h "management of healthcare".

The report is split into four main parts:

- Adult long-term devices used for bridging (long-term VADs and TAH)
- Adult short-term devices used for bridging (short-term VADs and ECMO)
- Adult short-term devices used post-heart transplant (short-term VADs and ECMO)
- Paediatric devices used for bridging (VAD and ECMO)

Each part includes an activity section where data are analysed on a per-implant basis, and a patient outcome section where data are analysed on a per-patient basis. The exceptions are the short-term devices used post-heart transplant which are also analysed on a per-transplant basis, and paediatric bridging devices which are analysed on a per-episode basis. Activity is analysed over the decade whilst outcomes are typically analysed for more recent

implants. See <u>Appendix A1</u> for a breakdown of the number of observations analysed in each section and notes on classifications and limitations.

Methods used to produce the report are described in Appendix A2.

Patient survival is analysed in two ways; from the point of first device implant to death, irrespective of subsequent intervention, and survival on support which is time from implant to death on support where explant or transplant events are censored. The reader should note that in both cases the results are not adjusted for potential differences in risk between patients treated at different centres. Such differences in "case-mix" may explain any variation in the centre-specific survival rates, thus no conclusions can be made about differences in the standard of care between centres.

2.1 Overview

Figure 2.1 shows the number of adult bridging implants reported over the last ten years, split by device type. In general, long-term device implants have decreased over the decade, with 57 in 2024/2025, while short-term implants have increased, with 166 in 2024/2025.

Figure 2.1 Total number of adult bridging device implants in the UK, by device type and financial year, 1 April 2015 to 31 March 2025

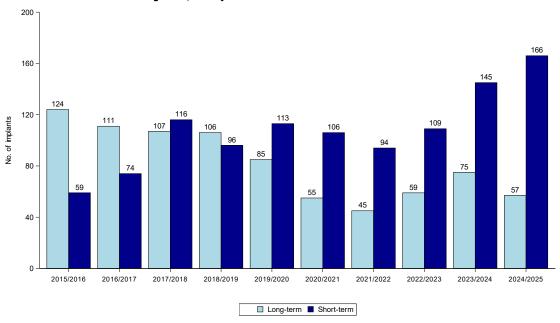
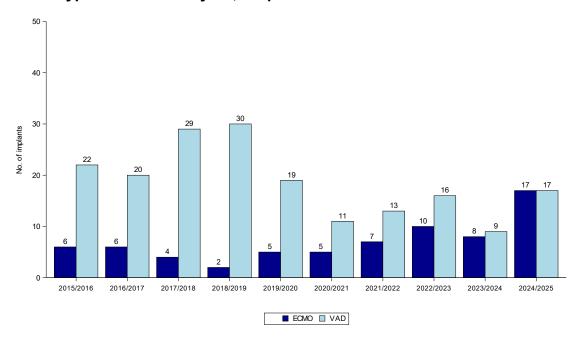


Figure 2.2 shows a breakdown of paediatric bridging implants over the last ten years. The number of VAD implants has reduced since 2018/2019 and the use of ECMO has recently increased.

Figure 2.2 Total number of paediatric bridging device implants in the UK, by device type and financial year, 1 April 2015 to 31 March 2025



In total (adult and paediatric combined) there were 2,158 bridging implants reported across the decade in 1,739 patients; 1,389 (80%) patients had a single device implant, 291 (17%) had two implants, 51 (3%) had three, 6 (0.4%) had four, and 2 (0.1%) had five (see **Table A1.4** and **Table A1.5** in Appendix A1 for details of device histories).

Figure 2.3 shows the number of adult post-heart transplant implants reported over the last ten years, split by primary graft dysfunction (<u>PGD</u>) and rejection (short-term implants beyond 30 days post-transplant) strategies. The number of implants for PGD has increased over the period, with 63 in 2024/2025. Implants for rejection are relatively uncommon, with the highest number recorded in 2021/2022.

Figure 2.3 Total number of adult post-transplant device implants in the UK, by strategy and financial year, 1 April 2015 to 31 March 2025

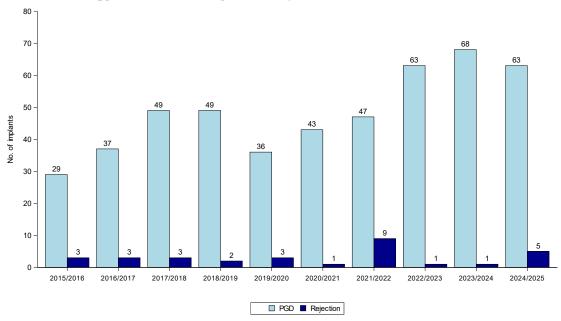
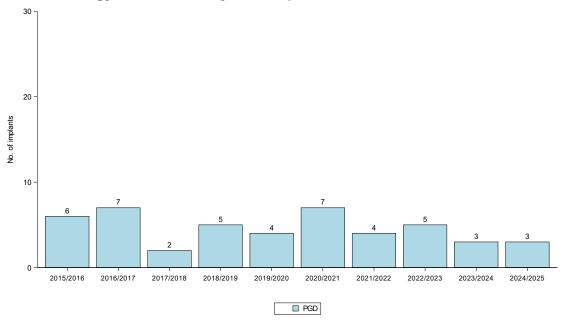


Figure 2.4 shows the same breakdown for paediatric post-transplant implants over the last ten years. There were no devices used for rejection in paediatric patients across the decade.

Figure 2.4 Total number of paediatric post-transplant device implants in the UK, by strategy and financial year, 1 April 2015 to 31 March 2025



In total (adult and paediatric combined) there were 561 post-transplant implants across the decade in 458 patients; 371 (81%) patients had a single device implant, 72 (16%) had two implants, 14 (3%) had three and 1 (0.2%) had four (see <u>Table A1.4</u> and <u>Table A1.5</u> in Appendix A1 for details of device histories).

Figure 2.5 shows the number of adult patients reported as alive on bridging support as of 31 March 2025 by centre and device type. In total, there were 327 patients alive on a long-term device and 10 alive on short-term support, with Birmingham having the highest number of patients on long-term support. **Figure 2.6** shows the same information but for paediatric patients. There were 16 paediatric patients alive on support on 31 March 2025, 14 of them on VAD support and 2 on ECMO support.

Figure 2.5 Number of adult patients alive on bridging support on 31 March 2025, by device type and centre

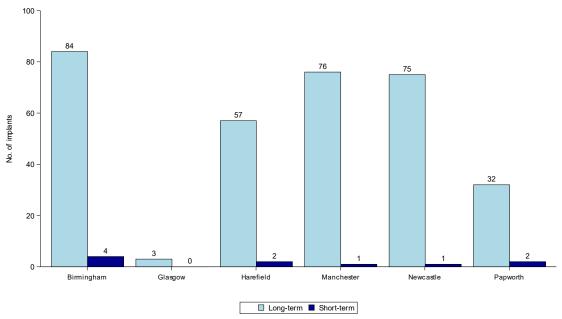
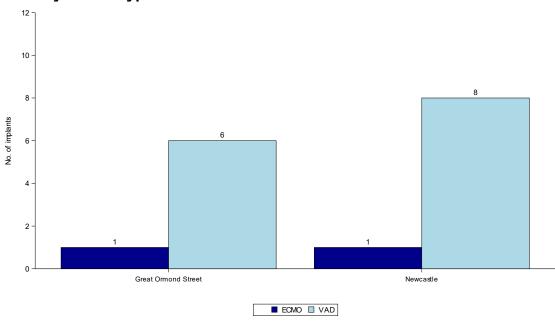


Figure 2.6 Number of paediatric patients alive on bridging support on 31 March 2025, by device type and centre



Tables 2.1 and **2.2** show a summary of the number of adult and paediatric patients and implants that have been reported to the MCS <u>Database</u> by centres for the period 1 April 2015 to 31 March 2025, and separately for the most recent year, 1 April 2024 to 31 March 2025. **Table 2.1** reflects the adult data while **Table 2.2** reflects the paediatric data.

Table 2.1 Number of adult patients receiving devices and number of implants, by strategy and centre, 1 April 2015 to 31 March 2025 Strategy Centre 1 April 2015 - 31 March 2025 1 April 2024 - 31 March 2025 No. of Type of device No. patients No. of Type of device No. patients TAH ST VAD* ECMO implants LT VAD TAH ST VAD* ECMO implants LT VAD Bridging Birmingham Glasgow¹ Harefield Manchester Newcastle Papworth¹ Total Post-transplant Birmingham Glasgow Harefield Manchester Newcastle Papworth **91**² **424**² 10³ **58**³ Total

^{*} Includes Berlin Heart devices

¹ Includes 3 implants performed at non-transplanting centre where patients were then transferred: 2 to Papworth and 1 to Glasgow.

² Includes 15 ST VAD and 16 ECMO used for rejection which are excluded from the rest of the report

³ Includes 2 ST VAD and 3 ECMO used for rejection which are excluded from the rest of the report

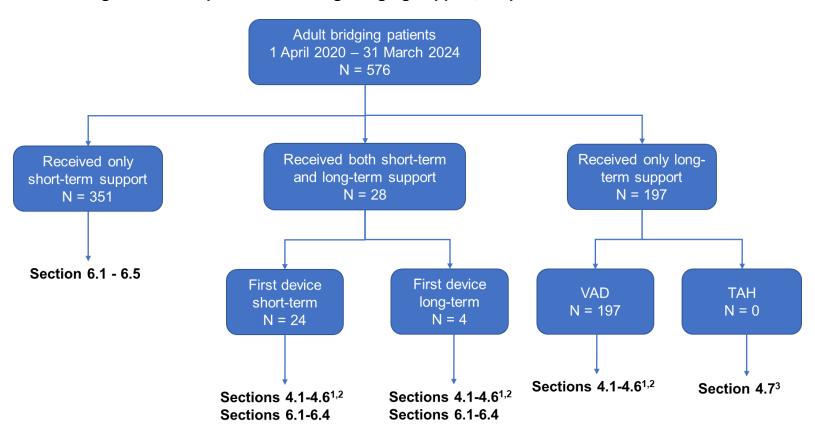
Table 2.2 Number of paediatric patients receiving devices and number of implants, by strategy and centre, 1 April 2015 to 31 March 2025

Strategy	Centre	1 Ap	oril 2015	- 31 Mar	ch 2025	1 A	pril 202	4 - 31 Mar	ch 2025
		No. of implants	Type o	of device ECMO	No. patients	No. of implants	Type o	of device ECMO	No. patients
Bridging	Great Ormond Street	130	85	45	102	18	6	12	13
	Newcastle ¹	126	101	25	91	16	11	5	12
	Total	256	186	70	193	34	17	17	25
Post-transplant	Great Ormond Street	22	1	21	22	0	0	0	0
	Newcastle	24	0	24	23	3	0	3	3
	Total	46	1	45	45	3	0	3	3

l Includes 3 implants performed at non-transplanting centre where patients were then transferred to Newcastle

Figure 2.7 shows a flow diagram of the number of adult patients receiving bridging support between 1 April 2020 and 31 March 2024, which is the period used for most of the outcome analyses, and which outcome section they are included in depending on their device history. This includes all patients in the long-term bridging, short-term bridging, and TAH outcomes sections as detailed also in <u>Table A1.1</u>. In total, 578 adult patients received bridging support in the period, of which 199 received only long-term support, 345 received only short-term support, and 34 received both long-term and short-term support.

Figure 2.7 Flow diagram of adult patients receiving bridging support, 1 April 2020 – 31 March 2024



¹ Section 4.5 uses a wider time period of implants; 1 April 2016 – 31 March 2024

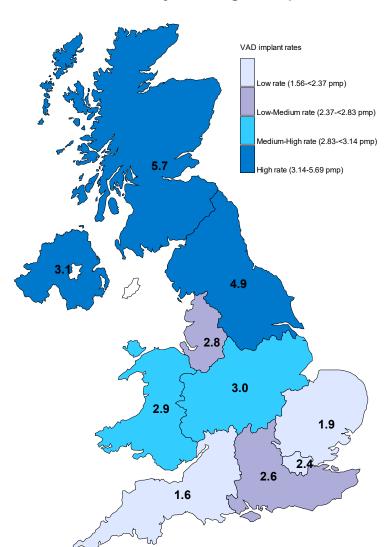
² 5 year survival from implant in section 4.6 uses implants during 1 April 2016 – 31 March 2020

³ Section 4.7 presents TAH activity across the decade; 1 April 2015 – 31 March 2025

Figure 2.8 shows the number of patients receiving MCS as a bridge to heart transplant per million population (pmp) between 1 April 2024 and 31 March 2025, by country/NHS region of patient residence. Overall, the number of patients receiving MCS was 3.0 pmp of the UK.

Since there will inevitably be some random variation in rates between areas, the systematic component of variation (SCV) was used to identify if the variation is more (or less) than a random effect for the different NHS regions in England only. The larger the SCV the greater the evidence of a high level of systematic variation between areas. Implant rates yielded an SCV of 0.08 (p-value = 0.004). The p-value shows the probability that an SCV of this size (or higher) would be observed by chance if only random variation existed and therefore, there is evidence of geographical variation beyond what would be expected at random. No adjustment has been made for area-specific demographic characteristics that may impact the rates of implantation such as age and sex. Therefore, these results should be interpreted with caution.

Figure 2.8 Number of patients receiving MCS as a bridge to heart transplantation per million population (pmp) in the UK, 1 April 2024 - 31 March 2025, by country/NHS region of patient residence



Country/	Patien	ts (pmp)
NHS region		,
in io rogion		
North East and Yorkshire	40	(4.9)
North West	21	(2.8)
Midlands	33	(3.0)
East of England	12	(1.9)
London	21	(2.4)
South East	24	(2.6)
South West	9	(1.6)
		, ,
England	160	(2.8)
Isle of Man	0	(0.0)
Channel Islands	0	(0.0)
		` ,
Wales	9	(2.9)
Scotland	31	(5.7)
Northern Ireland	6	(3.1)
TOTAL	206	(3.0)

ADULT LONG-TERM DEVICES USED FOR BRIDGING

Activity

3 Long-term bridging devices in adults

Figure 3.1

This section considers all patients who received a long-term device as a bridge to heart transplantation. All figures and tables in this section present information on a per implant basis as opposed to per patient, so if a single patient had more than one long-term device implant in the time period, each is counted. If a patient had a previous short-term device, their long-term device is included.

Figure 3.1 shows the total number of long-term bridging device implants in the last ten years nationally by device type (long-term VAD or TAH). During 2024/2025 there were 57 implants reported: 24% fewer than in 2023/2024. Figure 3.2 shows the trend per centre, with Harefield and Birmingham having a marked decline in implants over the decade. Last year's activity is shown by centre and device type in Figure 3.3. The highest number of implants last year was performed by Newcastle.

financial year and device type, 1 April 2015 to 31 March 2025 150 120

Number of adult long-term bridging device implants in the UK, by

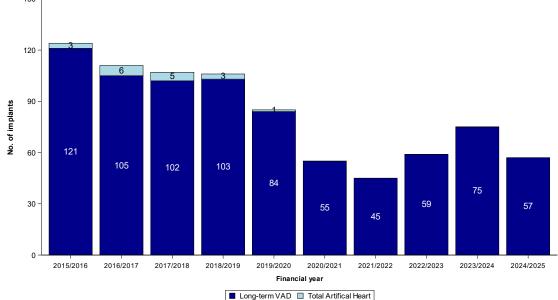


Figure 3.2 Number of adult long-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2015 to 31 March 2025

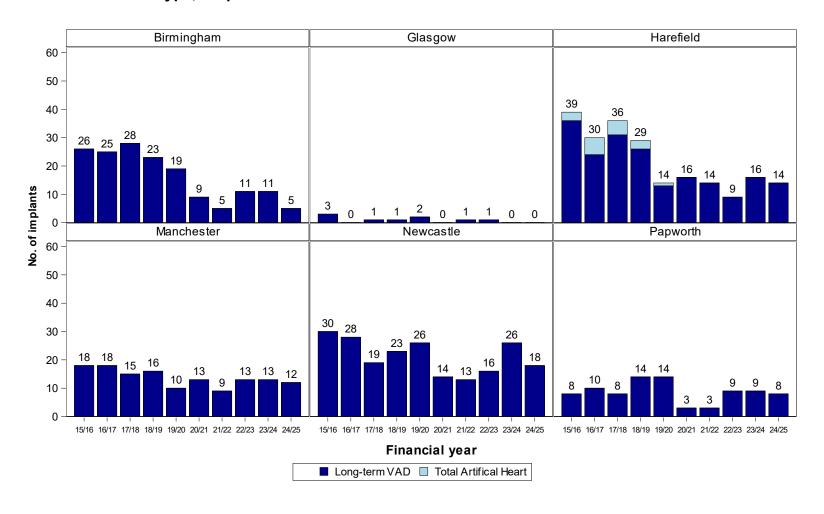


Figure 3.3 Number of adult long-term bridging device implants in the UK, by centre and device type, 1 April 2024 to 31 March 2025

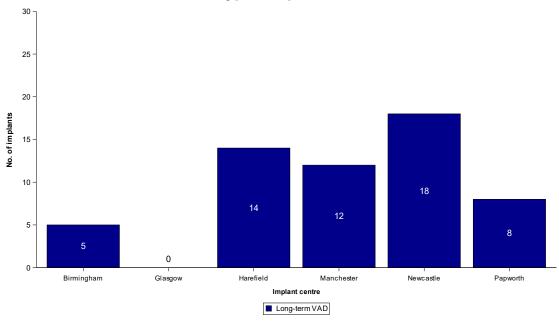
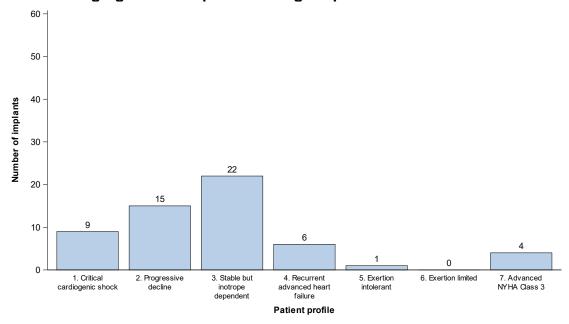


Figure 3.4 shows the <u>INTERMACS patient profile</u> at time of long-term VAD implantation for patients implanted during 2024/2025. Level 3 (stable but inotrope dependent) was the most common, followed by levels 2 (progressive decline), 1 (critical cardiogenic shock) and 4 (recurrent advanced heart failure).

Figure 3.4 INTERMACS patient profile of adult patients receiving long-term bridging device implants during 1 April 2024 – 31 March 2025



ADULT LONG-TERM DEVICES USED FOR BRIDGING

Patient Outcomes

4 Outcomes for adult patients with long-term bridging devices

This section only considers patients whose first long-term device was a <u>continuous-flow</u> long-term VAD. Patients who received prior short-term support are included in this section. All patients had follow-up information available (as detailed in **Table A1.3** in <u>Appendix A1</u>). Patients are analysed on a per-patient basis and patients who received a Total Artificial Heart are considered separately in <u>Section 4.7</u>.

4.1 Demographic characteristics

The demographic characteristics of the 225 patients analysed in this section are shown below in **Table 4.1**, by centre and overall. Nationally, 78% of patients were male, the median age was 55 years and 87% of patients received Heartmate III. Note that for some characteristics, such as BMI, there is a high proportion of missing data, and some summary statistics are not presented for Glasgow due to small numbers. Due to rounding, percentages may not sum to 100.

Table 4.1 Character	istics of adult patients who receiv	ed a first long-	term VAD b	etween 1 Apri	il 2020 and 31	March 2024, b	y centre	
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
Number of patients		33	2	52	46	68	24	225
Recipient age (years)	Median (IQR) ¹ Missing	54 (48-65) 0	- 0	53 (45-60) 0	54 (44-61) 0	55 (49-60) 0	54 (42-58) 0	55 (45-60) 0
Recipient sex	Male Female	24 (73) 9 (27)	2 (100) 0 (0)	40 (77) 12 (23)	39 (85) 7 (15)	55 (81) 13 (19)	15 (63) 9 (38)	175 (78) 50 (22)
Primary disease	Dilated cardiomyopathy Ischaemic heart disease Congenital heart disease Hypertrophic cardiomyopathy Valvular heart disease Other	4 (12) 28 (85) 0 (0) 0 (0) 0 (0) 1 (3)	0 (0) 1 (50) 0 (0) 0 (0) 0 (0) 1 (50)	23 (44) 24 (46) 1 (2) 1 (2) 1 (2) 2 (4)	25 (54) 18 (39) 0 (0) 2 (4) 1 (2) 0 (0)	37 (54) 27 (40) 3 (4) 1 (1) 0 (0) 0 (0)	11 (46) 9 (38) 1 (4) 2 (8) 0 (0) 1 (4)	100 (44) 107 (48) 5 (2) 6 (3) 2 (1) 5 (2)
INTERMACS patient profile	 Critical cardiogenic shock Progressive decline Stable but inotrope dependent 	5 (15) 3 (9) 20 (61)	0 (0) 0 (0) 1 (50)	7 (13) 18 (35) 24 (46)	7 (15) 9 (20) 20 (43)	4 (6) 15 (22) 27 (40)	1 (4) 2 (8) 3 (13)	24 (11) 47 (21) 95 (42)

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
	Recurrent advanced heart failure	5 (15)	1 (50)	3 (6)	9 (20)	22 (32)	5 (21)	45 (20)
	5. Exertion intolerant	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	5 (21)	6 (3)
	6. Exertion limited	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (8)	2 (1)
	7. Advanced NYHA Class 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	6 (25)	6 (3)
Pre-implant BMI	Median (IQR) ¹	27 (25-29)	-	26 (24-30)	26 (23-29)	27 (25-29)	28 (27-32)	27 (24-30)
	Missing	1	0	13	1	24	7	46
Pre-implant creatinine	Median (IQR) ¹	93 (74-123)	-	110 (87-152)	81 (64-107)	113 (100-147)	114 (90-140)	102 (80-129
(umol/l)	Missing	0	0	1	0	25	0	26
Pre-implant bilirubin (umol/l)	Median (IQR) ¹	17 (13-25)	-	21 (13-28)	15 (10-22)	21 (14-31)	16 (12-32)	17 (12-26)
	Missing	0	0	5	0	54	1	60
First device implanted	Heartware HVAD	0 (0)	0 (0)	14 (27)	0 (0)	16 (24)	0 (0)	30 (13)
	HeartMate III	33 (100)	2 (100)	38 (73)	46 (100)	52 (76)	24 (100)	195 (87)
Device configuration	LVAD	32 (97)	2 (100)	52 (100)	46 (100)	66 (97)	24 (100)	222 (99)
	RVAD	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)	0 (0)	2 (1)
	BiVAD	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0)
Conjunction ST RVAD support	No	23 (70)	2 (100)	44 (85)	38 (83)	52 (76)	22 (92)	181 (80)
	Yes	10 (30)	0 (0)	8 (15)	8 (17)	16 (24)	2 (8)	44 (20)
Previous transplant	No	33 (100)	2 (100)	52 (100)	46 (100)	68 (100)	24 (100)	225 (100)
Previous ST support	No	30 (91)	2 (100)	39 (75)	43 (93)	62 (91)	23 (96)	199 (88)
	Yes	3 (9)	0 (0)	13 (25)	3 (7)	6 (9)	1 (4)	26 (12)

4.2 Duration on support

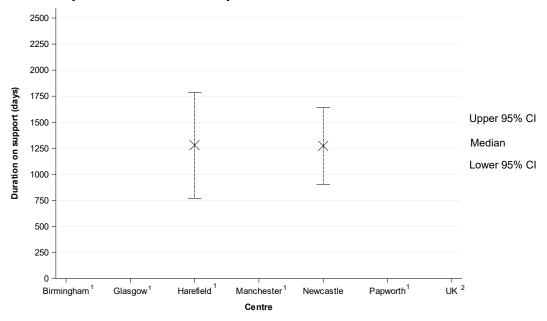
Table 4.2 and **Figure 4.1** show the <u>median</u> duration on long-term VAD support for patients implanted in the analysis period, both nationally and by centre. The <u>medians</u> and <u>confidence</u> <u>intervals</u> are estimated using the <u>Kaplan-Meier method</u> since not all patients have come to the end of their support, and this method allows these (censored) patients to be included in the analysis. Transplant, explant or death signify end of support. If a patient was subsequently given a short-term device, only time on the long-term device is counted. Nationally, the <u>median</u> time on long-term support was 1578 days (4.3 years). There is no evidence that the duration varies across centres (log-rank p=0.36) with medians not estimable for Birmingham, Papworth and Manchester as insufficient numbers of patients had come to the end of support at time of analysis (or for Glasgow due to small numbers of patients).

	an duration on long-term V een 1 April 2021 and 31 Mar					
Centre	Number of patients	Tir	ne on support (days)			
	•	<u>Median</u>	(95% confidence interval)			
Birmingham ¹	33	_	-			
Glasgow ²	2	-	-			
Harefield	52	1280	772 - 1788			
Manchester ¹	46	-	-			
Newcastle	68	1273	905 - 1641			
Papworth	24	-	-			
Overall ³	225	1578	-			
¹ Median duration on support cannot be estimated as insufficient numbers of patients have come to the						

end of support

² Median duration on support not presented due to a small number of patients

Figure 4.1 Median duration on long-term VAD support for adult patients implanted between 1 April 2020 and 31 March 2024



¹ Median duration on support cannot be estimated

³ <u>Confidence interval</u> of <u>median</u> duration on support cannot be estimated as insufficient numbers of patients have come to the end of support

² Confidence interval cannot be estimated

4.3 Rate of transplant listing

Figure 4.2 and **Table 4.3** show the rate of transplant listing for patients first implanted between 1 April 2020 and 31 March 2024, by centre. This includes listing on either the super-urgent, urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 22% of patients were on the list at implant, but this proportion ranged significantly across centres (chi-squared p=0.0006). The proportion still on a VAD at one year and not listed was 39% overall and was highest at Birmingham (76%). Note that Glasgow's figures are based on just two patients.

Figure 4.2 Heart transplant listing status with respect to long-term VAD implantation for adult patients receiving a first device 1 April 2020 – 31 March 2024, by centre and overall

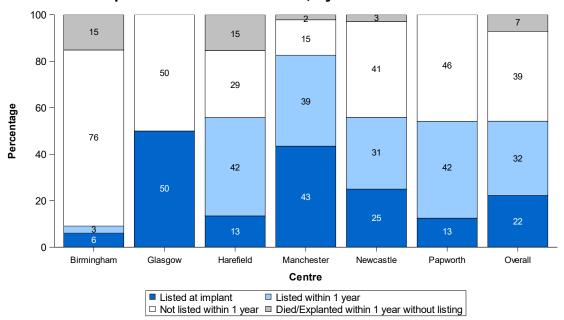


Table 4.3	Heart transplant list patients receiving a				
Centre	Number of patients	Listed at VAD implant	Listed within 1 year	Not listed within 1 year	Died/explanted within 1 year without listing
	N	N (%)	N (%)	N (%)	N (%)
Birmingham	33	2 (6)	1 (3)	25 (76)	5 (15)
Glasgow	2	1 (50)	0 (0)	1 (50)	0 (0)
Harefield	52	7 (13)	22 (42)	15 (29)	8 (15)
Manchester	46	20 (43)	18 (39)	7 (15)	1 (2)
Newcastle	68	17 (25)	21 (31)	28 (41)	2 (3)
Papworth	24	3 (13)	10 (42)	11 (46)	0 (0)
Overall	225	50 (22)	72 (32)	87 (39)	16 (7)

4.4 Competing outcomes

Whilst on VAD support, patients are susceptible to different outcomes. Death on support, transplant, and explant without transplant (with or without recovery) are all possible outcomes. **Figure 4.3** shows the <u>cumulative incidence</u> of each of these outcomes occurring from time of implant, for the cohort of patients receiving a first long-term device between 1 April 2020 and 31 March 2024. This is calculated using the <u>Aalen-Johansen method</u> to account for <u>competing outcomes</u>. At time zero, 100% of patients are on support and as time passes, patients either experience death on support, transplant or explant without transplant. At any time point, the proportion alive on support plus the proportions experiencing each outcome will sum to 100%. Deaths after transplant are not counted and these patients are classed simply as transplanted. Patients who were explanted and died within 30 days of explant are counted as deaths at time of explant. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one long-term device to another without a period free of support, this counts as time on support.

Figure 4.3 Cumulative incidence of transplant, death and explant for adult patients implanted with a first long-term VAD, 1 April 2020 to 31 March 2024

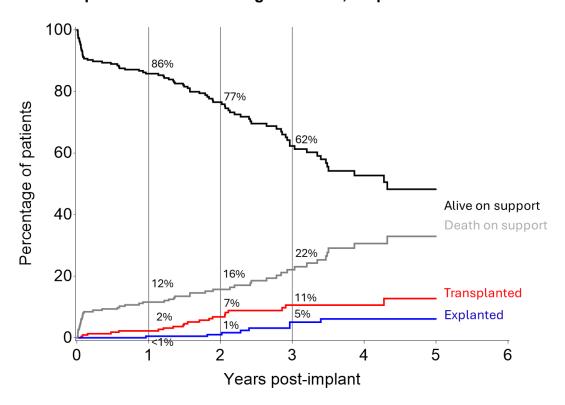


Table 4.4a and **Table 4.4b** shows the centre-specific one-year and three-year estimates for each competing outcome, respectively. The incidence of each outcome varies across centres.

Cumulative incidence of each outcome at 1 year, by centre, for adult patients implanted with a first long-term VAD, 1 April 2020 to 31 March 2024 Table 4.4a Centre Number of Transplanted Explanted Alive on Death on patients support support % % % % Birmingham Glasgow Harefield Manchester Newcastle Papworth Overall

Table 4.4b	Cumulative incide patients implanted				
Centre	Number of patients	Transplanted	Explanted	Alive on support	Death on support
		%	%	%	%
Birmingham	33	0	0	77	23
Glasgow	2	0	0	100	0
Harefield	52	9	3	55	33
Manchester	46	18	7	60	15
Newcastle	68	9	9	57	26
Papworth	24	18	0	82	0
Overall	225	11	5	62	22

4.5 Survival on support

This section presents <u>Kaplan-Meier</u> estimates of <u>patient survival during long-term VAD</u> <u>support</u>. The cohort used was extended in order to calculate 5 year survival rates, in comparison to the previous sections. All patients who received a <u>long-term VAD</u> were included, whether this was their first VAD or after a <u>short-term VAD</u>. Survival time is calculated as the time on long-term VAD support only, and death on long-term support (including patients who died within 30 days of explant) is the only event considered. Times were censored if the patient had their long-term VAD explanted, received a transplant from support or were alive on support at last report. This differs from the analysis in <u>Section 4.6</u> which considers a patient's overall survival from the point of implant and includes survival time after explant or transplant, as well as time on other subsequent devices.

Figure 4.4 shows survival on long-term support for the UK VAD population. **Table 4.5** shows the unadjusted centre-specific <u>survival on support rates</u> at 30 days, 1 year, 3 years and 5 years respectively along with the national rates. There was a significant difference between unadjusted survival on support at each time point between centres (log-rank $p \le 0.003$).

Figure 4.4 Patient survival during long-term VAD support for adult patients implanted 1 April 2016 – 31 March 2024

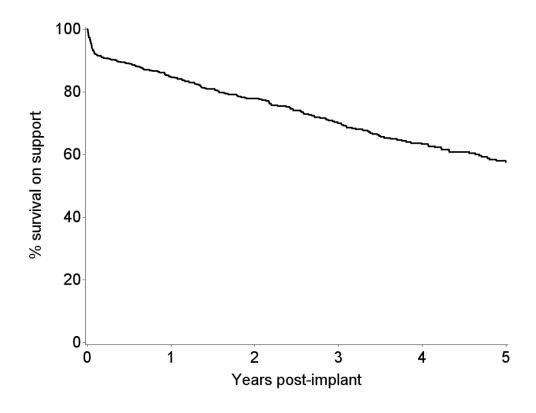


Table 4.5	Unadjusted	surviv	al during long	-term V	AD support, by	centre, 1	April 2016 to 3	31 March	2024
Centre	No. of patients) day survival (95% CI)		year survival (95% CI)		year survival 95% CI)	% 5	year survival (95% CI)
Birmingham	124	91.0	(84.4 - 94.9)	86.9	(79.5 - 91.8)	75.6	(66.5 - 82.5)	64.0	(54 - 72.4)
Glasgow ¹	6	-	-	-	-	-	-	-	-
Harefield	141	86.4	(79.5 - 91.1)	75.3	(67.2 - 81.7)	56.6	(47.4 - 64.8)	41.5	(31.2 - 51.4)
Manchester	104	94.2	(87.6 - 97.4)	91.3	(84 - 95.4)	87.1	(78.2 - 92.6)	81.9	(71.2 - 88.9)
Newcastle	157	96.1	(91.6 - 98.2)	84.6	(77.7 - 89.5)	60.6	(50.9 - 69.0)	41.8	(30.3 - 52.9)
Papworth	69	98.6	(90.2 - 99.8)	90.8	(80.5 - 95.8)	84.5	(71.8 - 91.7)	72.4	(41.6 - 88.8)
Number at risk	k	549		473		253		134	
Log-rank p-va	alue		0.003		0.002	<	0.0001		<0.0001
UK	601	92.6	(90.2 - 94.5)	84.7	(81.5 - 87.3)	70.0	(65.7 - 73.9)	57.5	(52.4 - 62.3)

¹ <u>Survival rates</u> for groups with fewer than 10 patients are not presented due to small numbers

4.6 Patient survival from implant

Overall survival rates from the point of first long-term VAD implant, not censored for transplant or explant, are presented in this section. Survival data from the UK Transplant Registry were incorporated, as was any additional survival time recorded on the MCS
Database for patients who were explanted. Time on additional devices is also counted, so for example if a patient had a period of long-term support, then a period of short-term support, all this time is included. Times are censored if the patient was still alive at last known event or follow-up.

<u>Survival rates</u> are calculated using the <u>Kaplan-Meier method</u> and are based on those patients recorded as receiving a first device between 1 April 2020 and 31 March 2024 for 30 day, 1-year, and 3-year, while 5-year survival rates are based on patients receiving a first device between 1 April 2016 and 31 March 2020. It is acknowledged that not all patients implanted between 1 April 2020 and 31 March 2024 have 3 year follow-up, and therefore the analysis will be changed next year to allow for adequate follow-up for all patients in the 3 year survival analysis.

In **Tables 4.6-4.9** and **Figures 4.5-4.8** the centre-specific <u>survival rates</u> are presented for 30 days, 1 year, 3 years and 5 years respectively. The survival rates are compared with the national rate and the uncertainty around this rate using <u>funnel plots</u> where outliers appear outside of the funnels; rates above the funnel are significantly high while rates below the funnel are significantly low. Rates for Glasgow are not included due to low activity.

The centre-specific rates are not adjusted for differences in risk between patients treated at different centres. These differences can be seen for the 30 day and 1 year survival rates cohort at the start of this section in **Table 4.1** which displays baseline characteristics for implants between 1 April 2020 and 31 March 2024 (including the number of patients who received prior short-term support).

The <u>unadjusted</u> centre-specific 30-day <u>survival rates</u> for patients implanted in the recent period are shown in **Table 4.6** and **Figure 4.5**. The rate for Papworth exceeded the upper 99.8% <u>confidence limit</u>, indicating a higher unadjusted rate than the national rate. All other centres were consistent with the national rate of 92.4%.

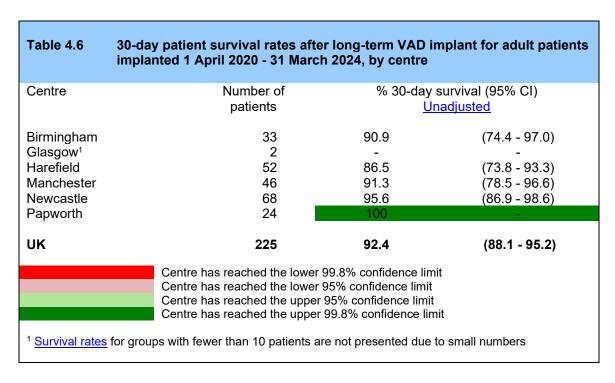
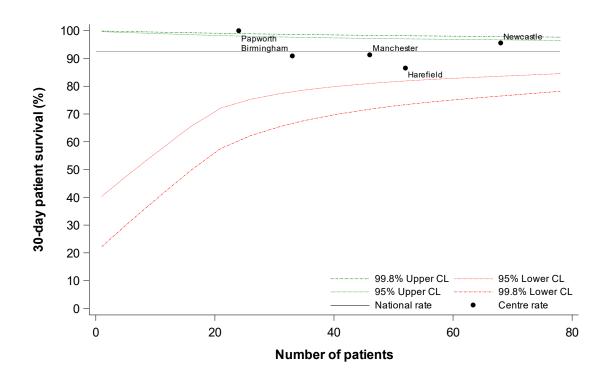


Figure 4.5 Unadjusted 30-day patient survival rates after long-term VAD implant for adult patients implanted 1 April 2020 - 31 March 2024, by centre



The <u>unadjusted</u> centre-specific 1-year <u>survival rates</u> are shown in **Table 4.7** and **Figure 4.6**. The rate for Papworth exceeded the upper 95% <u>confidence limit</u>, indicating a higher unadjusted rate than the national rate. All other centres were consistent with the national rate of 87.1%.

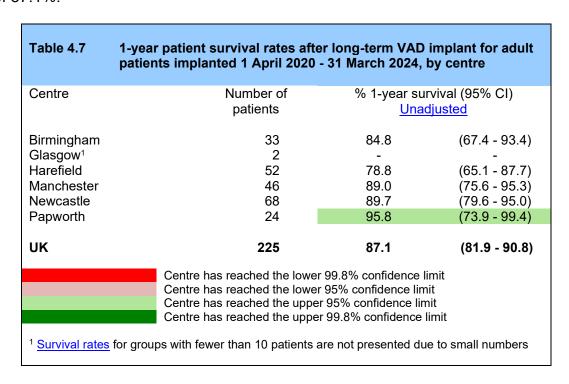
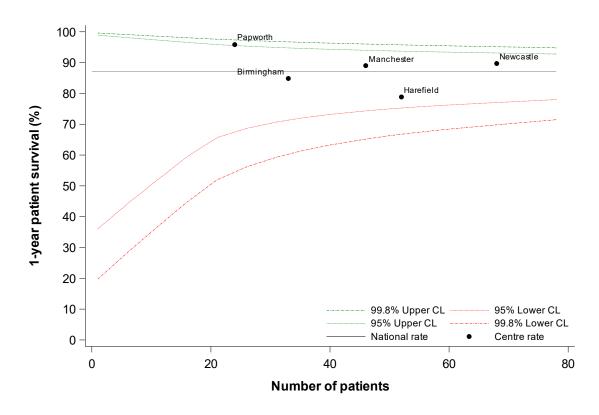


Figure 4.6 Unadjusted 1-year survival rates after long-term VAD implant for adult patients implanted 1 April 2020 - 31 March 2024, by centre



The <u>unadjusted</u> centre-specific 3-year <u>survival rates</u> are shown in **Table 4.8** and **Figure 4.7**. The rate for Manchester exceeded the upper 95% <u>confidence limit</u>, indicating a higher unadjusted rate than the national rate while the rate for Harefield was below the lower 95% <u>confidence limit</u>, indicating a lower unadjusted rate than the national rate.

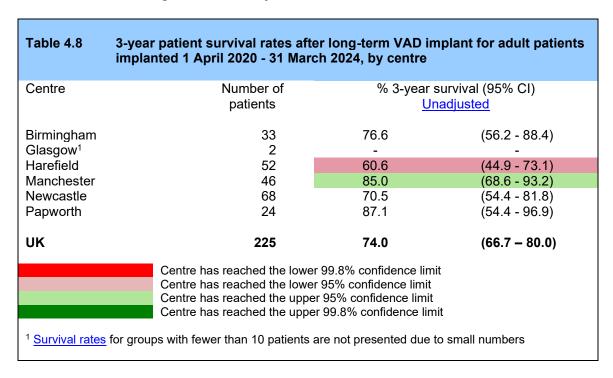
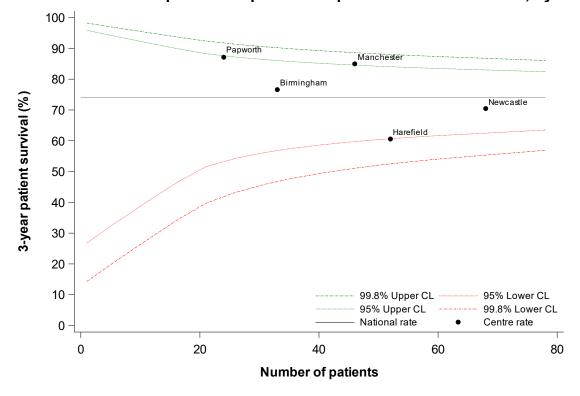


Figure 4.7 Unadjusted 3-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2020 - 31 March 2024, by centre



The <u>unadjusted</u> centre-specific 5-year <u>survival rates</u> are shown in **Table 4.9** and **Figure 4.8**. Note that this is calculated for a more historic cohort of patients compared with the previous analyses. The rate for Manchester exceeded the upper 99.8% <u>confidence limit</u>, indicating a higher unadjusted rate than the national rate while the rate for Harefield was below the lower 99.8% <u>confidence limit</u>, indicating a lower unadjusted rate than the national rate. There was also some evidence of a higher rate at Birmingham and a lower rate at Newcastle.

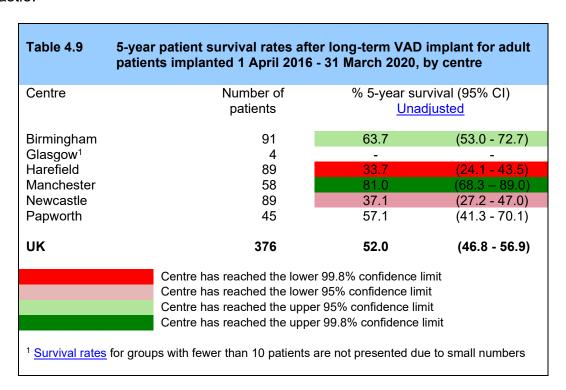
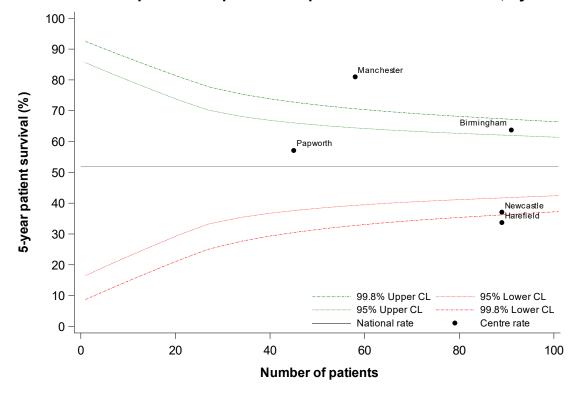


Figure 4.8 Unadjusted 5-year patient survival rates after long-term VAD implant for adult patients implanted 1 April 2016 – 31 March 2020, by centre



4.7 TAH outcomes

Table 4.10 shows the outcomes of the 18 patients who received a <u>TAH</u> as a bridge to transplant in the time period. All patients are considered, including those who received other MCS prior to the TAH and those who received a TAH post-transplant. Only Harefield have used TAH in the time period, however this is historic practice with Harefield not implanting any TAHs since April 2019. **Table 4.11** shows the 30-day and 1-year post-implant <u>survival rates</u> for these patients. The 30-day rate was 77.8% but this fell to 27.8% at 1 year, however caution should be taken when interpreting this rate due to the small cohort.

Table 4.10	Outcomes of TAH red	cipients, by im	plant centre, 1 A	pril 2015 to 3	1 March 2025
Centre	Number of patients N	Alive on support N (%)	Died not on list N (%)	Died on list N (%)	Survived to transplant N (%)
Harefield	18	0 (0)	8 (44)	2 (11)	8 (44)
Overall	18	0 (0)	8 (44)	2 (11)	8 (44)

Table 4.11	Patient survival rates a 1 April 2015 to 31 March	
Number of patients	% 30-day survival (95% CI)	% 1-year survival (95% CI)
18	77.8 (51.1 - 91)	27.8 (10.1 - 48.9)

ADULT SHORT-TERM DEVICES USED FOR BRIDGING

Activity

5 Short-term bridging devices in adults

This section considers all patients who received <u>short-term</u> support as a bridge to heart transplantation. All figures and tables present information on a per implant basis as opposed to per patient, so if a single patient had more than one short-term device implant in the time period, each one is counted.

Figure 5.1 shows the total number of short-term bridging device implants over the last ten years nationally by device type (<u>ECMO</u> or <u>short-term VAD</u>). During 2024/2025 there were 166 implants: 14% more than 2023/2024. Over the decade there have been more short-term VAD implants than ECMO procedures, however, around a quarter of the short-term VAD implants were reported to have involved some form of conjunction ECMO (either transient or ongoing). **Figure 5.2** shows the trend per centre, with most centres experiencing an increase over the decade in the number of short-term device implants. Last year's implant activity is shown by centre and device type in **Figure 5.3**; the highest number of short-term implants were for Harefield.

Figure 5.1 Number of adult short-term bridging device implants in the UK, by financial year and device type, 1 April 2015 to 31 March 2025

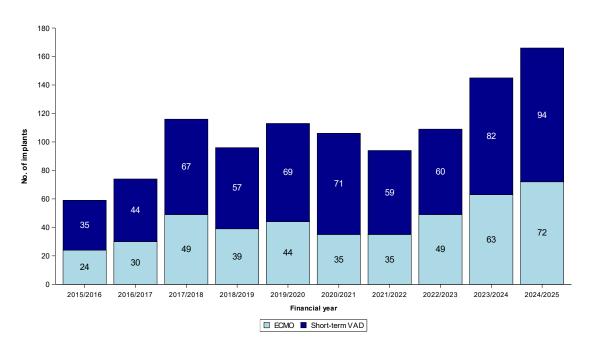


Figure 5.2 Number of adult short-term bridging device implants in the UK, by financial year, centre and device type, 1 April 2015 to 31 March 2025

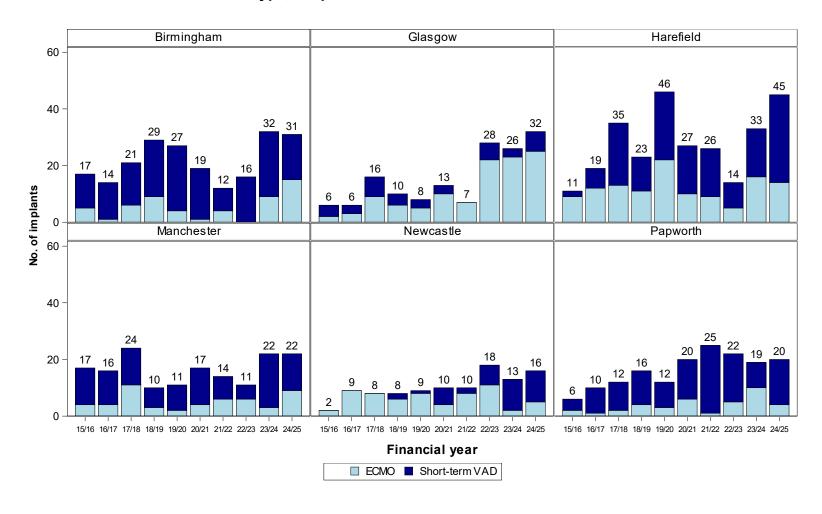


Figure 5.3 Number of adult short-term bridging device implants in the UK, by centre and device type, 1 April 2024 to 31 March 2025

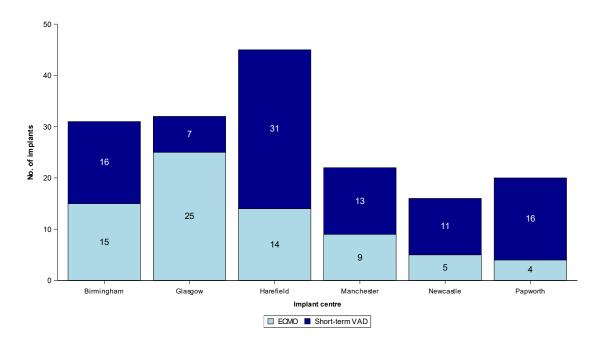
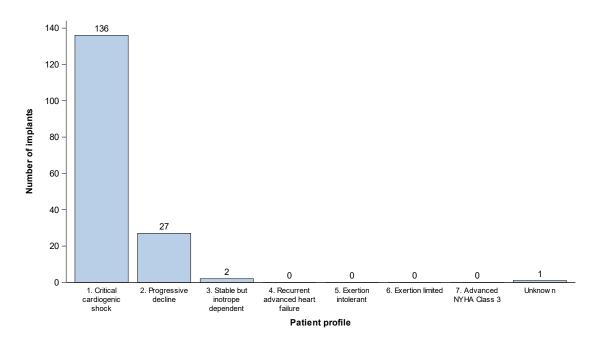


Figure 5.4 shows the <u>INTERMACS patient profile</u> at receipt of short-term support for patients implanted during 2024/2025. Most patients were profile 1 (critical cardiogenic shock).

Figure 5.4 INTERMACS patient profile for all short-term bridging device implants in adult patients in the UK, 1 April 2024 to 31 March 2025



ADULT SHORT-TERM DEVICES USED FOR BRIDGING

Patient Outcomes

6 Outcomes of adult patients receiving short-term bridging devices

This section only considers patients who received a <u>short-term device</u> (including <u>ECMO</u>) as a bridge to transplant. Patients who received prior long-term support are included, apart from in <u>Section 6.5</u> which considers patients who received short-term support only. Patients are analysed on a per-patient basis, as opposed to per implant.

6.1 Demographic characteristics

The demographic characteristics of the 379 patients analysed in **Sections 6.2-6.4** are shown below in **Table 6.1**, by centre and overall. Nationally, 74% of patients were male, the median age was 45 years, 39% of patients received ventricular assist (Centrimag) devices and 6% were bridged to a long-term device. Note that for some characteristics, particularly pre-implant lactate, there is a high proportion of missing data. Also, due to rounding, percentages may not sum to 100.

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
Number of patients		65	67	74	57	43	73	379
Recipient age (years)	Median (IQR)	50 (39-57)	52 (38-60)	43 (28-52)	39 (31-45)	48 (40-55)	45 (31-52)	45 (34-54)
	Missing	0	0	0	0	0	0	0
Recipient sex	Male	50 (77)	50 (75)	52 (70)	37 (65)	37 (86)	56 (77)	282 (74)
	Female	15 (23)	16 (24)	22 (30)	20 (35)	6 (14)	17 (23)	96 (25)
	Unknown	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0)
Primary disease	Dilated cardiomyopathy Ischaemic heart disease Congenital heart disease Hypertrophic cardiomyopathy Restrictive cardiomyopathy Valvular heart disease Infiltrative heart muscle disease	29 (45) 22 (34) 1 (2) 2 (3) 1 (2) 3 (5) 2 (3)	12 (18) 39 (58) 0 (0) 2 (3) 0 (0) 2 (3) 2 (3)	44 (59) 17 (23) 3 (4) 0 (0) 0 (0) 2 (3) 2 (3)	34 (60) 12 (21) 0 (0) 0 (0) 0 (0) 1 (2) 0 (0)	15 (35) 11 (26) 4 (9) 0 (0) 0 (0) 1 (2) 1 (2)	43 (59) 17 (23) 0 (0) 3 (4) 0 (0) 3 (4) 2 (3)	177 (47) 118 (31) 8 (2) 7 (2) 1 (0) 12 (3) 9 (2)
	Other	2 (3)	5 (7)	5 (7)	10 (18)	6 (14)	3 (4)	31 (8)
	Unknown	3 (5)	5 (7)	1 (1)	0 (0)	5 (12)	2 (3)	16 (4)

Table 6.1 Characteristics	of adult patients who received	short-term bri	idging suppo	ort between 1	April 2020 and	d 31 March	2024, by centre	
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
INTERMACS patient profile	Critical cardiogenic shock Progressive decline	45 (69) 17 (26)	47 (70) 17 (25)	58 (78) 14 (19)	42 (74) 6 (11)	27 (63) 14 (33)	34 (47) 33 (45)	253 (67) 101 (27)
	Stable but inotrope dependent	3 (5)	3 (4)	0 (0)	1 (2)	1 (2)	2 (3)	10 (27)
	Recurrent advanced heart failure	0 (0)	0 (0)	1 (1)	4 (7)	1 (2)	2 (3)	8 (2)
	Exertion intolerant Exertion limited	0 (0) 0 (0)	0 (0) 0 (0)	1 (1) 0 (0)	0 (0) 0 (0)	0 (0) 0 (0)	0 (0) 0 (0)	1 (0) 0 (0)
	7. Advanced NYHA Class 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Unknown	0 (0)	0 (0)	0 (0)	4 (7)	0 (0)	2 (3)	6 (2)
First device implanted	Percutaneous VAD	15 (23)	2 (3)	23 (31)	0 (0)	18 (42)	3 (4)	61 (16)
	Ventricular assist (Centrimag) Peripheral ECMO	36 (55) 12 (18)	6 (9) 49 (73)	17 (23) 31 (42)	38 (67) 8 (14)	1 (2) 20 (47)	49 (69) 13 (18)	147 (39) 133 (35)
	Central ECMO	2 (3)	10 (15)	3 (4)	11 (19)	4 (9)	6 (8)	36 (10)
Previous long-term support	No	64 (98)	67 (100)	73 (99)	56 (98)	37 (86)	72 (99)	369 (97)
	Yes	1 (2)	0 (0)	1 (1)	1 (2)	6 (14)	1 (1)	10 (3)
Bridged to long-term support	No	62 (95)	67 (100)	62 (84)	55 (96)	38 (88)	72 (99)	356 (94)
	Yes	3 (5)	0 (0)	12 (16)	2 (4)	5 (12)	1 (1)	23 (6)
Pre-implant creatinine (umol/l)	Median (IQR) ¹ Missing	119 (86-156) 3	132 (96-192) 20	124 (92-166) 26	123 (82-149) 27	- 36	108 (82-152) 6	117 (88-164) 118
Pre-implant bilirubin (umol/l)	Median (IQR) ¹ Missing	35 (23-55) 3	15 (8-27) 26	27 (16-38) 39	21 (13-44) 32	- 40	27 (14-55) 10	27 (14-44) 150
Pre-implant lactate (mmol/l)	Median (IQR) ¹ Missing	3 (2-5) 14	3 (1-6) 30	4 (2-8) 45	- 49	- 40	3 (2-4) 62	3 (2-5) 240
Pre-implant cardiac arrest	No Yes	60 (92) 5 (8)	40 (60) 27 (40)	61 (82) 13 (18)	46 (81) 11 (19)	32 (74) 11 (26)	46 (65) 25 (35)	285 (76) 92 (24)
Pre-implant intubation and ventilation	No Yes	59 (91) 6 (9)	57 (85) 10 (15)	54 (73) 20 (27)	35 (61) 22 (39)	30 (70) 13 (30)	62 (87) 9 (13)	297 (79) 80 (21)

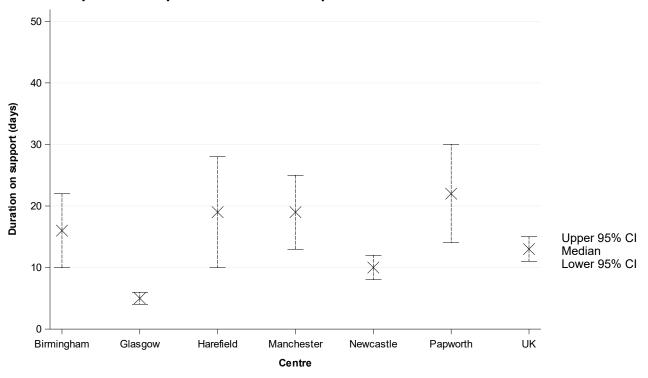
Table 6.1 Characteristics of adult patients who received short-term bridging support between 1 April 2020 and 31 March 2024, by centre								
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
Pre-implant renal replacement therapy	No Yes	64 (98) 1 (2)	61 (91) 6 (9)	66 (89) 8 (11)	47 (82) 10 (18)	23 (53) 20 (47)	68 (93) 5 (7)	329 (87) 50 (13)
Medians not presented for centres wit	th less than 10 observations reported							

6.2 Duration on support

Table 6.2 and **Figure 6.1** show the <u>median</u> duration on short-term support for patients implanted in the analysis period, both nationally and by centre. The <u>medians</u> and <u>confidence intervals</u> are estimated using the <u>Kaplan-Meier method</u>. Transplant, explant, death or transfer to a long-term device signify end of short-term support. If a patient went from <u>ECMO</u> to short-term <u>VAD</u>, all this time is counted. Nationally, the <u>median</u> time on support was 13 days and ranged from 5 days at Glasgow to 22 days at Papworth (log-rank p<0.0001).

Table 6.2	Median duration on short-term bridging device support for adult patients implanted between 1 April 2020 and 31 March 2024, by centre									
Centre	Number of	Time	on support (days)							
	patients	<u>Median</u>	(95% confidence interval)							
Birmingham	65	16	10 - 22							
Glasgow	67	5	4 - 6							
Harefield	74	19	10 - 28							
Manchester	57	19	13 - 25							
Newcastle	43	10	8 - 12							
Papworth	73	22	14 - 30							
Overall	379	13	11 - 15							

Figure 6.1 Median duration on short-term bridging device support for adult patients implanted between 1 April 2020 and 31 March 2024



6.3 Rate of transplant listing

Figure 6.2 and **Table 6.3** show the rate of transplant listing for patients first implanted between 1 April 2020 and 31 March 2024, by centre. This includes listing on the superurgent, urgent or non-urgent heart transplant lists (whichever occurred first) and considers time on long-term support if bridged to a long-term device. Overall, 21% of patients were on the list at short-term implant, which was a slightly smaller proportion than that observed for long-term implants (24%). This proportion ranged significantly between 11% at Manchester to 35% at Birmingham (chi-squared p=0.006). The proportion that died or were explanted within 1 month without listing was 43% overall and ranged significantly across centres (chi-squared p=0.0005).

Figure 6.2 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2020 – 31 March 2024, by centre and overall

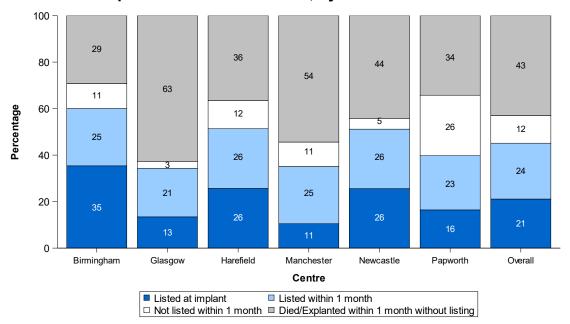


Table 6.3 Heart transplant listing status with respect to short-term device implantation for adult patients receiving a first bridging device 1 April 2020 - 31 March 2024, by centre and overall Centre Number of Listed at Listed within Not listed Died/explanted within patients implant 1 month within 1 month 1 month without listing Ν N (%) N (%) N (%) N (%) Birmingham 65 23 (35) 16 (25) 7 (11) 19 (29) Glasgow 67 9 (13) 14 (21) 42 (63) 2 (3) Harefield 74 19 (26) 19 (26) 9 (12) 27 (36) Manchester 57 6 (11) 14 (25) 6 (11) 31 (54) 19 (44) Newcastle 43 11 (26) 11 (26) 2 (5) Papworth 73 12 (16) 17 (23) 19 (26) 25 (34) 379 80 (21) 45 (12) Overall 91 (24) 163 (43)

6.4 Competing outcomes

Whilst on short-term support, patients are susceptible to different outcomes. Death on support, transplant, transfer to long-term support and explant without transplant are all possible outcomes. **Figure 6.3** shows the <u>cumulative incidence</u> of each of these outcomes occurring from time of implant, for the cohort of adult patients receiving a first short-term device between 1 April 2020 - 31 March 2024. This is calculated using the <u>Aalen-Johansen method</u> to account for <u>competing outcomes</u>. At time zero, 100% of patients are on support and as time passes, patients either experience death on support, transplant, transferral to long-term support or explant without transplant. At any time point, the proportion alive on support plus the proportions experiencing each outcome will sum to 100%. Deaths after transplant are not counted and these patients are classed simply as transplanted. Patients who were explanted and died within 30 days of explant are counted as deaths at time of explant. Any subsequent VAD support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one short-term device to another without a period free of support, this counts as time on support.

For this cohort, nationally, one month after short-term device implant, 20% of patients were explanted, 28% died on short-term support, 26% remained alive on support, 22% received a transplant, and 4% were transferred to a long-term device. At two months, there was an increase in the incidence of transplant to 32% and death to 31%, leading to a reduction in the proportion that remained alive on support, down to 12%.

Figure 6.3 Cumulative incidence of transplant, death, transferral to long-term device and explant for adult patients implanted with a first short-term bridging device, 1 April 2020 - 31 March 2024

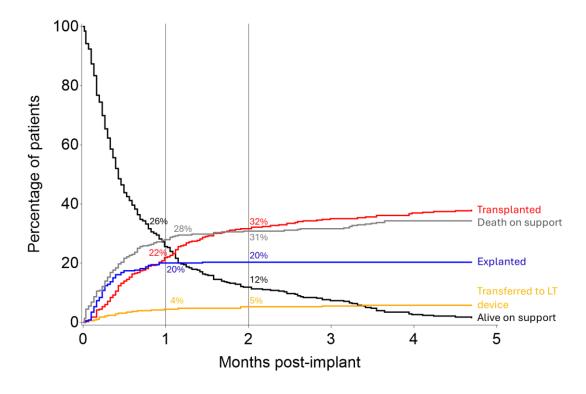


Table 6.4 shows the centre-specific 30-day estimates for each competing outcome. The incidence of each outcome varies across centres. Note that a patient may be counted as explanted but go on to have further support after a period without support, so this does not always represent recovery.

	Cumulative incidence with a first short-term					s implanted
Centre	Number of patients	Transplanted	Transferred to LT device	Explanted	Alive on support	Death on support
	·	%	%	%	%	%
Birmingham	65	29	5	5	31	31
Glasgow	67	30	0	31	4	34
Harefield	74	15	11	32	31	11
Manchester	57	14	0	23	32	32
Newcastle	43	23	12	19	9	37
Papworth	73	21	1	10	40	29
Overall	379	22	4	20	26	28

6.5 Patient survival from implant

Overall survival rates from the point of first short-term VAD implant, not censored for transplant or explant, are presented in this section. Survival data from the UK Transplant Registry were incorporated, as was any additional survival time recorded on the MCS
Database for patients who were explanted. Patients who received a short-term device as a bridge to long-term support are excluded from this analysis and instead included in Section 4.6 (as are patients who received prior long-term support). Times are censored if the patient was still alive at last known event or follow-up.

<u>Survival rates</u> are calculated using the <u>Kaplan-Meier method</u> and are based on those patients recorded as receiving a first device between 1 April 2020 and 31 March 2024. In **Tables 6.6** and **6.7** and **Figures 6.4** and **6.5** the centre-specific <u>survival rates</u> for implants are presented for 90 days and 1 year, respectively. The centre-specific rates are not adjusted for potential differences in risk between patients treated at different centres. These differences can be seen in **Table 6.5** which displays the baseline characteristics of the 345 patients included in this analysis. The survival rates are compared with the national rate and the uncertainty around this rate using <u>funnel plots</u> where outliers appear outside of the funnels; rates above the funnel are significantly high while rates below the funnel are significantly low.

The demographic characteristics of the 345 patients in this analysis are shown below in **Table 6.5**, by centre and overall. Nationally, 73% of patients were male, the median age was 45 years and 42% of patients received ventricular assist (Centrimag) devices. Note that for some characteristics, particularly pre-implant lactate, there is a high proportion of missing data. Also, due to rounding, percentages may not sum to 100.

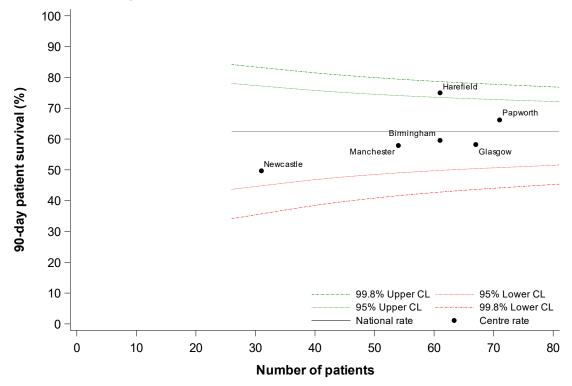
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
Number of patients		61	67	61	54	31	71	345
Recipient age (years)	Median (IQR) Missing	50 (37-56) 0	52 (38-60) 0	40 (25-50) 0	40 (31-45) 0	49 (40-54) 0	45 (30-52) 0	45 (34-54) 0
Recipient sex	Male Female Unknown	46 (75) 15 (25) 0 (0)	50 (75) 16 (24) 1 (1)	41 (67) 20 (33) 0 (0)	35 (65) 19 (35) 0 (0)	26 (84) 5 (16) 0 (0)	55 (77) 16 (23) 0 (0)	253 (73) 91 (26) 1 (0)
Primary disease	Dilated cardiomyopathy Ischaemic heart disease Congenital heart disease Hypertrophic cardiomyopathy Restrictive cardiomyopathy Valvular heart disease Infiltrative heart muscle disease Other Unknown	28 (46) 19 (31) 1 (2) 2 (3) 1 (2) 3 (5) 2 (3) 2 (3) 3 (5)	12 (18) 39 (58) 0 (0) 2 (3) 0 (0) 2 (3) 2 (3) 5 (7) 5 (7)	39 (64) 9 (15) 3 (5) 0 (0) 0 (0) 2 (3) 2 (3) 5 (8) 1 (2)	33 (61) 11 (20) 0 (0) 0 (0) 0 (0) 0 (0) 0 (0) 10 (19) 0 (0)	9 (29) 7 (23) 3 (10) 0 (0) 0 (0) 1 (3) 0 (0) 6 (19) 5 (16)	41 (58) 17 (24) 0 (0) 3 (4) 0 (0) 3 (4) 2 (3) 3 (4) 2 (3)	162 (47) 102 (30) 7 (2) 7 (2) 1 (0) 11 (3) 8 (2) 31 (9) 16 (5)
NTERMACS patient profile	 Critical cardiogenic shock Progressive decline Stable but inotrope dependent Recurrent advanced heart failure Exertion intolerant Exertion limited Advanced NYHA Class 3 Unknown 	42 (69) 16 (26) 3 (5) 0 (0) 0 (0) 0 (0) 0 (0) 0 (0)	47 (70) 17 (25) 3 (4) 0 (0) 0 (0) 0 (0) 0 (0) 0 (0)	50 (82) 9 (15) 0 (0) 1 (2) 1 (2) 0 (0) 0 (0) 0 (0)	40 (74) 5 (9) 1 (2) 4 (7) 0 (0) 0 (0) 0 (0) 4 (7)	22 (71) 9 (29) 0 (0) 0 (0) 0 (0) 0 (0) 0 (0) 0 (0)	33 (46) 33 (46) 2 (3) 1 (1) 0 (0) 0 (0) 0 (0) 2 (3)	234 (68) 89 (26) 9 (3) 6 (2) 1 (0) 0 (0) 0 (0) 6 (2)

		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
First device implanted	Percutaneous VAD	13 (21)	2 (3)	15 (25)	0 (0)	12 (39)	3 (4)	45 (13)
	Ventricular assist (Centrimag)	36 (59)	6 (9)	16 (26)	37 (69)	1 (3)	48 (70)	144 (42)
	Peripheral ECMO	10 (16)	49 (73)	28 (46)	7 (13)	17 (55)	12 (17)	123 (36)
	Central ECMO	2 (3)	10 (15)	2 (3)	10 (19)	1 (3)	6 (9)	31 (9)
Pre-implant creatinine (umol/l)¹	Median (IQR) Missing	117 (85-148) ⁻	132 (96-192) 20	119 (89-162) 25	128 (79-167) 27	- 27	108 (82-148) 6	116 (86-160) 108
Pre-implant bilirubin (umol/l)¹	Median (IQR)	37 (23-56)	15 (8-27)	30 (18-37)	25 (13-46)	-	27 (14-55)	28 (14-46)
	Missing	3	26	36	32	29	10	136
Pre-implant lactate (mmol/l)¹	Median (IQR)	3 (2-5)	3 (1-6)	4 (2-9)	-	-	3 (2-4)	3 (2-6)
	Missing	12	30	37	46	28	60	213
Pre-implant cardiac arrest	No	56 (92)	40 (60)	50 (82)	45 (83)	23 (74)	45 (65)	259 (76)
	Yes	5 (8)	27 (40)	11 (18)	9 (17)	8 (26)	24 (35)	84 (24)
Pre-implant intubation and ventilation	No	55 (90)	57 (85)	46 (75)	34 (63)	21 (68)	60 (87)	273 (80)
	Yes	6 (10)	10 (15)	15 (25)	20 (37)	10 (32)	9 (13)	70 (20)
Pre-implant renal replacement	No	60 (98)	61 (91)	54 (89)	44 (81)	17 (55)	66 (93)	302 (88)
herapy	Yes	1 (2)	6 (9)	7 (11)	10 (19)	14 (45)	5 (7)	43 (12)

The <u>unadjusted</u> centre-specific 90-day <u>survival rates</u> for patients receiving short-term support are shown in **Table 6.6** and **Figure 6.4**. The national survival rate was 62.4. Harefield exceeded the upper 95% <u>confidence limit</u> while all other centres remained within the 95% confidence interval.

Table 6.6	90-day patient survival rates after patients implanted 1 April 2020 a		•						
Centre	Number of patients	•	ırvival (95% CI) <u>djusted</u>						
Birmingham Glasgow Harefield Manchester Newcastle Papworth	61 67 61 54 37 71	59.6 58.2 75.0 57.9 49.7 66.2	(46.0 - 70.8) (45.5 - 68.9) (62.0 - 84.1) (43.4 - 69.9) (30.8 - 66.0) (53.9 - 75.9)						
UK	UK 351 62.4 (57 - 67.3)								
Centre has reached the lower 99.8% confidence limit Centre has reached the lower 95% confidence limit Centre has reached the upper 95% confidence limit Centre has reached the upper 99.8% confidence limit									

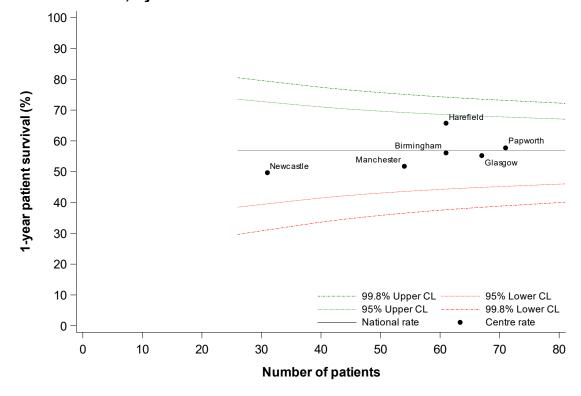
Figure 6.4 Unadjusted 90-day patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2020 and 31 March 2024, by centre



The <u>unadjusted</u> centre-specific 1-year <u>survival rates</u> are shown in **Table 6.7** and **Figure 6.5**. The national survival rate was 56.9% and all centre rates were within the 95% confidence limits.

Table 6.8	1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2020 and 31 March 2024, by centre								
Centre	Number of patients	% 1-year survival (95% CI) <u>Unadjusted</u>							
Birmingham Glasgow Harefield Manchester Newcastle Papworth	61 67 61 54 31 71	56.1 55.2 65.7 51.8 49.7 57.7	(42.6 - 67.6) (42.6 - 66.2) (52.0 - 76.4) (37.4 - 64.3) (30.8 -66.0) (45.4 - 68.2)						
UK	345	56.9	(51.4 - 62.0)						
Centre has reached the lower 99.8% confidence limit Centre has reached the lower 95% confidence limit Centre has reached the upper 95% confidence limit Centre has reached the upper 99.8% confidence limit									

Figure 6.5 Unadjusted 1-year patient survival rates after short-term bridging device implant for adult patients implanted 1 April 2020 and 31 March 2024, by centre



ADULT SHORT-TERM DEVICES USED POST-HEART TRANSPLANT

Activity

7 Short-term post-transplant devices in adults

This section considers all patients who received <u>short-term support</u> within 30 days following heart transplantation. The International Society for Heart and Lung Transplantation defines <u>primary graft dysfunction (PGD)</u> as graft dysfunction without a discernible cause and defines severe PGD as needing MCS. Therefore, the data in this section predominantly indicates the level of severe PGD in the UK heart transplant population, but also includes a small number of patients with secondary graft dysfunction who required MCS.

All figures and tables present information on a per transplant basis; if a single patient had more than one transplant, the device type is based on all devices used in that episode. Short-term devices used more than 30 days post-heart transplant (rejection) are excluded (31 recorded in the time period) as are long-term devices used post-transplant (classed as bridging devices).

Figure 7.1a shows the total number of transplants requiring short-term device implants within 30 days in the last ten years, nationally, by device type (<u>ECMO</u>, <u>short-term VAD</u> and ECMO and short-term VAD). During 2024/2025 there were 53 transplants requiring support: 5% lower than 2023/2024 but 2.12 times higher than in 2014/2015. **Figure 7.2a** shows the trend per centre and **Figure 7.3a** shows last year's activity by centre and device type, indicating that Birmingham had the highest number of transplants requiring support in 2023/2024.

Figures **7.1b**, **7.2b** and **7.3b** show the proportion of transplants requiring short-term support within 30 days out of the total number of adult heart transplants by financial year, financial year and centre, and centre respectively. The denominator of adult heart transplants includes both DBD and DCD heart transplants, any re-transplants, as well as any multiorgan heart transplants. See Section 8.4 for a breakdown of the number and proportion of adult heart transplants requiring support by donor type.

Figure 7.1a Number of adult heart transplants requiring short-term support within 30 days, by financial year and device type, 1 April 2015 to 31 March 2025

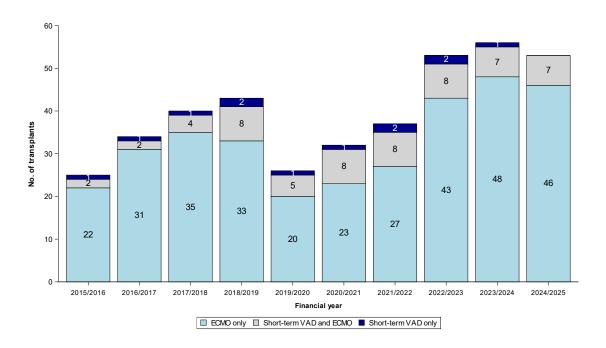


Figure 7.1b Proportion of transplants requiring short-term support within 30 days (PGD), out of total number of adult heart transplant by financial year, 1 April 2015 to 31 March 2025

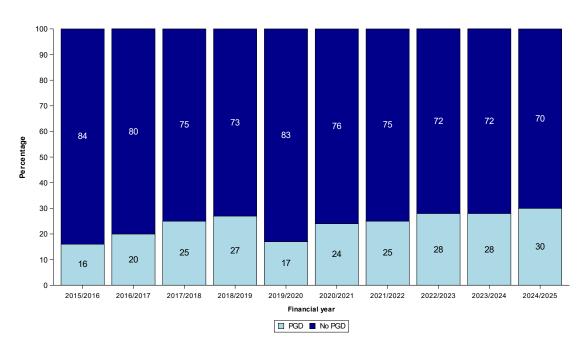


Figure 7.2a Number of adult heart transplants requiring short-term support within 30 days, by financial year, centre and device type, 1 April 2015 to 31 March 2025

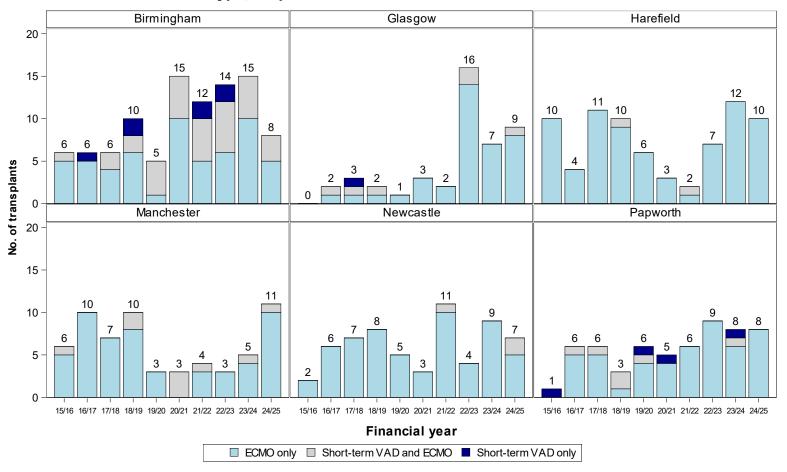


Figure 7.2b Proportion of transplants requiring short-term support within 30 days (PGD), out of total number of adult heart transplant by financial year and centre, 1 April 2015 to 31 March 2025

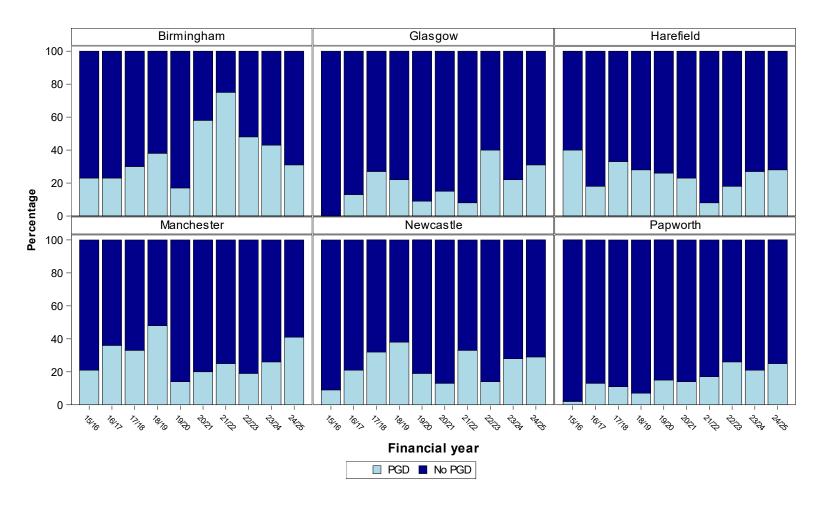


Figure 7.3a Number of adult heart transplants requiring short-term support within 30 days, by centre and device type, 1 April 2024 to 31 March 2025

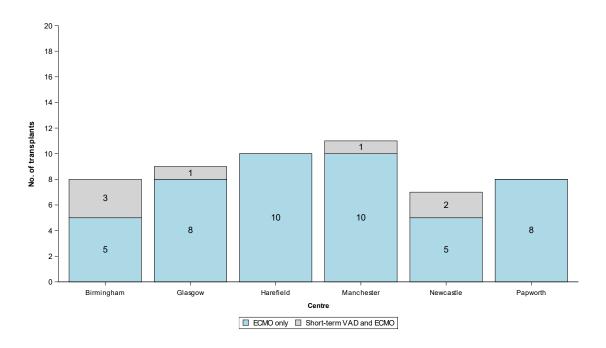
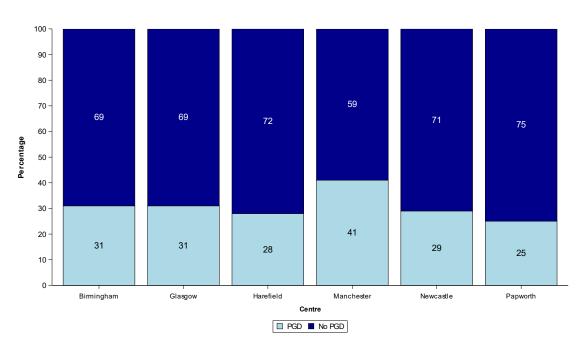


Figure 7.3b Proportion of transplants requiring short-term support within 30 days (PGD), out of total number of adult heart transplants, by centre, 1 April 2024 to 31 March 2025



ADULT SHORT-TERM DEVICES USED POST-HEART TRANSPLANT

Patient Outcomes

8 Outcomes of adult patients receiving short-term devices within 30 days post-heart transplant

This section analyses patients on a per-patient basis, as opposed to per implant. If a patient was moved from one short-term device to another, this is counted as one observation.

8.1 Demographics characteristics

The transplant characteristics (as reported on the <u>UKTR</u> and <u>MCS Database</u>) of the 178 patients analysed in this section are shown in **Table 8.1**, by centre and overall. Nationally, 66% of patients were in hospital pre-transplant, the median age was 48 years and 58% of patients received central ECMO only. The median ischaemia time was 4.0 hours. For some characteristics, due to rounding, percentages may not sum to 100.

Table 8.1 Characteristics of ac and 31 March 2024, I	dult patients receiving short by centre	-term support v	vithin 30 day	ys post-hear	t transplant l	oetween 1 A	pril 2020	
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)
Number of patients		56	28	24	15	27	28	178
Urgency at transplant	Non-urgent	11 (20)	7 (25)	3 (13)	3 (20)	3 (11)	15 (54)	42 (24)
	Urgent	22 (39)	13 (46)	16 (67)	6 (40)	22 (81)	6 (21)	85 (48)
	Super-urgent	23 (41)	8 (29)	5 (21)	6 (40)	2 (7)	7 (25)	51 (29)
Recipient age at transplant (years)	Median (IQR)	45 (36-57)	53 (40-60)	49 (37-57)	44 (19-53)	46 (37-51)	51 (37-58)	48 (37-56)
	Missing	0	0	0	0	0	0	0
Diabetes at registration	No	47 (84)	24 (86)	20 (83)	15 (100)	23 (85)	25 (89)	154 (87)
	Yes	7 (13)	3 (11)	2 (8)	0 (0)	2 (7)	2 (7)	16 (9)
	Missing	2 (4)	1 (4)	2 (8)	0 (0)	2 (7)	1 (4)	8 (4)
Recipient primary disease at registration	Coronary heart disease	12 (21)	2 (7)	4 (17)	9 (60)	1 (4)	2 (7)	30 (17)
	Cardiomyopathy	33 (59)	25 (89)	17 (71)	5 (33)	16 (59)	18 (64)	114 (64)
	Congenital heart disease	8 (14)	0 (0)	1 (4)	0 (0)	8 (30)	1 (4)	18 (10)
	Graft failure/Rejection	0 (0)	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)	2 (1)
	Other	3 (5)	1 (4)	2 (8)	1 (7)	0 (0)	7 (25)	14 (8)
Recipient BMI (kg/m²)	Median (IQR)	26 (24-29)	28 (26-30)	27 (24-29)	26 (25-31)	23 (21-27)	27 (25-28)	26 (24-29)
	Missing	0	0	0	0	0	0	0

Table 8.1 Characteristics of adult patients receiving short-term support within 30 days post-heart transplant between 1 April 2020 and 31 March 2024, by centre Birmingham Glasgow Harefield Manchester Newcastle Papworth Total N (%) 9 (33) In hospital at transplant No 14 (25) 10 (36) 6 (25) 4 (27) 17 (61) 60 (34) Yes 42 (75) 18 (64) 18 (75) 11 (73) 18 (67) 11 (39) 118 (66) If in hospital, recipient on inotropes No 21 (50) 1 (6) 2 (11) 8 (73) 1 (6) 8 (73) 41 (35) Yes 21 (50) 17 (94) 3 (27) 16 (94) 3 (27) 76 (65) 16 (89) If in hospital, recipient on VAD None 22 (52) 15 (83) 12 (67) 2 (18) 15 (83) 2 (18) 68 (58) LVAD 4 (10) 2 (11) 1 (6) 3 (27) 3 (17) 1 (9) 14 (12) 0 (0) RVAD 0(0)0(0)0(0)0(0)1 (9) 1 (1) 5 (28) 35 (30) **BiVAD** 16 (38) 1 (6) 6 (55) 0(0)7 (64) If in hospital, recipient on TAH 42 (100) 18 (100) 18 (100) 18 (100) No 11 (100) 11 (100) 118 (100) 17 (94) If in hospital, recipient on ECMO No 41 (98) 14 (78) 17 (94) 11 (100) 11 (100) 111 (94) 0 (0) 6 (5) 3 (17) Yes 1 (2) 1 (6) 1 (6) 0(0)Unknown 0(0)1 (6) 0(0)0(0)0(0)0(0)1 (1) If in hospital, recipient on IABP No 42 (100) 7 (39) 18 (100) 11 (100) 18 (100) 11 (100) 107 (91) Yes 0(0)0 (0) 0(0)11 (61) 0(0)0(0)11 (9) Recipient serum creatinine (umol/l) Median (IQR) 72 (57-89) 101 (90-125)114 (84-130) 72 (46-115) 106 (76-131)97 (73-115) **90 (66-118)** Missing 0 6 0 0 0 0 CVA Donor cause of death 45 (80) 22 (79) 20 (83) 12 (80) 22 (81) 25 (89) 146 (82) Trauma 0(0)0(0)2 (13) 5 (19) 3 (5) 1 (4) 11 (6) Other 8 (14) 6 (21) 4 (17) 1 (7) 0(0)2 (7) 21 (12) Median (IQR) 39 (28-49) 41 (34-50) 38 (31-50) 30 (25-38) 32 (25-38) 36 (30-46) 37 (28-47) Donor age (years) 0 Missing 0 0 25 (22-28) 24 (21-29) 25 (21-27) 24 (22-28) 26 (24-28) 26 (23-29) Donor BMI (kg/m²) Median (IQR) 27 (24-31) Missing 0 0 0 0 0 0 0 No 19 (34) 6 (25) 6 (40) 12 (43) 69 (39) Donor past smoker 13 (46) 13 (48) 14 (52) Yes 36 (64) 15 (54) 17 (71) 9 (60) 16 (57) 107 (60) Unknown 1 (2) 0(0)1 (4) 0(0)0(0)0 (0) 2 (1)

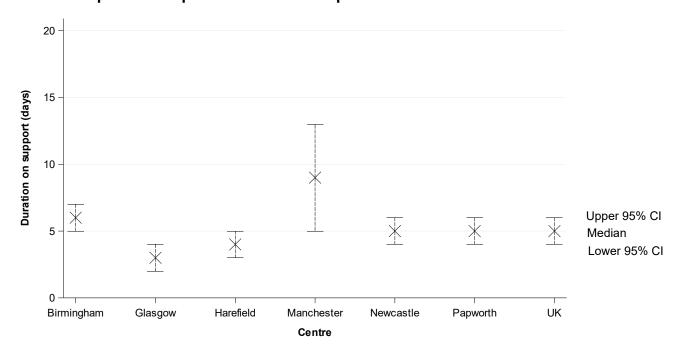
	Table 8.1 Characteristics of adult patients receiving short-term support within 30 days post-heart transplant between 1 April 2020 and 31 March 2024, by centre								
		Birmingham N (%)	Glasgow N (%)	Harefield N (%)	Manchester N (%)	Newcastle N (%)	Papworth N (%)	Total N (%)	
Donor: Recipient sex misn	natch RF:DF RF:DM RM:DM RM:DF	20 (36) 1 (2) 29 (52) 6 (11)	8 (29) 1 (4) 15 (54) 4 (14)	5 (21) 1 (4) 14 (58) 4 (17)	7 (47) 1 (7) 7 (47) 0 (0)	5 (19) 4 (15) 17 (63) 1 (4)	5 (18) 4 (14) 13 (46) 6 (21)	50 (28) 12 (7) 95 (53) 21 (12)	
Total ischaemia time (hou	Median (IQR) Missing	3.7 (3.2-4.5) 3 5	3.5 (2.9-4.2) 6	4.5 (3.9-5.7) 1	3.6 (3.1-4.3) ·	4.2 (3.3-5.4) 2	4.8 (3.5-7)	4.0 (3.3-5.3) 15	
First device implanted	Percutaneous VAD Ventricular assist (Centrimag) Peripheral ECMO Central ECMO	1 (2) 6 (11) 45 (80) 4 (7)	0 (0) 0 (0) 7 (25) 21 (75)	0 (0) 1 (4) 2 (8) 21 (88)	0 (0) 0 (0) 1 (7) 14 (93)	0 (0) 0 (0) 9 (33) 18 (67)	0 (0) 2 (7) 0 (0) 26 (93)	1 (1) 9 (5) 64 (36) 104 (58)	

8.2 Duration on support

Table 8.2 and **Figure 8.1** show the <u>median</u> duration on short-term support for patients implanted in the analysis period, both nationally and by centre. The <u>medians</u> and <u>confidence intervals</u> are estimated using the <u>Kaplan-Meier method</u>. This includes time spent on any short-term device post-transplant so if a patient went from <u>ECMO</u> to short-term <u>VAD</u>, all this time is counted. Nationally, the <u>median</u> time on support was 5 days and was similar across centres. Manchester had a small number of patients on support for a number of weeks leading to a wide estimate for the median.

Table 8.2 Median duration on short-term device support within 30 days post-heart transplant for adult patients implanted between 1 April 2020 and 31 March 2024, by centre										
Centre		Number of patients	Tim Median	ne of support (days) (95% confidence interval)						
		•								
Birmingham		56	6	5 - 7						
Glasgow		28	3	2 - 4						
Harefield		24	4	3 - 5						
Manchester		15	9	5 - 13						
Newcastle		27	5	4 - 6						
Papworth		28	5	4 - 6						
Overall		178	5	4 - 6						

Figure 8.1 Median duration on short-term device support for PGD for adult patients implanted between 1 April 2020 and 31 March 2024



8.3 Patient survival from implant

This analysis looks at the rate of survival from the point of first short-term device implant post-heart transplant. This uses data from the <u>UK Transplant Registry (UKTR)</u> on post-transplant survival. <u>Survival rates</u> are calculated using the <u>Kaplan-Meier method</u> where times are censored if the patient was still alive at last known follow-up. If the patient was retransplanted, any subsequent survival time is included. The rates are estimated at 90 days and 1 year and are based on the 178 patients recorded as receiving a short-term device for <u>PGD</u> between 1 April 2020 – 31 March 2024. Survival rates are given nationally and for individual centres. Note that the centre-specific rates are unadjusted for potential differences in risk between patients treated at different centres.

The <u>unadjusted</u> 90-day and 1-year <u>survival rates</u> for patients in the time period are shown in **Tables 8.3**, **8.4** and **8.5**, respectively. The national rates of survival were 79.7% and 73.3%, respectively.

Table 8.3	90-day patient survival ra for adult patients implan			
Centre	Number of patients	Number of deaths	% 90-day survival (95% CI) <u>Unadjusted</u>	
Birmingham Glasgow Harefield Manchester Newcastle Papworth	56 28 24 15 27 28	6 6 6 3 6 9	89.3 78.6 75.0 80.0 76.9 67.9	(77.7 - 95.0) (58.4 - 89.8) (52.6 - 87.9) (50.0 - 93.1) (55.7 - 88.9) (47.3 - 81.8)
UK	178	36	79.7	(73.0 - 84.9)

	r patient survival rate ult patients implante			post-heart transplant centre	
Centre	Number of patients	Number of deaths	% 1-year survival (95% CI) <u>Unadjusted</u>		
Birmingham	56	9	83.6	(70.8 - 91.1)	
Glasgow	28	7	75.0	(54.6 - 87.2)	
Harefield	24	11	53.5	(31.8 - 71.0)	
Manchester	15	3	80.0	(50.0 - 93.1)	
Newcastle	27	7	72.9	(51.4 - 86.1)	
Papworth	28	10	64.3	(43.8 - 78.9)	
UK	178	47	73.3	(66.1 - 79.2)	

8.4 Patient survival from heart transplant

Table 8.5 shows the number of adult heart transplants performed between 1 April 2020 and 31 March 2024, by centre, donor type and whether the recipient received short-term MCS within 30 days of transplant. Patient survival from point of transplant is also presented for 90-days and 1-year post-transplant. <u>Survival rates</u> are calculated using the <u>Kaplan-Meier method</u> where times are censored if the patient was still alive at last known follow-up. The rates are based on the 505 DBD and 165 DCD adult heart transplants performed in the time period, including any re-transplants as well as multi-organ heart transplants.

Transplants requiring support had significantly worse patient survival rates at both 90-days and 1-year compared to transplants without support in both DBD transplants (p<0.0001) and DCD transplants (p<0.0001).

Table 8.6	Number of adult heart transplants with and without short-term MCS within 30 days, by donor type and centre, and 90 day and 1
	year survival rates nationally, 1 April 2020 – 31 March 2024

	DBD			DCD			
	Required support	No support	Total	Required support	No support	Total	
	Number of	Number of	Number of	Number of	Number of	Number of	
Centre	transplants (%)	transplants (%)	transplants	transplants (%)	transplants (%)	transplants	
Birmingham	46 (52)	42 (48)	88	9 (50)	9 (50)	18	
Glasgow	24 (26)	70 (74)	94	4 (18)	18 (82)	22	
Harefield	15 (19)	65 (81)	80	8 (21)	31 (79)	39	
Manchester	12 (21)	44 (79)	56	3 (30)	7 (70)	10	
Newcastle	17 (19)	71 (̀81)́	88	10 (34)	19 (66)	29	
Papworth	14 (14)	85 (86)	99	14 (̀30)́	33 (70)	47	
uk	128 (25)	377 (75)	505	48 (29)	117 (71)	165	
90-day survival (95% CI)	77.6 (69.2-84.0)	96.5 (94.1-98.0)	91.8 (89.0-93.9)	83.3 (69.4-91.3)	100(-)	95.1 (90.4-97.5	
1-year survival (95% CI)	75.1 (66.5-81.8)	94.1 (91.2-96.1)	89.4 (86.3-91.8)	66.0 (50.6-77.6)	95.6 (89.9-98.2)	87.0 (80.7-91.3	

PAEDIATRIC DEVICES USED FOR BRIDGING Activity

9 Mechanical circulatory support in paediatric patients

This section considers all paediatric (aged less than 16 years) patients who received mechanical circulatory support as a bridge to heart transplantation between 1 April 2015 and 31 March 2025, as reported to the MCS Database by 15 October 2025. Note that 46 post-transplant MCS implants were reported in this period, which are excluded from this section. **Figures 9.1a**, **9.2a**, and **9.3a**, as well as all tables in this activity section present information on a per implant basis as opposed to per patient, so if a single patient had more than one implant in the period, each one is included (see Table A1.5 in Appendix A1 for details of device histories). **Figures 9.1b**, **9.2b** and **9.3b** present information on a per episode basis as opposed to per implant, so if a single patient had more than one type of device in a continuous period of support, these devices will be grouped and the episode only counted once in the financial year in which the first device of the episode was implanted.

Figure 9.1a shows the total number of bridging device implants each year nationally by device type (<u>VAD</u> and <u>ECMO</u>). In 2024/2025, there were 34 implants, twice the number in 2023/2024 and the highest level of activity recorded in the past decade. Overall, there were 256 implants, with VAD implants making up 73% (however, approximately 8% of the VAD implants were reported to have involved some form of conjunction ECMO, either transient or ongoing). **Figure 9.2a** shows the trend per centre for the two paediatric centres. Last year's activity is shown by centre and device type in **Figure 9.3a**.

Figures **9.1b**, **9.2b** and **9.3b** show the same data but on a per episode bases as opposed to a per implant basis, by financial year, financial year and centre, and centre respectively. Each episode is assigned to the financial year in which the first device of the episode was implanted.

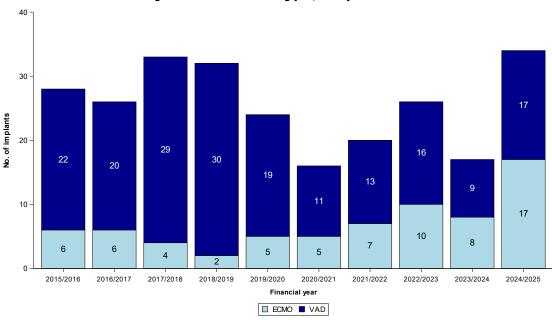


Figure 9.1a Number of paediatric bridging device implants in the UK, by financial year and device type, 1 April 2015 to 31 March 2025

Figure 9.1b Number of paediatric bridging episodes in the UK, by financial year and devices implanted, 1 April 2015 to 31 March 2025

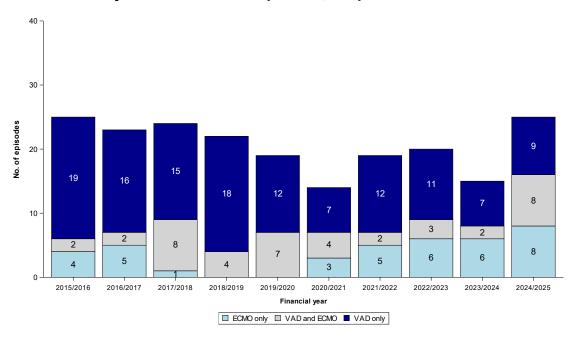


Figure 9.2a Number of paediatric bridging device implants in the UK, by financial year, centre and device type, 1 April 2015 to 31 March 2025

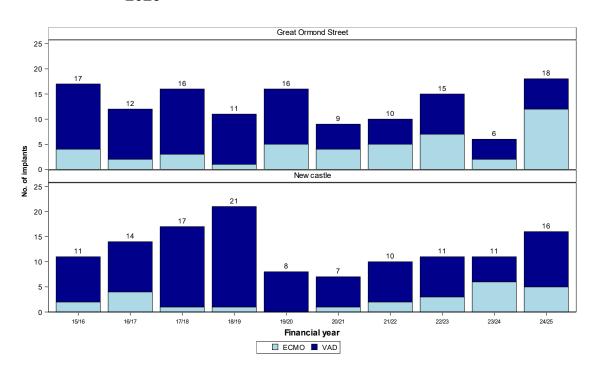


Figure 9.2b Number of paediatric bridging episodes in the UK, by financial year, centre and devices implanted, 1 April 2015 to 31 March 2025

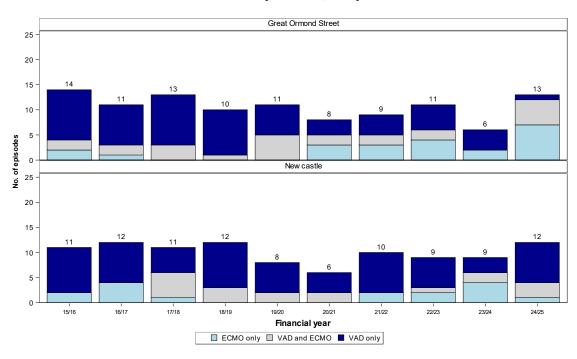


Figure 9.3a Number of paediatric bridging device implants in the UK, by centre and device type, 1 April 2024 to 31 March 2025

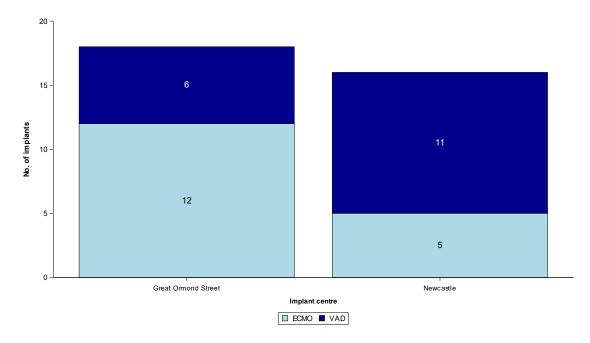


Figure 9.3b Number of paediatric bridging episodes in the UK, by centre and devices implanted, 1 April 2024 to 31 March 2025

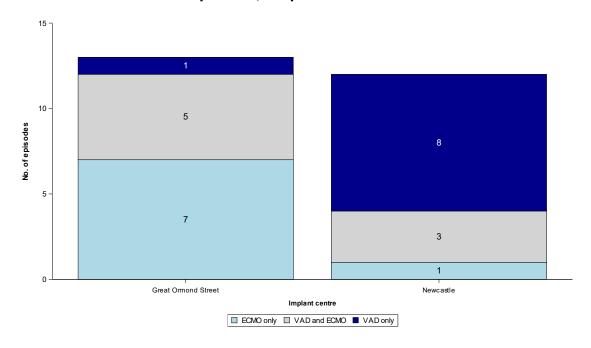
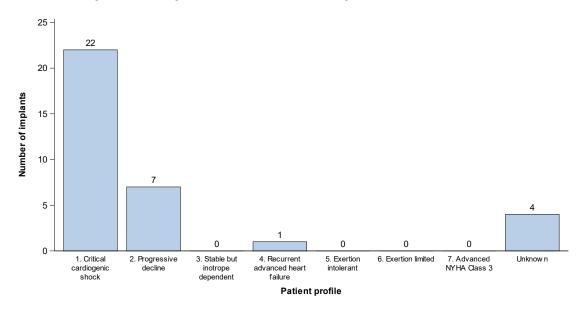


Figure 9.4 shows the <u>INTERMACS patient profile</u> at implant for paediatric patients implanted during 2024/2025. Most patients implanted were either level 1 (critical cardiogenic shock) or level 2 (progressive decline).

Figure 9.4 INTERMACS patient profile for all bridging devices used in paediatric patients in the UK, 1 April 2024 to 31 March 2025



PAEDIATRIC DEVICES USED FOR BRIDGING Patient Outcomes

10 Outcomes of paediatric patients receiving bridging devices

This section considers all paediatric patients who received any type of bridging support between 1 April 2020 and 31 March 2024. Patients are analysed on a per-patient basis, as opposed to per implant. If a patient was moved from one device to a different device, the entire time they were on support is considered (see <u>Table A1.5</u> in <u>Appendix A1</u> for details of device histories).

10.1 Demographic characteristics

The demographic characteristics of the 61 patients who received bridging support in the analysis period are shown below in **Table 10.1**, by centre and overall. Nationally, 54% of patients were male, the median age was 3 and the most common device was ECMO only, followed by Berlin Heart Excor. Note that for some characteristics there is a high proportion of missing data. Also, due to rounding, percentages may not sum to 100.

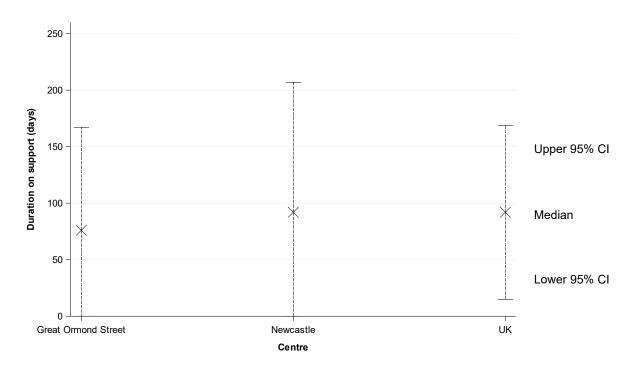
Table 10.1 Characteristics of paediatric patients who received a bridging device between 1 April 2020 and 31 March 2024, by centre					
		Great Ormond Street N (%)	Newcastle N (%)	Total N (%)	
Number of patients		31	30	61	
Recipient age (years)	Median (IQR)	5 (1-12)	2 (0-9)	3 (0-11)	
	Missing	0	0	0	
Recipient sex	Male	20 (65)	13 (43)	33 (54)	
	Female	11 (35)	17 (57)	28 (46)	
Primary disease	Dilated cardiomyopathy	28 (90)	26 (87)	54 (89)	
	Ischaemic heart disease	0 (0)	1 (3)	1 (2)	
	Congenital heart disease	1 (3)	0 (0)	1 (2)	
	Other	0 (0)	3 (10)	3 (5)	
	Unknown	2 (6)	0 (0)	2 (3)	
INTERMACS patient profile	 Critical cardiogenic shock Progressive decline Stable but inotrope dependent Recurrent advanced heart failure Exertion intolerant Exertion limited Advanced NYHA Class 3 	11 (35) 17 (55) 2 (6) 1 (3) 0 (0) 0 (0) 0 (0)	28 (93) 2 (7) 0 (0) 0 (0) 0 (0) 0 (0) 0 (0)	39 (64) 19 (31) 2 (3) 1 (2) 0 (0) 0 (0) 0 (0)	
Height (cm)	Median (IQR)	97 (73-121)	79 (63-105)	89 (68-116)	
	Missing	8	9	17	
Weight (kg)	Median (IQR)	13 (7-20)	13 (7-24)	13 (7-23)	
	Missing	8	6	14	
Body surface area (m²)	Median (IQR)	0.60 (0.38-0.80)	0.53 (0.33-0.71)	0.54 (0.38-0.77)	
	Missing	8	12	20	
First device implanted	Berlin Heart Excor	17 (55)	0 (0)	17 (28)	
	Heartware HVAD	0 (0)	2 (7)	2 (3)	
	HeartMate III	0 (0)	2 (7)	2 (3)	
	Impella	0 (0)	1 (3)	1 (2)	
	Centrimag/Levitronix	0 (0)	16 (53)	16 (26)	
	ECMO only	14 (45)	9 (30)	23 (38)	

10.2 Duration on support

Table 10.2 and **Figure 10.1** show the <u>median</u> duration on support for patients implanted between 1 April 2020 and 31 March 2024, both nationally and by centre. The <u>medians</u> and <u>confidence intervals</u> are estimated using the <u>Kaplan-Meier method</u> since not all patients may have come to the end of support and this method allows these (censored) patients to be included in the analysis. Transplant, explant or death signify end of support. Nationally, the <u>median</u> time on support was 92 days.

Table 10.2	able 10.2 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2020 and 31 March 2024, by centre					
Centre		Number of patients	Time <u>Median</u>	e on support (days) (95% <u>confidence interval</u>)		
Great Ormono Newcastle	d Street Hospital	31 30	76 92	0 - 167 0 - 207		
Overall		61	92	15 - 169		

Figure 10.1 Median duration on support for paediatric patients implanted with a bridging device between 1 April 2020 and 31 March 2024



10.3 Rate of transplant listing

Figure 10.2 and **Table 10.3** show the rate of transplant listing for patients implanted between 1 April 2020 and 31 March 2024 by centre. This includes listing on the superurgent, urgent or non-urgent heart transplant lists (whichever occurred first). Overall, 51% of patients were on the list at implant, with a further 41% listed after implant, 7% who had died or been explanted within one-year post-implant without being listed and 2% who were not listed within one-year.

Figure 10.2 Heart transplant listing status with respect to bridging device implantation for paediatric patients implanted 1 April 2020 – 31 March 2024, by centre and overall

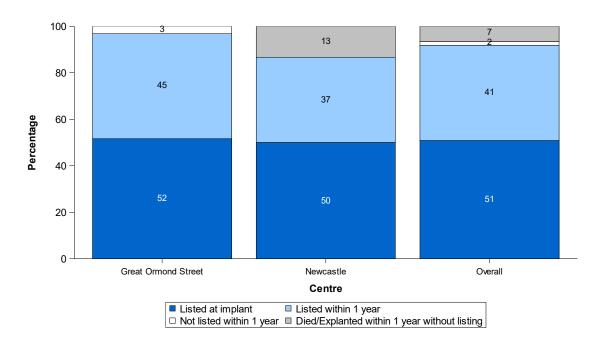


Table 10.3 Heart transplant listing status with respect to bridging device implantation for paediatric patients implanted 1 April 2020 - 31 March 2024, by centre and overall					
Centre	Number of	Listed at	Listed within	Not listed	Died/explanted within
	patients	implant	1 year	within 1 year	1 year without listing
	N	N (%)	N (%)	N (%)	N (%)
Great Ormond Street	31	16 (52)	14 (45)	1 (3)	0 (0)
Newcastle	30	15 (50)	11 (37)	0 (0)	4 (13)
Overall	61	31 (51)	25 (41)	1 (2)	4 (7)

10.4 Competing outcomes

Whilst on support, patients are susceptible to different outcomes. Death on support, transplant and explant without transplant (with or without recovery) are all possible outcomes. **Figure 10.3** shows the <u>cumulative incidence</u> of each of these outcomes occurring from time of implant, for the cohort of paediatric patients receiving a first device between 1 April 2020 and 31 March 2024. This is calculated using the <u>Aalen-Johansen method</u> to account for <u>competing outcomes</u>. At time zero, 100% of patients are on support and as time passes, patients either experience death on support, transplant or explant without transplant. At any time point, the proportion alive on support plus the proportions experiencing each outcome will sum to 100%. Deaths after transplant are not counted and these patients are classed simply as transplanted. Patients who were explanted and died within 30 days of explant are counted as deaths at time of explant. Any subsequent device support post-explant is not counted and any such patients are classed simply as explanted. If a patient is moved from one device to another without a period free of support, this counts as time on support.

For this cohort, one month after receiving a device, 64% of patients remained alive on support, 20% received a heart transplant, 11% had their device explanted and 5% died on support. At three months, the incidence of transplantation rose to 31%, the incidence of death rose to 8%, and the proportion explanted remained at 11%, leaving 49% left on support. By six months, 39% had received a heart transplant, 11% were explanted, 10% had died on support, leaving 39% alive on support.

Figure 10.3 Cumulative incidence functions for transplant, death and explant for paediatric patients receiving a bridging device, 1 April 2020 to 31 March 2024

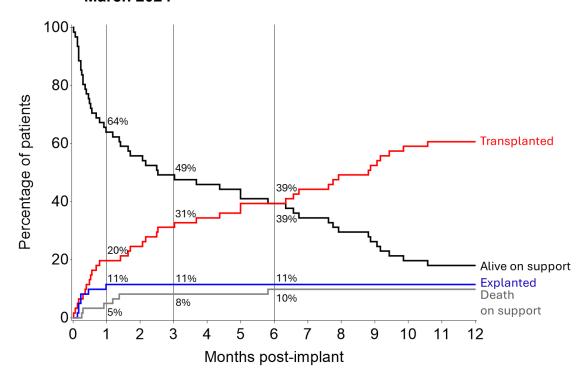


Table 10.4 shows the centre-specific estimates for each competing outcome. A higher proportion of patients had received a transplant by 6 months at Great Ormond Street (55%) compared with Newcastle (23%). Note that these percentages represent a small number of patients. Additionally, a patient may be counted as explanted but go on to have further support after a period without support, so this does not always represent recovery.

Table 10.4	Cumulative incidence implanted with a first					
Period	Centre	Number of patients	Transplanted %	•	Alive on support %	Death on support %
30 day	Great Ormond Street Newcastle	31 30	32 7	6 17	61 67	0 10
	Overall	61	20	11	64	5
90 day	Great Ormond Street Newcastle	31 30	48 13	6 17	45 53	0 17
	Overall	61	31	11	49	8
6 month	Great Ormond Street Newcastle	31 30	55 23	6 17	35 43	3 17
	Overall	61	39	11	39	10

10.5 Patient survival from implant

Overall survival rates from the point of first device implant, not censored for transplant or explant, are presented in this section. Survival data from the <u>UK Transplant Registry</u> were incorporated, as was any additional survival time recorded on the <u>MCS Database</u> for patients who were explanted. Time on additional devices is also counted, so for example if a patient had several periods of support, all this time is included. Times are censored if the patient was still alive at last known event or follow-up.

<u>Survival rates</u> are calculated using the <u>Kaplan-Meier method</u>. The rates are estimated at 30 days, 90 days and 1 year and are given nationally and for individual centres in **Tables 10.5**, **10.6** and **10.7**. The centre-specific rates are unadjusted for potential differences in risk between patients treated at different centres. The national rate of survival at each time point was 95.1%, 91.7% and 88.2%, respectively.

Table 10.5 30-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2020 – 31 March 2024, by centre					
Centre	Number of patients	Number of deaths	•	survival (95% CI) nadjusted	
Great Ormond Street	31	0	100.0	(-)	
Newcastle	30	3	89.9	(71.8 - 96.6)	
UK	61	3	95.1	(85.4 - 98.4)	

Table 10.6 90-day patient survival rates after bridging device implant for paediatric patients implanted 1 April 2020 – 31 March 2024, by centre						
Centre	Number of patients	Number of deaths	•	survival (95% CI) adjusted		
Great Ormond Street	31	0	100.0	(-)		
Newcastle	30	5	82.7	(63.2 - 92.4)		
UK	61	5	91.7	(81.1 - 96.4)		

Table 10.7 1-year patient survival rates after bridging device implant for paediatric patients implanted 1 April 2020 – 31 March 2024, by centre					
Centre	Number of patients	Number of deaths	•	survival (95% CI) adjusted	
Great Ormond Street	31	1	96.8	(79.2 - 99.5)	
Newcastle	30	6	78.9	(58.9 – 90.0)	
UK	61	7	88.2	(76.8 - 94.2)	

APPENDIX

A1: Data

The cohort of patients in this report varies by section and type of analysis. **Tables A1.1** and **A1.2** summarise the number of adult and paediatric patients/implants (respectively) in each cohort and the section this applies to.

Table A1.1 Data analy	sed for adults		
Time period	Report Section	Exclusion criteria	No. implants/ patients/ transplants
Adult – Long-term bridgi 1 April 2015 – 31 March 20	_	None	824 implants
1 April 2020 – 31 March 20	 Duration on support Rate of transplant listing Competing outcomes Patient survival from implant (30 day, 1 year and 3 years) 	 TAH and <u>pulsatile devices</u> Patients with no follow-up information 	225 patients
1 April 2016 – 31 March 20		 TAH and <u>pulsatile devices</u> Patients with no follow-up information 	376 patients
1 April 2016 – 31 March 20	924 • Survival on support	 TAH and pulsatile devices Patients with no follow-up information 	601 patients
1 April 2015 – 31 March 20	25 • TAH outcomes	None	18 patients
Adult - Short-term bridg	ng		
1 April 2015 – 31 March 20	• Introduction/Activity	None	1078 implants
1 April 2020 – 31 March 20	 Duration on support Rate of transplant listing Competing outcomes Survival on support 	 Patients with no follow-up information 	379 patients
1 April 2020 – 31 March 20		 Patients who had a long-term device before or after the short-term device Patients with no follow-up information 	345 patients
Adult - Short-term post-	ransplant		
1 April 2015 – 31 March 20	125 • Introduction	 Long-term devices used post-transplant 	515 implants
1 April 2015 – 31 March 20	25 • Activity	 Implants for rejection Long-term devices used post-transplant 	399 transplants
1 April 2020 – 31 March 20	Duration on supportPatient survival from implant	 Implants for rejection Long-term devices used post-transplant Patients with no follow-up information 	178 patients
1 April 2020 – 31 March 20	• Patient survival from heart transplant	None	670 transplants

Table A1.2 Data analysed	for paediatrics		
Time period	Report Section	Exclusion criteria	No. implants/ patients
Paediatric - Bridging devices	S		
1 April 2015 – 31 March 2025	 Introduction/Activity 	None	256 implants
1 April 2015 – 31 March 2025 1 April 2020 – 31 March 2024	 Activity Duration on support Rate of transplant listing Competing outcomes Patient survival from implant 	None • Patients with no follow-up information	206 episodes 61 patients

Limitations and classifications:

- BiVADs are counted as one implant.
- "Bridging" includes devices entered onto the <u>MCS Database</u> under "bridge to decision" as well as "bridge to transplant" along with any long-term devices used post-transplant.
- Patients who received concurrent short-term support with long-term support are classed simply as long-term device recipients.
- Patients who received concurrent ECMO support with a VAD are classed simply as VAD recipients.
- Any paediatric (age<16) activity reported by an adult only centre is presented in the adult sections.
- Berlin Heart implants into adult patients are counted as short-term support.

Table A1.3 details the number of patients meeting the criteria for each of the four patient outcomes sections, along with how many were excluded due to no follow-up post-implant and the number of patients with no follow-up information received in the previous year. Any patients who have been lost to follow-up are also reported here.

Table A1.3	Follow-up infor report	mation for patients	s analysed	in the patie	nt outcomes sec	tions of the
Outcomes section	Centre	Patients meeting section criteria	Patients with no follow-up	Patients analysed	Patients with no follow-up in last year¹ (%)	Patients lost to follow-up (%)
Adult long-term	Birmingham	33	0	33	0 (0)	0 (0)
bridging	Glasgow	2	Ö	2	0 (0)	0 (0)
	Harefield	- 52	Ö	52	0 (0)	0 (0)
	Manchester	46	Ö	46	0 (0)	0 (0)
	Newcastle	68	Ö	68	0 (0)	0 (0)
	Papworth	24	0	24	0 (0)	0 (0)
	Overall	225	0	225	0 (0)	0 (0)
Adult short-term	Birmingham	65	0	65	2 (3)	1 (2)
bridging	Glasgow	67	0	67	0 (0)	0 (0)
	Harefield	75	1	74	1 (1)	18 (24)
	Manchester	57	0	57	1 (2)	3 (5)
	Newcastle	43	0	43	5 (12)	0 (0)
	Papworth	73	0	73	1 (1)	0 (0)
	Overall	380	1	379	10 (3)	22 (6)
Adult post-	Birmingham	56	0	56	0 (0)	0 (0)
transplant	Glasgow	28	0	28	0 (0)	0 (0)
	Harefield	24	0	24	0 (0)	0 (0)
	Manchester	15	0	15	0 (0)	0 (0)
	Newcastle	27	0	27	5 (19)	0 (0)
	Papworth	28	0	28	1 (4)	0 (0)
	Overall	178	0	178	6 (3)	0 (0)
Paediatric bridging	Great Ormond Street	31	0	31	2 (6)	0 (0)
	Newcastle	30	0	30	5 (17)	0 (0)
	Overall	61	0	61	7 (11)	0 (0)

¹Patients analysed who are not reported as deceased and no information on patient status has been returned via MCS <u>Database</u> or <u>UK Transplant Registry</u> since 1 June 2024

Table A1.4 details the device history of adult patients receiving a device between 1 April 2015 and 31 March 2025 by strategy. **Table A1.5** shows the same information for paediatric recipients. In both these tables, a dash ("-") between devices indicate that the subsequent device was implanted immediately following explanation of the prior device and a slash ("/") indicates the patient had a period of no support between the two devices.

Table A1.4 Device history of adult patients receiving device implants, 1 April 2015 to 31 March 2025 by strategy No. of post-transplant **Device history** No. of bridging patients patients LT 627 LT-ECMO 12 LT-ECMO-LT 1 2 LT-ECMO-ST LT-ECMO-ST-ST 1 LT-LT 28 LT-LT-ECMO 1 LT-LT-ECMO-ST 1 LT-LT-LT 1 4 LT-ST LT-ST-ST 1 LT/ECMO 4 1 LT/ECMO-LT LT/LT LT/LT-LT 1 LT/ST 2 LT/ST-ST-ST 1 TAH 9 ST 369 18 ST-ECMO 10 ST-ECMO-ST 3 ST-ECMO-ST-LT 1 40 ST-LT ST-LT-LT 1 ST-LT-LT-ECMO 1 ST-ST 25 2 ST-ST-ECMO 2 ST-ST-ECMO-LT 1 ST-ST-LT 4 ST-ST-ST 1 ST-ST/ECMO 2 ST-TAH 2 ST/ECMO 1 ST/LT 1 ST/ST-ECMO 1 **ECMO** 223 310 ECMO-ECMO 7 3 **ECMO-LT** 33 ECMO-LT-ECMO 1 **ECMO-LT-LT** 1 ECMO-LT-LT-ST 1 ECMO-LT-ST 1 **ECMO-ST** 84 47 2 ECMO-ST-ECMO 3 10 ECMO-ST-LT **ECMO-ST-ST** 3 2 ECMO-ST-ST-ST 1 ECMO-ST-ST-ST/LT 1 **ECMO-ST-TAH** ECMO-ST/ECMO 1 ECMO-ST/LT 1 ECMO-ST/LT-ECMO 1 ECMO-ST/ST 1 ECMO-ST/TAH 1 **ECMO-TAH** 5 3 ECMO/ECMO 16 ECMO/ECMO/ECMO

Table A1.4 Device history of adult patients receiving device implants, 1 April 2015 to 31 March 2025 by strategy

Device history	No. of bridging patients	No. of post-transplant patients
ECMO/ECMO/ST	1	
ECMO/ST	3	1
ECMO/ST-ECMO		1
ECMO/ST/ST		1
Overall	1546	413

LT = Long-Term VAD, ST = Short-Term VAD, TAH = Total Artificial Heart, ECMO = Extracorporeal Membrane Oxygenation. Note: a dash ("-") between devices indicate that the subsequent device was implanted immediately following explantation of the prior device and a slash ("/") indicates the patient had a period of no support between the two devices

Table A1.5 Device history of paediatric patients receiving device implants, 1 April 2015 to 31 March 2025 by strategy

Device history	No. of bridging patients	No. of post-transplant patients
ВН	40	patient
BH-ECMO	1	
HVAD	25	
HVAD-CM-ECMO-CM	1	
HVAD-ECMO-HVAD	1	
CM	46	
CM-BH	6	
CM-BH-CM	1	
CM-BH-CM-BH	1	
CM-BH/CM	1	
CM-BH/ECMO	1	
CM-CM	2	
CM-ECMO	1	
CM/CM	1	
ST	0.5	.1
ECMO	25	44
ECMO-BH	12	
ECMO-CM	4	
ECMO-HM ECMO-HVAD	1 5	
ECMO-HVAD-ECMO	ე 1	
ECMO-IM	2	
ECMO-IM-ECMO	1	
ECMO/BH	1	
ECMO/CM	4	
ECMO/ECMO	2	
ECMO/ECMO/CM	1	
ECMO/HVAD	1	
HM	2	
IM	3	
Overall	193	45

BH = Berlin Heart; HVAD = Heartware HVAD, CM = Centrimag, ECMO = Extracorporeal Membrane Oxygenation, IM = Impella. Note: a dash ("-") between devices indicate that the subsequent device was implanted immediately following explantation of the prior device and a slash ("/") indicates the patient had a period of no support between the two devices

A2: Methods

Analysis of geographical variation in MCS rates

Patients were assigned to NHS regions in England or country for Wales, Scotland and Northern Ireland using their postcode of residence, as reported at implant. Patients were only counted once regardless of how many devices they received in the period. The number of patients receiving a device per million population (pmp) of NHS region/country was obtained using mid-2022 population estimates based on the Office for National Statistics (ONS) 2022 Census figures (denominator). No NHS region age- or sex-specific standardisation of rates was performed when calculating the systematic component of variation. The MCS rates pmp were categorised into four groups – low, low-medium, medium-high and high – based on the quartiles of their distribution and visualised in a map using contrasting colours.

Systematic component of variation

For a given individual who is a resident in a given English NHS region, provision of a bridging device is modelled as a Bernoulli trial. At the whole area level, this becomes a Binomial process which can be approximated by a Poisson distribution when rare events are modelled.

To allow for the possibility that, even after allowing for area-specific Poisson rates, area differences remain, introduce an additional multiplicative rate factor which varies from area to area. Postulate a non-parametric distribution for the multiplicative factor, with variance σ^2 . If the factor is one for all areas, then area differences are fully explained by the area-specific Poisson rate. If the factor varies with a nonzero variance, σ^2 , then we conclude that there are unexplained area differences.

The systematic component of variation (SCV; McPherson et al., N Engl J Med 1982, 307: 1310-4) is the moment estimator of σ^2 . Under the null hypothesis of homogeneity across areas, the SCV would be zero. The SCV, therefore, allows us to detect variability across areas beyond that expected by chance; the larger the SCV, the greater the evidence of systematic variation across areas.

A one-sided p-value for the hypothesis that the SCV is greater than zero versus the null hypothesis that the SCV is equal to zero was derived using a parametric bootstrap where data were simulated from the Poisson distribution that would be consistent with the null hypothesis (multiplicative rate factor is equal to one in all areas and σ^2 equal to zero). The observed SCV was then compared against this simulated data to calculate the probability that an SCV of at least this size would be observed due to chance if the null hypothesis were true.

10,000 bootstrap samples of size 7 (number of areas) were simulated, where the bridging implant count in each area was drawn from a Poisson distribution with its expected value being the area-specific expected count (the rate of bridging implants in the total population multiplied by the population of the area) . The SCV was then calculated in each of the 10,000 samples and a bootstrap p-value for the SCV in the observed data was estimated as:

$$P_{boot} = \frac{1 + \#\{SCV_{sim} \ge SCV_{obs}\}}{10000 + 1}$$

where $\#\{SCV_{sim} \geq SCV_{obs}\}$ is the number of SCV values in the simulated datasets which are greater than or equal to the SCV in the observed data. This follows the simulation method given in Ibanez et al., BMC Health Services Research, 2009, 9:60. No adjustment was made for area-specific demographic characteristics that may impact the rates of bridging implantation such as age and sex.

Unadjusted survival rates

The <u>Kaplan-Meier method</u> is used to estimate <u>unadjusted</u> patient <u>survival rates</u>. Patients can be included in this method of analysis irrespective of the length of follow-up recorded. If a patient is alive at the end of the follow-up then information about the survival of the patient is censored, which means they have not yet experienced the outcome of death.

Funnel plots

The funnel plot is a graphical method to show how consistent the <u>survival rates</u> of the different centres are with the national rate. The graph shows for each centre a survival rate plotted against the number of procedures undertaken, with the national rate and <u>confidence limits</u> around this national rate superimposed. In this report, 95% and 99.8% <u>confidence limits</u> were used. Centres that lie within the <u>confidence limits</u> have survival rates that are statistically consistent with the national rate. When a centre is close to or outside the limits, this is an indication that the centre may have a rate that is different from the national rate.

A3: Glossary of terms

Aalen-Johansen method

A method for calculating the cause-specific <u>cumulative incidence</u> which allows for patients experiencing one of a set of outcomes where each outcome may preclude or change the probability of a patient experiencing any of the others ("competing risks"). It allows for patients with incomplete follow-up to be included as per the <u>Kaplan-Meier method</u>.

Competing outcomes

A situation when patients or subjects can experience one or more events or outcomes which 'compete' with the outcome of interest. For instance, when the event of interest is death on VAD support, receiving a transplant or having ones' device explanted and recovering are competing outcomes. Generally, the competing outcomes hinder the observation of the event of interest or modify the chance that this event occurs.

Confidence interval (CI)

When an estimate of a quantity such as a <u>survival rate</u> is obtained from data, the value of the estimate depends on the set of patients whose data were used. If, by chance, data from a different set of patients had been used, the value of the estimate may have been different. There is therefore some uncertainty linked with any estimate. A confidence interval is a range of values whose width gives an indication of the uncertainty or precision of an estimate. The number of patients analysed influences the width of a confidence interval. Smaller data sets tend to lead to wider confidence intervals compared to larger data sets. Estimates from larger data sets are therefore more precise than those from smaller data sets. Confidence intervals are calculated with a stated probability, usually 95%. We then

say that there is a 95% chance that the confidence interval includes the true value of the quantity we wish to estimate.

Confidence limit

The upper and lower bounds of a confidence interval.

Continuous-flow device

An electrically driven rotary pump that pumps blood continuously throughout the cardiac cycle.

Cumulative incidence

The probability of an event (death, transplant or explant in this context) occurring before a particular point in time.

ECMO

Extra Corporeal Membrane Oxygenation. The term ECMO is this report is used to describe veno-arterial (VA) ECMO, rather than veno-venous (VV) ECMO.

INTERMACS patient profile

Level 1: Critical cardiogenic shock describes the patient who is "crashing and burning"; in which patients have life—threatening hypotension despite rapidly escalating inotropic support, occasionally with IABP placement as well, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. Patients may have less than 24 hours survival expected without mechanical support.

Level 2: <u>Progressive decline</u> describes the patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Level 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmia, clinical ischemia, or other intolerance.

Level 3: Stable but inotrope dependent describes the patient who is clinically stable on mild–moderate doses of intravenous inotropes after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between patients who are truly stable at Level 3 and those who have unappreciated decline rendering them Level 2.

Level 4: is the level of <u>"recurrent"</u> rather than "refractory" decompensation. After interventions such as hospitalization for intravenous diuretics, these patients can be stabilized briefly on an oral regimen at close to normal volume status. However, they experience brief relapses into fluid retention. These patients should be carefully considered for more intensive management and surveillance programs, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy.

Level 5: describes patients who are comfortable at rest but are <u>exercise intolerant</u> for most activity, living predominantly within the house or housebound. They have no

congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as housebound.

Level 6: is a similar patient who is generally without any evidence of fluid overload and able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes or any meaningful physical exertion.

Level 7: describes patients who are clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. Any decompensation requiring intravenous diuretics or hospitalization within the previous 2 weeks should make the person a Level 4 or lower.

ISHLT Mechanically Assisted Circulatory Support Registry Users' Guide (2012). Birmingham, AL (http://www.ishlt.org/ContentDocuments/IMACS Users Guide Final 032414.pdf)

Kaplan-Meier method

A method that allows patients with incomplete follow-up information to be included in estimating <u>survival rates</u> and other time related statistics such as median duration on support. For example, when estimating one year patient survival rates, a patient may be followed up for only nine months before they relocate. If we calculated a crude survival estimate using the number of patients who survived for at least a year, this patient would have to be excluded as it is not known whether or not the patient was still alive at one year after VAD implantation. The Kaplan-Meier method allows information about such patients to be used for the length of time that they are followed-up, when this information would otherwise be discarded. Such instances of incomplete follow-up are not uncommon and the Kaplan-Meier method allows the computation of estimates that are more meaningful in these cases.

Long-term (LT) devices

Long-term devices are implantable and intended to support the patient for years. Patients can be discharged from hospital with a LT device. Most LT devices are <u>continuous-flow</u> devices but some are <u>pulsatile</u>.

MCS

Mechanical Circulatory Support.

MCS Database

Database used for an ongoing extensive audit to capture in-depth data prior to and at implant of device, explant, transplant and death along with follow-up at various time points post-implant and post-explant. The database captures data on long-term and short-term mechanical circulatory support, including VADs, TAH and ECMO, for the purpose of bridge to transplant, bridge to decision (in this report both analysed together as "bridging"), primary graft dysfunction and "other" (allowing capture of devices for rejection). Devices used post-cardiotomy are not funded via the NHS England bridge to transplant or recovery programme and so are excluded from the MCS Database. Destination Therapy is not explicitly captured on the database but these cases may be captured within "bridge to transplant" or "bridge to decision" where the patient never received a transplant.

Median

The midpoint in a series of numbers, so that half the data values are larger than the median, and half are smaller.

Patient survival rate

The estimated percentage of patients who are still alive. This is usually specified for a given time period after implant. For example, a 1 year patient survival rate is the estimated percentage of patients who are still alive 1 year after their first device implant.

Primary graft dysfunction

In this report primary graft dysfunction (PGD) is defined as all VADs and ECMOs used for graft failure within 30 days of heart transplantation.

Pulsatile device

A device that mimics the natural pulsing action of the heart.

p value

In the context of comparing listing rates across centres, as an example, the p value is the probability that the differences observed in the rates across centres occurred by chance. As this is a probability, it takes values between 0 and 1. If the p value is small, say less than 0.05, this implies that the differences are unlikely to be due to chance and there may be some identifiable cause for these differences. If the p value is large, say greater than 0.1, then it is quite likely that any differences seen are due to chance.

Rejection

Rejection is defined as all VADs and ECMOs used for graft failure more than 30 days after heart transplantation.

Short-term (ST) devices

Short-term devices are intended to support the heart for a short period of time (days or weeks). Patients cannot leave hospital with the device.

Survival on support

The percentage of patients who are still alive and on VAD support. Unlike patient survival from implant, survival on support is censored at time of device explantation or transplantation. This is usually specified for a given time period after implantation. For example, a three-year survival on support rate is the estimate of patients who are still alive on support three years after their first short-term or long-term VAD implantation.

TAH

Total Artificial Heart.

UK Transplant Registry

A national database held by NHS Blood and Transplant collecting data on all organ transplant procedures. Information is accrued prospectively at recipient registration on the national transplant list, at organ donation, at time of transplantation and at regular intervals thereafter.

Unadjusted survival rate

Unadjusted <u>patient survival rates</u> do not take account of potential confounders and are based only on the number of patients at a given centre and the number and timing of those that die within the post-implant period of interest. In this case, unlike for risk-adjusted rates, all patients are assumed to be equally likely to die at any given time. However, some centres may have lower unadjusted survival rates than others simply because they happen to have patients that have increased risks of death. All results presented in this report are unadjusted as the risk factors affecting survival post-MCS in the UK have not yet been examined.

VAD

Ventricular Assist Device. A mechanical pump used to increase the amount of blood that flows through the body, relieving the symptoms of advanced heart failure.

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