EXCEL REGISTRY REPORT

3-YEAR REPORT

01/2019 - 12/2021

25 March 2022

EXCEL

FOREWORD

We are delighted to present the Australian and New Zealand Extracorporeal Membrane Oxygenation (EXCEL) Report for 2019-2021. This report further extends the EXCEL Registry's previous reports, reflecting the continued growth in clinical data and device and procedure follow up by the registry. In particular, this report includes separate data on patients who were retrieved to a major ECMO centre, comparing outcomes between those retrieved and all other patients.

Importantly, for the first time, we report data on patients receiving ECMO for COVID-19, including summary device and outcome information. In the future, the EXCEL Registry will be an extremely important national repository of ongoing data relating to COVID-19. We thank all research coordinators and clinicians who have provided the EXCEL Registry with specific information related to confirmed cases of COVID-19, to assist us in better understanding the device profile associated with this disease. In the past two years, there have been many challenges associated with the COVID-19 pandemic. We again thank our colleagues who have continued to support the EXCEL Registry through completion of their data collection throughout this period.

The EXCEL Registry thanks the funding partners for their continued support, ensuring the ongoing success of this important register. We also welcome our new funding partner for 2022-2024, The Dicker Family. Craig Dicker, who survived VV-ECMO, has joined our Steering Committee and we welcome his input as a consumer representative.

The EXCEL Registry is gaining increasing interest from researchers and industry who have research or safety questions that the registry can assist to answer. On request, we have produced new reports for NSW and Victorian sites to compare practice within their jurisdictions, and comparing major centres head-to-head to compare clinical practice and outcomes. We thank all those people who support the registry through the provision of their clinical and Patient Reported Outcome (PROMs) information. We also thank the EXCEL Registry team for their registry expertise and hard work. In particular, we thank the Management Committee for their hard work over the past three years.

We hope that you find the EXCEL Registry's 2019-2021 Report interesting reading, and we commend it to you.

ACKNOWLEDGEMENTS

The EXCEL Registry would like to acknowledge the support from 2019-2021 of the **National Health and Medical Research Council**, **the Heart Foundation**, **the International ECMO Network**, **the Critical Care Research Group (QLD)**, **the Alfred Hospital (VIC)**, **The University Hospital Geelong (VIC)**, **St Vincent's Hospital (NSW)** and **Royal Prince Alfred Hospital (NSW)**. We would like to acknowledge in-kind support from the Australian and New Zealand Intensive Care Research Centre, Monash University, the Australian and New Zealand Intensive Care Society and Fiona Stanley Hospital (WA).

We are grateful for the contributions made by the EXCEL Registry Management Committee. We acknowledge the leadership of the chair of the Management Committee, who is also the EXCEL Registry academic lead and data custodian. We would like to acknowledge the contributions of the EXCEL Registry project team (Ms Natalie Linke and Mr Bentley Fulcher) including Data Analysts (Ms Vanessa Singh, Mr Farhad Salimi). We also gratefully acknowledge the dedication of the steering committee members, clinician researchers including: Professors Stephen Bernard, Daniel Brodie, Jamie Cooper, Eddy Fan, John Fraser, David Pilcher, Andrew Udy; A/Professors David Gattas, Ingrid Hopper, Priya Nair, Neil Orford, Rachael Parke, Dion Stub and Vin Pellegrino; Drs Aidan Burrell, , Ed Litton and Ben Reddi; research coordinator Heidi Buhr, Dr Lisa Higgins, Dr Shay McGuinness, A/prof Rachael Parke, Ms Jasmine Board, Sue Huckson, Tony Trapani and consumers (Ms Shannah Anderson and Mr Craig Dicker).

This work would not have been possible without the ongoing efforts of the many intensive care specialists, nurses, research coordinators and other hospital staff who contribute data to the EXCEL Registry, including the Principal Investigators for their sites. We would like to thank them for their commitment. We would also like to thank the patients who allow the EXCEL Registry to retain their data and recognise the importance of the EXCEL Registry.

This report is presented on behalf of the members of the EXCEL Management Committee, with thanks to Dr Farhad Salimi, Senior Data Analyst, Clinical Outcomes Data Reporting and Research Program. Further information about the EXCEL Registry can be found on the EXCEL website: https://www.monash.edu/medicine/sphpm/anzicrc/research/excel.

If you have any questions please contact EXCEL Chief Investigator Professor Carol Hodgson.

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CONTENTS

List of Figures

List of Tables


22
4
8,1
1:2,0
547
525
7,9
15
Fi
Et
33
52
48
4,0
3,0
1,5
MAK
Air
1,0
60
30

EXECUTIVE SUMMARY

The Australian and New Zealand Extracorporeal Membrane Oxygenation Registry (EXCEL) is overseen by a national Management Committee that has broad stakeholder representation, including clinicians, researchers, funders, end-users and consumers. Throughout 2019-2021, 27 sites participated in the EXCEL Registry, representing an estimated 88% of total eligible sites. The overwhelming majority of ECMO runs reported to the registry occur in tertiary hospitals, which perform over 90% of all ECMO procedures in Australia and New Zealand. In order to determine our capture rate, we cross-referenced the Australian and New Zealand Intensive Care Society (ANZICS) adult patient database, which collects data from 174/183 (95.1%) of adult ICUs across the country. Between the dates June 1, 2020 to December 31, 2020, ANZICS registered 223 unique adult patients receiving ECMO and EXCEL registered 203 unique adult patients receiving ECMO. This indicates that the EXCEL registry was successful in capturing a very high percentage (91%) of ECMO incidences in Australia.

Approximately 180 clinicians from 28 different hospitals have contributed data to the EXCEL registry. At 31 December 2021, the EXCEL Registry had collected data on 888 patients receiving ECMO. As we have a waiver of consent for hospital data, there is no missing data due to opt-out. The majority of ECMO was veno-arterial (46% VA-ECMO), with 34% veno-venous (VV- ECMO) and 20% extracorporeal cardiopulmonary resuscitation (ECPR). In 2019, 161 patients were added to the registry; in 2020, 276 patients were added to the registry; and in 2021, 451 patients were added which shows the exponential growth of the registry over the three years.

From 2019-2021, the mean (SD) age of patients receiving ECMO was 50.5 (14.6) years. Most patients were admitted to hospital from home (49%), but most patients were admitted to ICU for ECMO from ICU in another hospital (28%). The ICU length of stay was median (IQR) 14.9 (6.9, 29.3) days and the hospital length of stay was median (IQR) 24.9 (10.2, 46) days. Most patients (58% survived. For VV-ECMO, VA-ECMO and ECPR respectively, the most common indication was ARDS (70%), Peri-operative support (23%) and Acute myocardial infarction (AMI) (48%). The most common complications were renal (78%) with over half of the patients receiving ECMO also on continual renal replacement therapy. Cardiovascular complications occurred in 64% patients on ECMO, and bleeding complications in 51%.

Led by Dr Sridevi Shetty from Royal Prince Alfred Hospital, we have looked at the data of patients retrieved versus not retrieved in four high volume ECMO sites. A total of 566 ECMO cases were analysed (160 VV-ECMO and 406 VA-ECMO), which included 136 retrieved patients (57 VV-ECMO and 79 in VA-ECMO). The median age of the total study population was 54 with a median APACHE IV score of 80. Retrieved VV-ECMO patients had higher median RESP score than non-retrieved patients (median (IQR) 3 (1-6) Vs 2 (-1-4), $p = 0.05$) but had similar durations of ECMO support (8.0 vs 6.3 days). Retrieved VA-ECMO patients also had a higher SOFA score (median (IQR) 11.0 (8-13) vs 9.0 (7-11), $p = 0.028$) compared to non-retrieved patients. There was no difference in the primary outcome of all-cause mortality, with similar risk-adjusted 90-day hospital survival between the groups. The complications rates were higher in the retrieved group.

One unique aspect of the EXCEL Registry is the detailed patient reported outcome measures (PROMS) at 6 and 12 months. We evaluated 393 patients with data available on the incidence of death and new disability at 6-months after ECMO. Death or disability was reported in 260 of 393 (66.2%) patients at 6-months and was higher in patients receiving ECPR. Of the cohort, 198 (50.4%) patients had died at 6-months after ECMO initiation. Of the survivors, 62 of 193 (32.1%) reported disability at 6-months. Disability was common in physical, psychological and cognitive functioning, and over one quarter of people who were working prior to their illness had not returned to work due to their health.

The EXCEL Registry provides reports to sites biannually, including risk adjusted mortality, complications, healthcare utilisation, ICU and hospital outcomes and patient reported outcomes at 6-months. Our data follows the patient journey, so that data is not duplicated if a patient is transferred from one hospital to another and it is directly aligned with the international Extracorporeal Life Support Organization (ELSO) registry. We provide direct upload of data from EXCEL to ELSO for healthcare services with a signed agreement. In 2020 we added additional data points to determine the use of ECMO in patients with COVID-19, aligned with the data in the international registry (ELSO). We currently have 5 registry-embedded clinical trials, including three randomised controlled trials that are funded by the MRFF, , with three more in planning for 2022. From 2019-2021, we have had 13 requests for data form the EXCEL registry, all from clinician researchers at the sites participating in the registry. The EXCEL Registry encourages secondary use of data from external stakeholders including researchers, clinicians, government agencies and industry.

ABBREVIATIONS AND ACRONYMS

Table 1: Abbreviations and Acronyms

AMI	Acute myocardial infarction
ANZICS	Australian and New Zealand Intensive Care Society
ARDS	Acute respiratory distress syndrome
CNS	Central nervous system
COVID-19	Coronavirus disease of 2019
CPR	Cardiopulmonary resuscitation
DVT	Deep vein thromboembolism
ECPR	Extracorporeal cardiopulmonary resuscitation used for advanced resuscitation
ED	Emergency Department
ELSO	Extracorporeal Life Support Organisation
GI	Gastrointestinal
ICU	Intensive Care Unit
IQR	Interquartile range
LA	Left atrium
LOS	Length of stay
LVD	Left ventricular distention
NHMRC	National Health and Medical Research Council
PA	Pulmonary artery
REDCap	Research Electronic Data Capture
RESP	Respiratory ECMO survival prediction
SD	Standard deviation
TBI	Traumatic brain injury
VA	Venoarterial ECMO used for cardiac indication
VAD	Ventricular assist device
VF	Ventricular fibrillation
VV	Venovenous ECMO used for a respiratory indication
WHODAS 2.0 12L	World Health Organisation Disability Assessment Schedule 2.0 12 Level

SITE ENROLMENT

The EXCEL Registry continues to engage eligible sites in Australia and New Zealand to contribute data to the registry. An eligible site is defined as a site currently undertaking ECMO as identified by Australian modification of the International statistical classification of diseases and health related problems, 10th revision (ICD-10-AM) coding data provided by the Australian Government Department of Health, or as reported by external sources (internet search, surgeons or site staff).

The list of eligible sites is dynamic and updated regularly based on information obtained from intensive care clinicians and site staff, and information gleaned from internet search engines and websites. The EXCEL Registry maintains a ‘watch list’ of sites identified as having the potential to undertake occasional ECMO.

A participating site is defined as any site that has been granted ethics and governance approval and data collection for the registry has commenced. As of 31 December 2021, 91% of total eligible ECMO runs were captured in the EXCEL Registry. Engagement is the proportion of eligible sites that are currently participating. The most common reason that eligible sites are not participating is that the implementation process has not yet been completed. The total number of participating sites throughout 2021 was 27 Of the 27 sites, 5% were private and 95% were public hospitals (Figure 1).

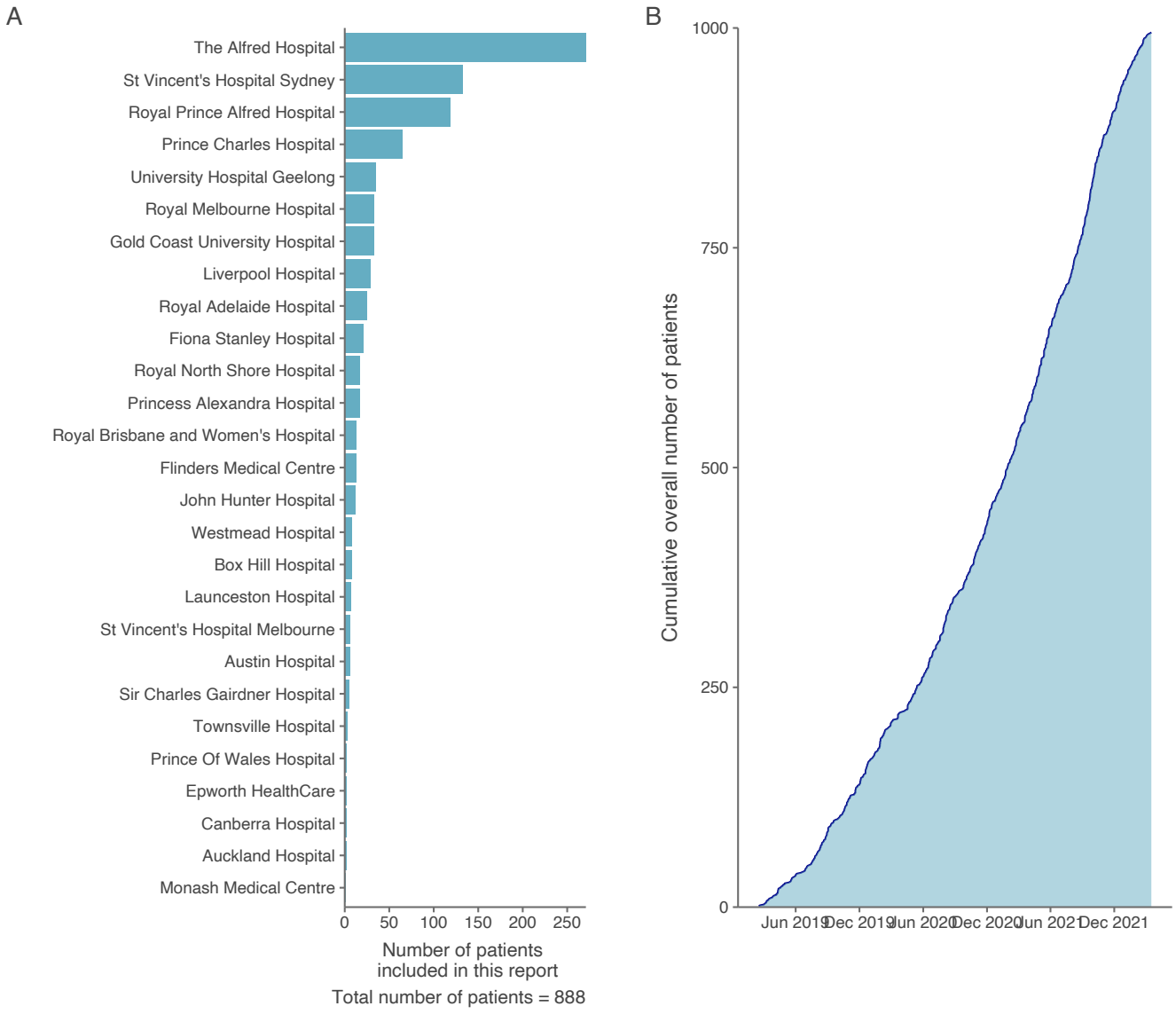


Figure 1: Number of patients included between January 2020 – December 2020 (A), Cumulative overall site enrolment from 2019 to 2021 (B)

DATA COMPLETION

All data entered in this report has been collected by Investigators and Research Coordinators at each of the participating sites. Data is available to download by the Principal Investigator via the EXCEL REDCap database. Data is provided confidentially to the EXCEL Registry.

Over 80% of data was completed for all forms within the registry, with over 95% of data completed for most forms. This work would not have been possible without the ongoing efforts of the many intensive care specialists, nurses, research coordinators and other hospital staff who contribute data to the EXCEL Registry. We would like to thank them for their commitment. We would also like to thank the patients who allow the EXCEL Registry to retain their data (Figure 2).

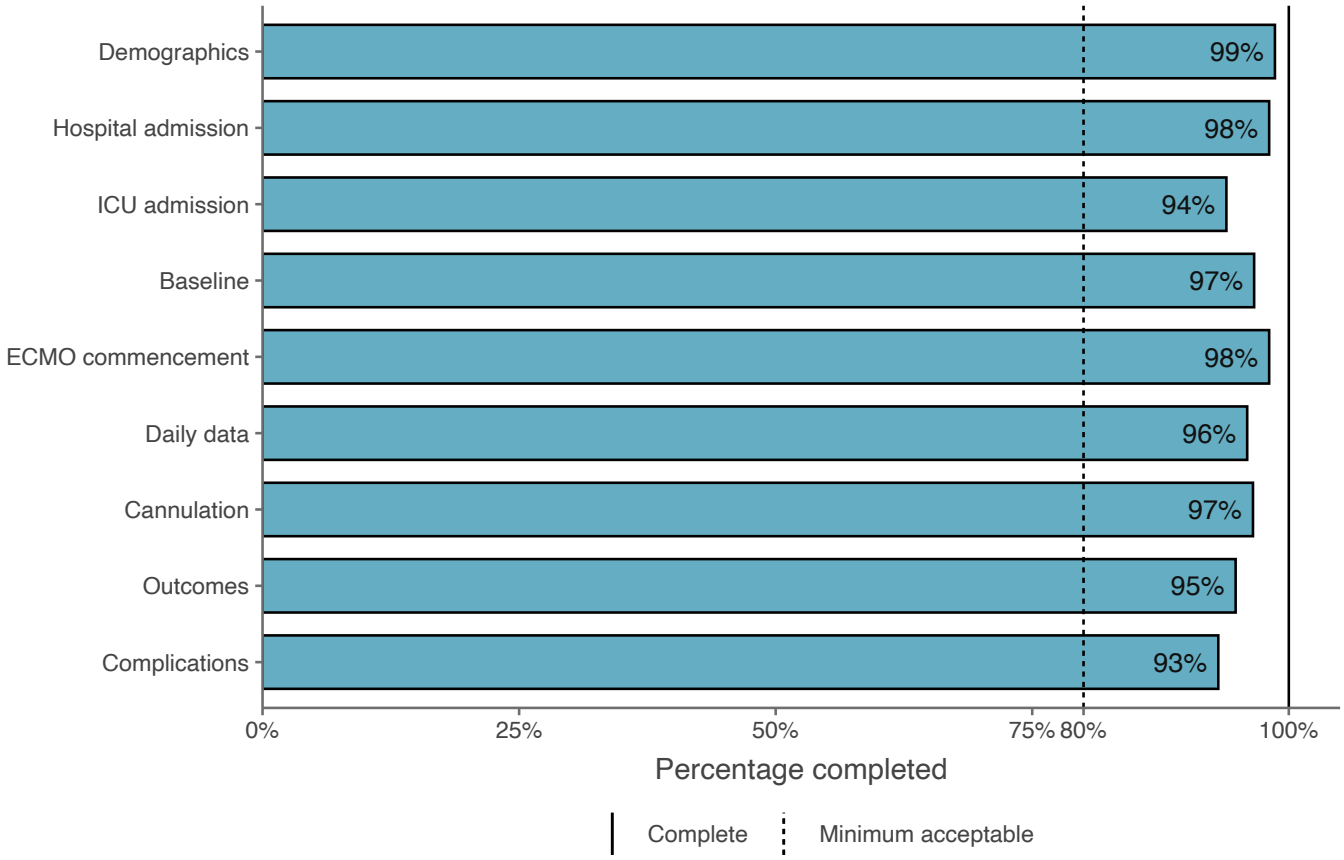


Figure 2: Data completion: EXCEL registry forms

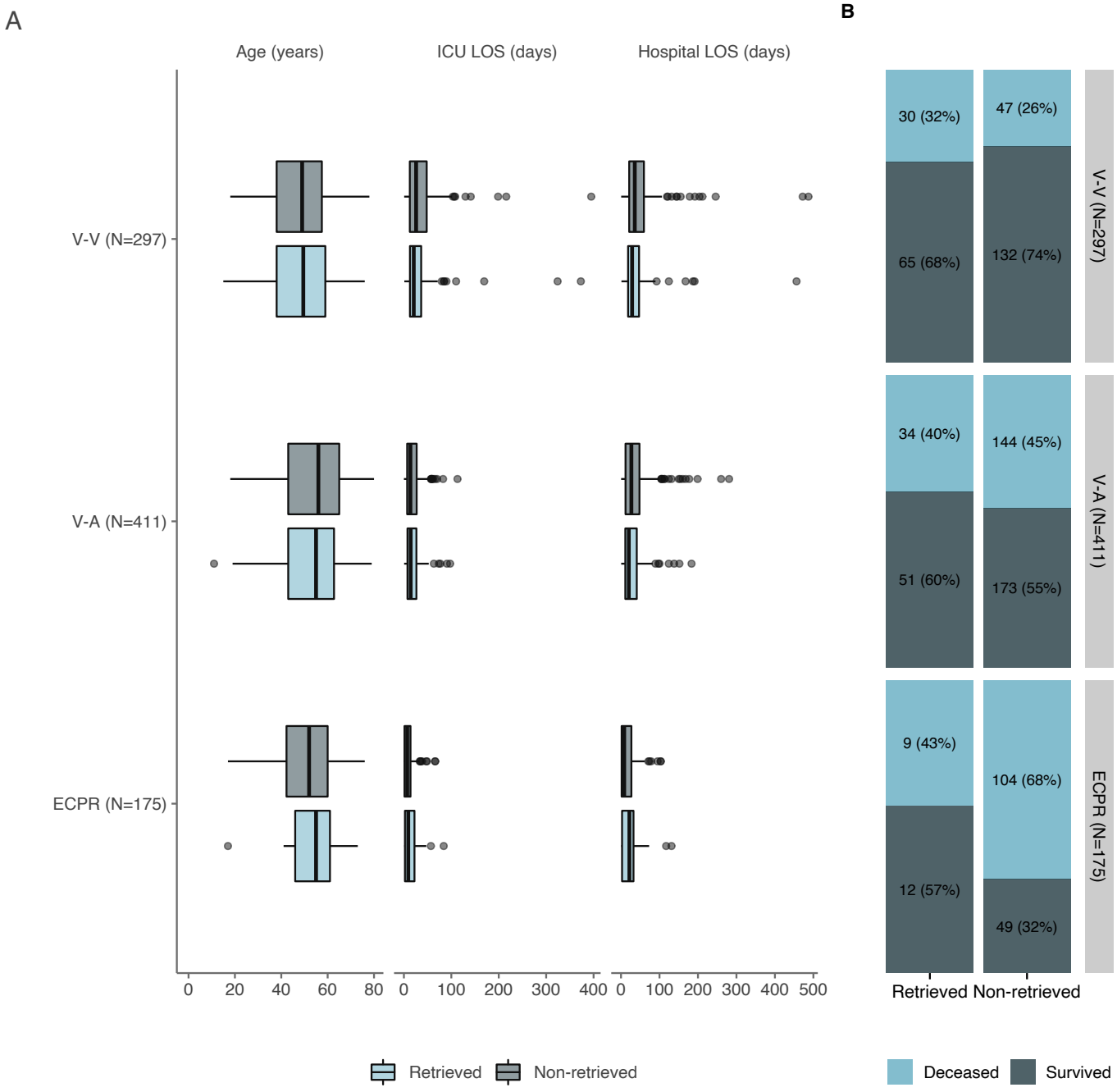
SUMMARY DATA

Table 2 shows the summary data across all sites, separated for the type of ECMO (VV-ECMO, VA-ECMO and ECPR). There were 94 (11%) patients who were diagnosed with COVID-19 who received ECMO in this period.

Table 2: Summary information by ECMO mode

	V-V (N=300)	V-A (N=411)	ECPR (N=177)	Total (N=888)
COVID-19 status				
- Confirmed COVID-19 patients	89 (30.2%)	4 (1.0%)	1 (0.6%)	94 (10.7%)
- Other patients	206 (69.8%)	401 (99.0%)	175 (99.4%)	782 (89.3%)
- Total	295	405	176	876
- Missing	5	6	1	12
Age				
- Mean (SD)	47.5 (14.1)	52.8 (14.9)	50.2 (14.0)	50.5 (14.6)
- Median (IQR)	49.0 (38.0, 58.0)	56.0 (43.0, 64.0)	52.0 (43.0, 60.0)	52.0 (40.8, 62.0)
- Range	15.0 - 78.0	11.0 - 80.0	17.0 - 76.0	11.0 - 80.0
- Missing	0	0	0	0
ECMO commencement location				
- Bedside	236 (78.7%)	175 (42.6%)	134 (78.4%)	545 (61.8%)
- Operative theatre	53 (17.7%)	206 (50.1%)	7 (4.1%)	266 (30.2%)
- Cath lab	11 (3.7%)	30 (7.3%)	30 (17.5%)	71 (8.0%)
- Total	300	411	171	882
- Missing	0	0	6	6
ECMO outcome				
- Deceased	78 (28.3%)	178 (44.3%)	115 (65.3%)	371 (43.4%)
- Survived	198 (71.7%)	224 (55.7%)	61 (34.7%)	483 (56.6%)
- Total	276	402	176	854
- Missing	24	9	1	34
ECMO duration				
- Mean (SD)	15.2 (27.2)	6.9 (6.6)	4.2 (5.2)	9.1 (16.9)
- Median (IQR)	8.4 (4.4, 16.5)	5.0 (2.9, 8.9)	2.8 (1.0, 5.5)	5.5 (2.7, 10.0)
- Range	0.1 - 86.9	0.0 - 48.8	0.0 - 49.1	0.0 - 86.9
- Missing	24	14	5	43
ICU length of stay (days)				
- Mean (SD)	35.7 (45.9)	18.9 (17.0)	10.7 (13.5)	22.7 (30.7)
- Median (IQR)	24.0 (12.5, 44.9)	13.8 (6.9, 26.9)	7.0 (1.5, 14.9)	14.9 (6.9, 29.3)
- Range	0.5 - 215.8	0.0 - 113.0	0.0 - 83.9	0.0 - 215.8
- Missing	27	12	6	45
Hospital length of stay (days)				
- Mean (SD)	48.5 (59.5)	35.7 (36.8)	18.0 (23.5)	36.1 (44.7)
- Median (IQR)	33.1 (20.3, 56.3)	25.9 (11.6, 46.4)	8.7 (2.0, 27.2)	24.9 (10.2, 46.0)
- Range	0.4 - 290.9	0.2 - 280.9	0.0 - 131.2	0.0 - 290.9
- Missing	31	14	1	46

Figure 3 shows the age, ICU length of stay and hospital length of stay between patients who received ECMO at one centre (non-retrieved) and patients who were transported from one hospital to another for ECMO while receiving ECMO (retrieved). It also shows the outcome of these patients separated for type of ECMO (VV-ECMO, VA-ECMO and ECPR). Of the retrieved patients, 68%, 60% and 57% survived respectively after VV-ECMO, VA-ECMO and ECPR.



Note: Non-retrieved patients received ECMO at one centre and were not transported from one ECMO centre to another

Figure 3: Summary data for patients who were retrieved on ECMO

Pre-ECMO DATA

Data collected immediately prior to ECMO commencement.

Indications

Tables 3, 4 and 5 show the indication for ECMO. For VV-ECMO, VA-ECMO and ECPR respectively, the most common indication was ARDS (70%), peri-operative support (23%) and acute myocardial infarction (48%). VV-ECMO was used post lung transplant (7%) and VA-ECMO was used post heart transplant (7%).

Table 3: ECMO indication (V-V)

	Overall (N=300)
Respiratory indication	
- ARDS (risk factor)	197 (69.9%)
- Asthma	15 (5.3%)
- Chronic end stage lung disease	11 (3.9%)
- Direct lung trauma	10 (3.5%)
- Drug/toxin pulmonary disease	4 (1.4%)
- Focal lung disease (not ARDS)	19 (6.7%)
- Post lung transplant	21 (7.4%)
- Pulmonary vasculitis/haemorrhage	5 (1.8%)
- Total	282
- Missing	18

Table 4: ECMO indication (V-A)

	Overall (N=411)
Cardiac indication	
- Peri-operative support	93 (23.3%)
- Acute myocardial infarction (AMI)	87 (21.8%)
- Acute decompensated heart failure	77 (19.3%)
- Post heart transplant	29 (7.3%)
- Pulmonary embolism	28 (7.0%)
- Chronic cardiomyopathy	27 (6.8%)
- Myocarditis	24 (6.0%)
- Primary arrhythmia (Channelopathy)	10 (2.5%)
- Septic shock	9 (2.3%)
- Advanced pulmonary hypertension	6 (1.5%)
- Toxic	5 (1.3%)
- Chronic graft (heart) dysfunction	2 (0.5%)
- Congenital heart disease	2 (0.5%)
- Total	399
- Missing	12

Table 5: ECMO indication (ECPR)

	Overall (N=177)
Indication	
- Acute myocardial infarction (AMI)	80 (47.6%)
- Primary arrhythmia (Channelopathy)	22 (13.1%)
- Pulmonary embolism	20 (11.9%)
- Acute decompensated heart failure	11 (6.5%)
- Peri-operative support	7 (4.2%)
- Toxic	7 (4.2%)
- Myocarditis	6 (3.6%)
- Septic shock	3 (1.8%)
- Chronic cardiomyopathy	3 (1.8%)
- Congenital heart disease	3 (1.8%)
- Advanced pulmonary hypertension	3 (1.8%)
- Chronic graft (heart) dysfunction	2 (1.2%)
- Post heart transplant	1 (0.6%)
- Focal lung disease (not ARDS)	0 (0.0%)
- ARDS (risk factor)	0 (0.0%)
- Direct lung trauma	0 (0.0%)
- Chronic end stage lung disease	0 (0.0%)
- Post lung transplant	0 (0.0%)
- Pulmonary vasculitis/haemorrhage	0 (0.0%)
- Asthma	0 (0.0%)
- Drug/toxin pulmonary disease	0 (0.0%)
- Total	168
- Missing	9

Admission

Table 6: Hospital and ICU admission source

	Overall (N=888)
Hospital admission source	
- Home	439 (49.4%)
- Other acute hospital ICU	284 (32.0%)
- Other acute hospital (not ICU/ED)	98 (11.0%)
- Other hospital ED (like ICU above)	65 (7.3%)
- Rehabilitation	1 (0.1%)
- Mental health	1 (0.1%)
- Total	888
- Missing	0
ICU admission source	
- ICU, other hospital	251 (28.4%)
- Operative theatre/recovery	234 (26.5%)
- Emergency department	162 (18.3%)
- Ward	110 (12.5%)
- Catheter lab	63 (7.1%)
- Other hospital	59 (6.7%)
- Direct ICU admission (from home)	3 (0.3%)
- ICU, same hospital	1 (0.1%)
- Total	883
- Missing	5

ECMO DATA

Length of stay

Table 7 describe the duration of time on EMCO and the length of stay in ICU and in hospital for each type of ECMO (VV-ECMO, VA-ECMO and ECPR). Patients on V-V-ECMO had the longest ECMO run (median 8.4 days) and the longest ICU and hospital stay (median 24 and 33.1 respectively).

Table 8 describes the length of stay stratified by transfer status (retrieved versus non-retrieved patients). Patients who were retrieved had a longer duration of ECMO (median 7.3 days versus 4.9 days) and a longer ICU length of stay (median 17.1 versus 13.9 days).

Table 7: Length of stay (days) stratified by ECMO type

	V-V (N=300)	V-A (N=411)	ECPR (N=177)	Total (N=888)
ECMO duration				
- Median (IQR)	8.4 (4.4, 16.5)	5.0 (2.9, 8.9)	2.8 (1.0, 5.5)	5.5 (2.7, 10.0)
- Total	276	397	172	845
- Missing	24	14	5	43
ICU length of stay (days)				
- Median (IQR)	24.0 (12.5, 44.9)	13.8 (6.9, 26.9)	7.0 (1.5, 14.9)	14.9 (6.9, 29.3)
- Total	273	399	171	843
- Missing	27	12	6	45
Hospital length of stay (days)				
- Median (IQR)	33.1 (20.3, 56.3)	25.9 (11.6, 46.4)	8.7 (2.0, 27.2)	24.9 (10.2, 46.0)
- Total	269	397	176	842
- Missing	31	14	1	46

Table 8: Length of stay (days) stratified by transfer status

Type of ECMO		Retrieved (N=209)	Non-retrieved (N=674)	Total (N=883)
V-V	ECMO duration			
	- Median (IQR)	8.8 (5.5, 16.2)	7.9 (3.8, 16.5)	8.4 (4.4, 16.5)
	- Total	92	182	274
	- Missing	10	13	23
	ICU length of stay (days)			
	- Median (IQR)	20.8 (12.7, 36.4)	25.7 (12.5, 48.1)	24.0 (12.5, 44.9)
	- Total	94	178	272
	- Missing	8	17	25
	Hospital length of stay (days)			
	- Median (IQR)	28.8 (18.3, 46.9)	35.8 (21.2, 59.5)	33.1 (20.2, 56.2)
	- Total	93	174	267
	- Missing	9	21	30
V-A	ECMO duration			
	- Median (IQR)	6.1 (3.3, 11.4)	4.9 (2.7, 8.3)	5.0 (2.9, 8.9)
	- Total	85	312	397
	- Missing	1	13	14
	ICU length of stay (days)			
	- Median (IQR)	14.3 (7.5, 26.4)	13.7 (6.9, 26.9)	13.8 (6.9, 26.9)
	- Total	86	313	399
	- Missing	0	12	12
	Hospital length of stay (days)			
	- Median (IQR)	20.3 (11.2, 40.9)	26.9 (11.7, 48.0)	25.9 (11.6, 46.4)
	- Total	85	312	397
	- Missing	1	13	14
ECPR	ECMO duration			
	- Median (IQR)	4.7 (2.5, 10.7)	2.5 (1.0, 5.5)	2.8 (1.0, 5.5)
	- Total	21	150	171
	- Missing	0	4	4
	ICU length of stay (days)			
	- Median (IQR)	9.2 (2.2, 22.3)	6.9 (1.3, 13.9)	7.0 (1.5, 15.0)
	- Total	21	149	170
	- Missing	0	5	5
	Hospital length of stay (days)			
	- Median (IQR)	21.8 (2.7, 32.4)	8.3 (1.6, 27.0)	8.9 (2.0, 27.3)
	- Total	21	153	174
	- Missing	0	1	1

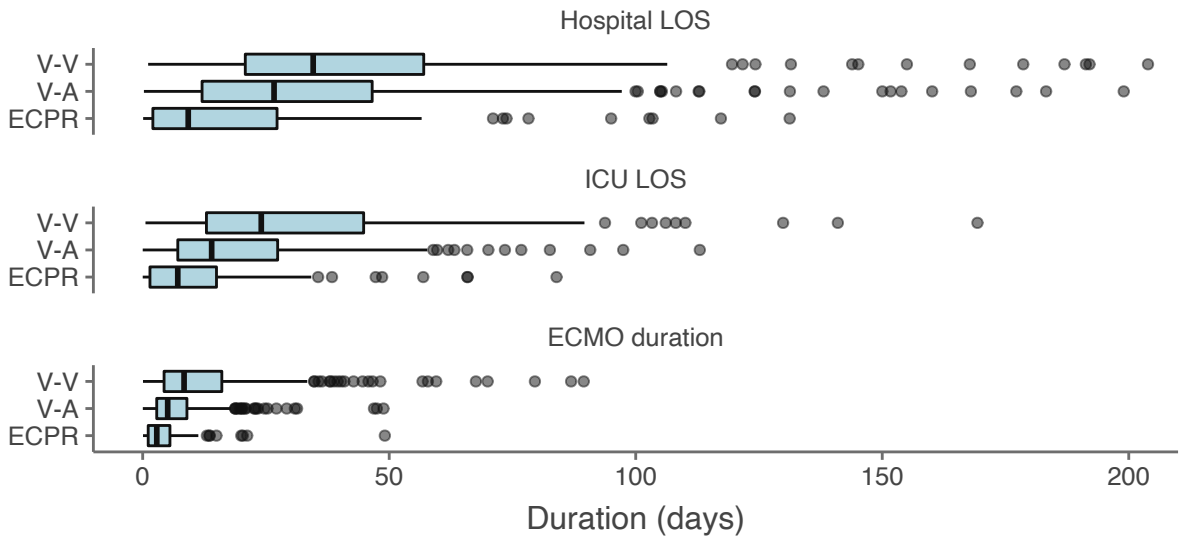


Figure 4: Distribution of length of stay stratified by ECMO mode

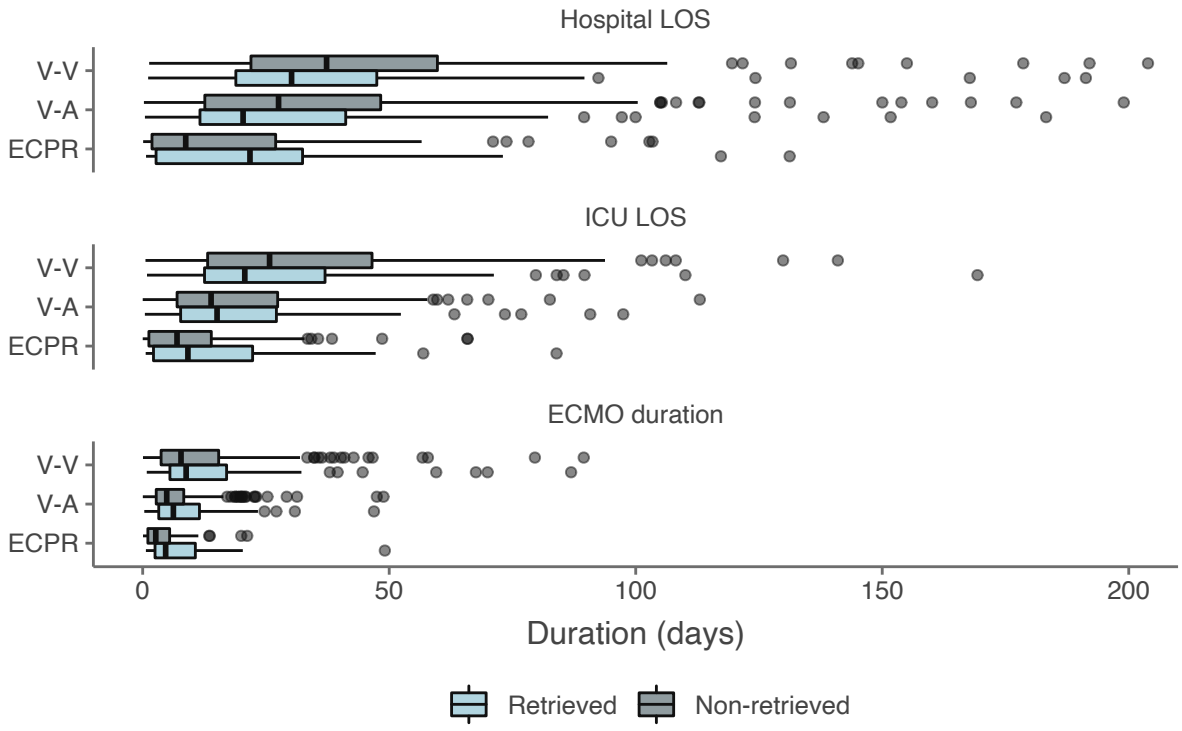


Figure 5: Distribution of length of stay stratified by transfer status

ECMO trips

Table 9: Number of trips while on ECMO stratified by ECMO type

	V-V (N=300)	V-A (N=411)	ECPR (N=177)	Total (N=888)
Number of operative theatre trips[1]				
- Mean (SD)	1.4 (0.9)	2.4 (1.4)	2.0 (1.2)	2.0 (1.3)
- Range	1.0 - 7.0	1.0 - 11.0	1.0 - 6.0	1.0 - 11.0
- Missing	20	7	10	37
Number of radiology trips[1]				
- Mean (SD)	2.3 (2.0)	1.9 (1.7)	2.3 (1.9)	2.1 (1.8)
- Range	1.0 - 9.0	1.0 - 10.0	1.0 - 10.0	1.0 - 10.0
- Missing	21	8	8	37

[1] Trips occur when a patient is physically transferred to another location to facilitate imaging and/or procedure

ECMO discontinuation

Table 10: ECMO discontinuation reason stratified by ECMO type

	V-V (N=300)	V-A (N=411)	ECPR (N=177)	Total (N=888)
ECMO discontinuation reason				
- Expected recovery	202 (73.2%)	239 (59.5%)	77 (43.5%)	518 (60.6%)
- Poor prognosis	33 (12.0%)	80 (19.9%)	47 (26.6%)	160 (18.7%)
- ECMO mortality	31 (11.2%)	44 (10.9%)	48 (27.1%)	123 (14.4%)
- Bridge to VAD	1 (0.4%)	29 (7.2%)	2 (1.1%)	32 (3.7%)
- Bridge to heart transplant	0 (0.0%)	6 (1.5%)	1 (0.6%)	7 (0.8%)
- ECMO complication	3 (1.1%)	4 (1.0%)	0 (0.0%)	7 (0.8%)
- Bridge to lung transplant	3 (1.1%)	0 (0.0%)	0 (0.0%)	3 (0.4%)
- Unknown	2 (0.7%)	0 (0.0%)	1 (0.6%)	3 (0.4%)
- Resource limitation	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
- Bridge to pumpless lung assist (PA to LA)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.1%)
- Total	276	402	177	855
- Missing	24	9	0	33

ICU therapies

Table 11: ICU therapies

	V-V (N=300)	V-A (N=411)	ECPR (N=177)
Second ECMO Run			
- Yes	2 (0.7%)	10 (2.6%)	3 (1.8%)
- No	269 (99.3%)	370 (97.4%)	163 (98.2%)
- Missing	29	31	11
Renal Replacement Therapy			
- Yes	137 (50.0%)	275 (69.4%)	96 (55.5%)
- No	137 (50.0%)	121 (30.6%)	77 (44.5%)
- Missing	26	15	4


Wards 5-6
Intensive Care Unit

COMPLICATIONS

Table 12: Proportion of patients with complications

Complications category	
Renal	78.4%
Cardiovascular	63.6%
Bleeding	51.4%
Infection	50.0%
Mechanical	21.0%
Neurological	18.3%
Pulmonary	11.5%

Major complications are reported to the registry under 7 main categories, renal, cardiovascular, bleeding, infection, mechanical, neurological and pulmonary (Table 12). The most common complications were Renal (78.4%), Cardiovascular (63.6%), Bleeding (51.4%) and Infection (50.0%).

Figures 6, 7 and 8 report complications for each type of ECMO (VV-ECMO, VA-ECMO and ECPR). Renal replacement therapy was the most common complication across all types of ECMO, but for VV-ECMO lung infection was reported for over 40% of cases, and for VA-ECMO and ECPR cardiac arrythmia were among the most common complications.

Figure 9 describes the differences in major complications between patients who were retrieved and non-retrieved. Patient hypoxia and deep vein thrombosis (DVT) were more common in retrieved patients.

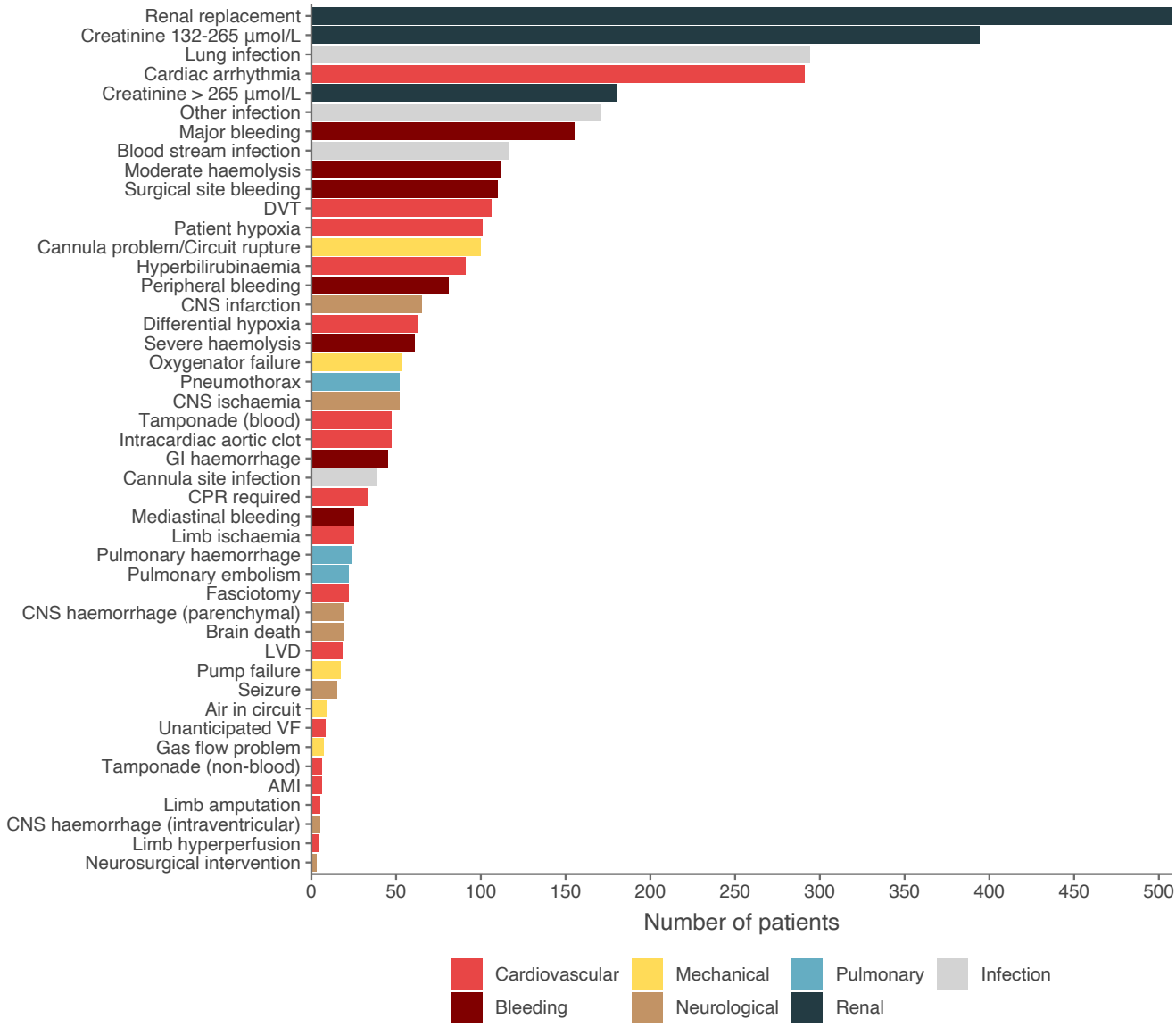


Figure 6: Distribution of post-ECMO complications

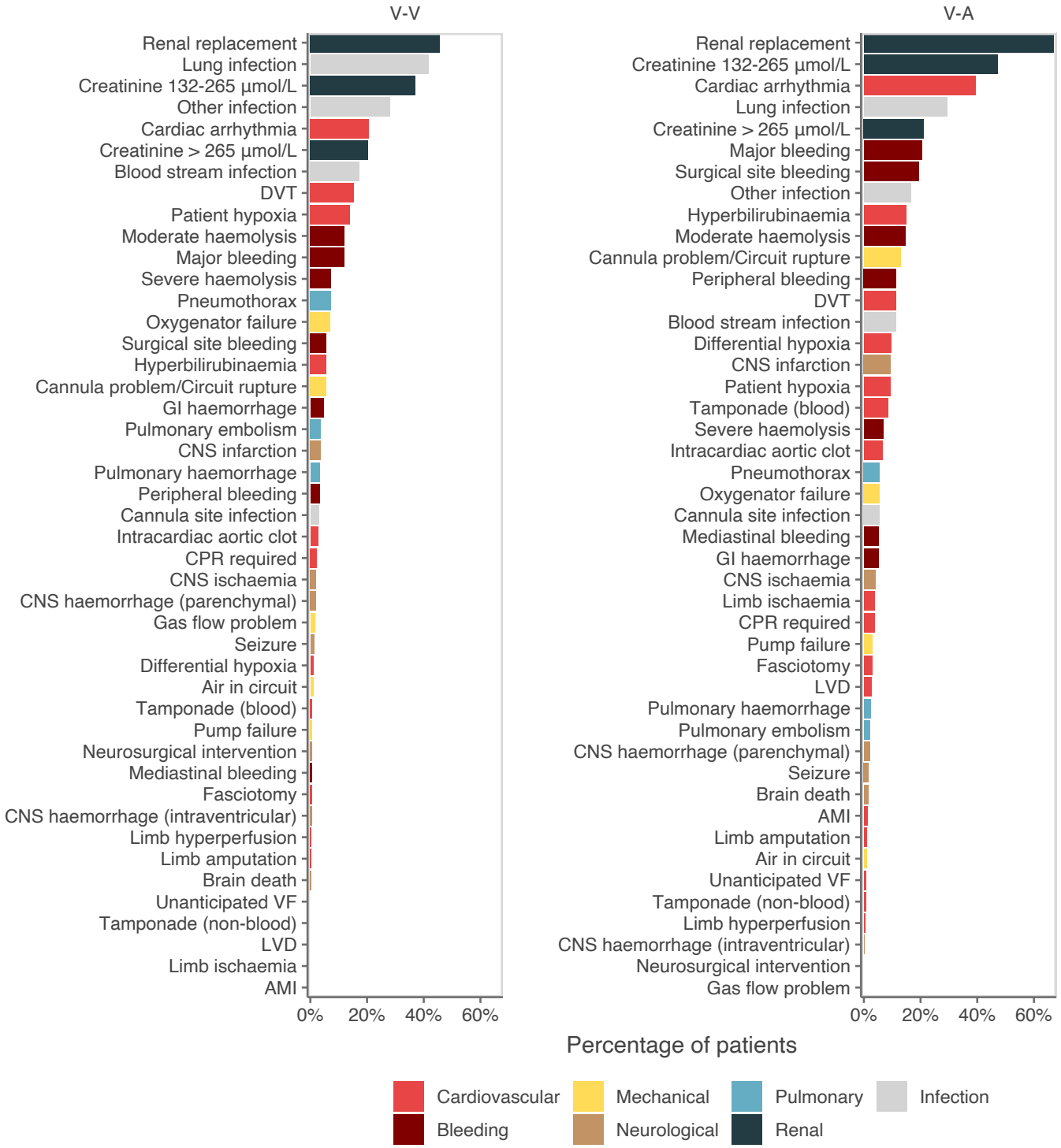


Figure 7: Distribution of post-ECMO complications stratified by ECMO mode (V-V and V-A)

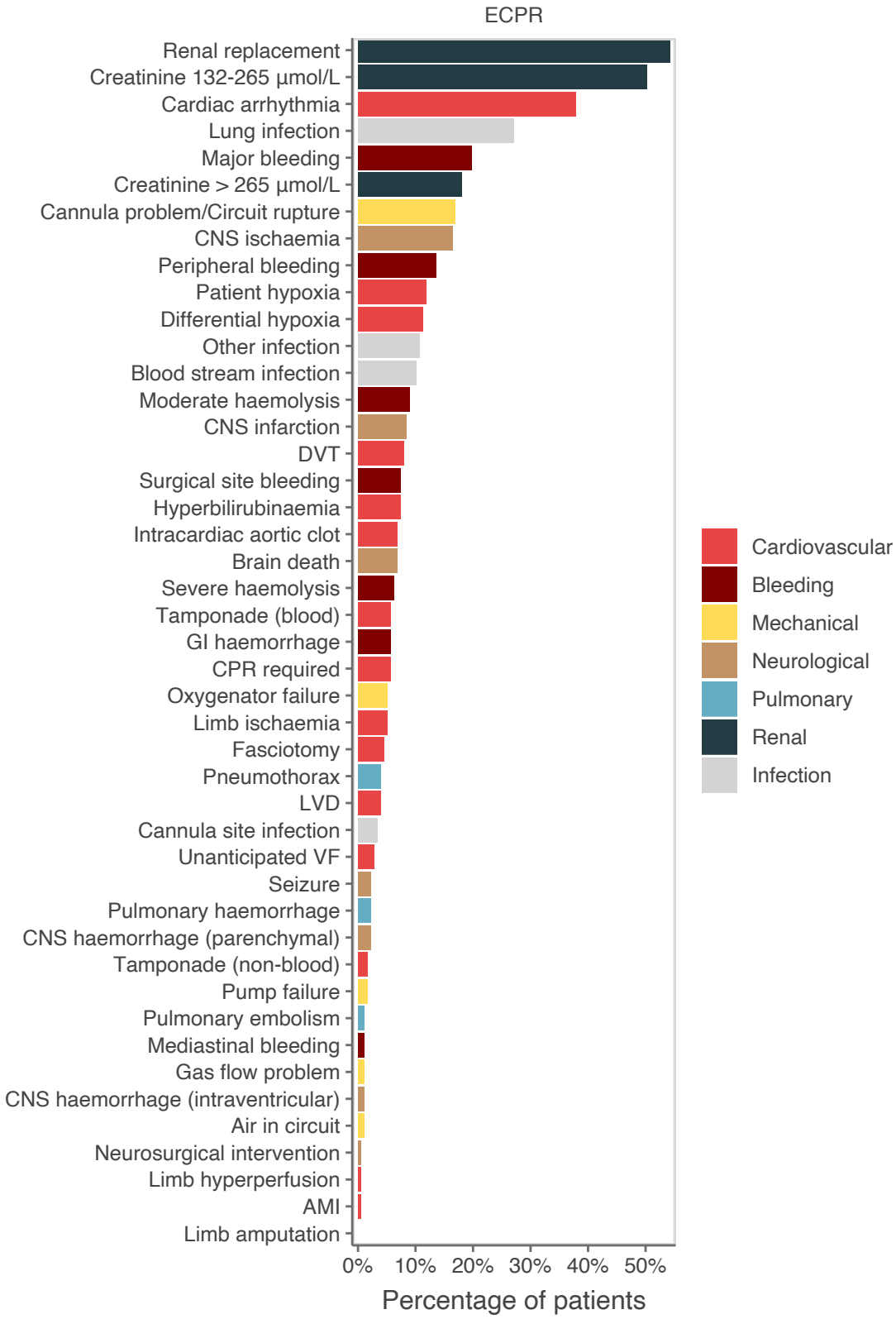


Figure 8: Distribution of post-ECMO complications stratified by ECMO mode (ECR)

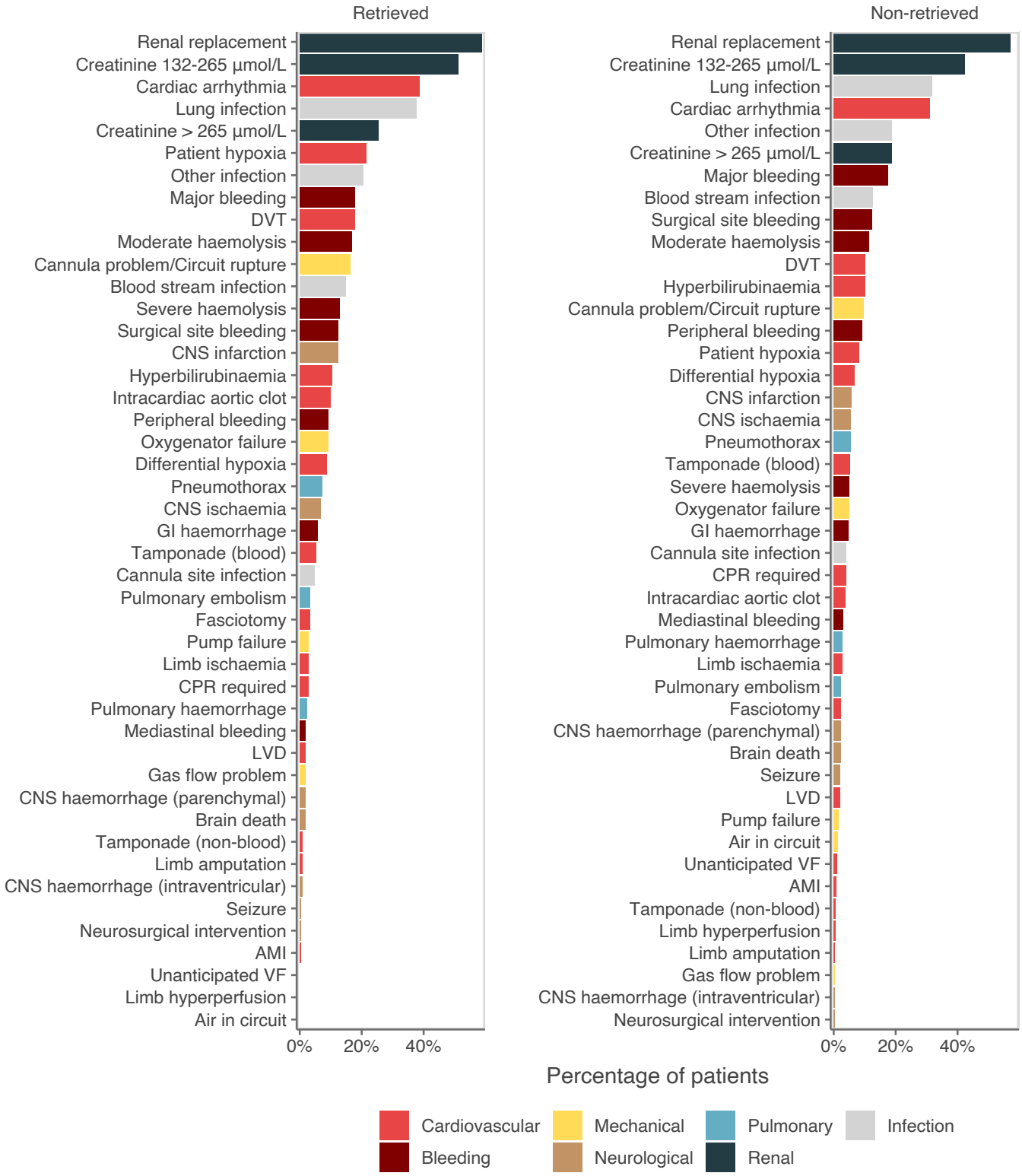


Figure 9: Distribution of post-ECMO complications stratified by transfer status

OUTCOME DATA

Proximate cause of death

Table 13: Proximate cause of death stratified by ECMO type

	V-V (N=300)	V-A (N=411)	ECPR (N=177)	Total (N=888)
Proximate cause of death				
- Cardiogenic shock	0 (0.0%)	83 (46.6%)	41 (36.0%)	124 (33.5%)
- Neurological no TBI without brain death	9 (11.5%)	32 (18.0%)	21 (18.4%)	62 (16.8%)
- Distributive (Septic) shock	27 (34.6%)	24 (13.5%)	8 (7.0%)	59 (15.9%)
- Other	7 (9.0%)	19 (10.7%)	14 (12.3%)	40 (10.8%)
- Hypoxic respiratory failure	27 (34.6%)	2 (1.1%)	3 (2.6%)	32 (8.6%)
- Neurological no TBI with brain death	5 (6.4%)	6 (3.4%)	13 (11.4%)	24 (6.5%)
- Arrhythmia	1 (1.3%)	6 (3.4%)	6 (5.3%)	13 (3.5%)
- Neurological TBI without brain death	1 (1.3%)	0 (0.0%)	5 (4.4%)	6 (1.6%)
- Hypovolaemic shock	0 (0.0%)	2 (1.1%)	2 (1.8%)	4 (1.1%)
- Metabolic	0 (0.0%)	3 (1.7%)	0 (0.0%)	3 (0.8%)
- Neurological TBI with brain death	1 (1.3%)	1 (0.6%)	1 (0.9%)	3 (0.8%)
- Total	78	178	114	370

The most common cause of death was cardiogenic shock (124 (33.5%)) and neurological no tbi without brain death (62 (16.8%)). There were 24 (6.5%) patients who suffered a neurological event that resulted in brain death during or after ECMO. A further 62 (16.8%) died because of a neurological event that did not cause brain death (14).

Discharge destination

Table 14: Discharge destination post-ECMO stratified by ECMO type

	V-V (N=300)	V-A (N=411)	ECPR (N=177)	Total (N=888)
ICU discharge destination				
- Ward	160 (58.0%)	206 (51.2%)	61 (35.1%)	427 (50.1%)
- Deceased	74 (26.8%)	172 (42.8%)	108 (62.1%)	354 (41.5%)
- Other hospital ICU	36 (13.0%)	22 (5.5%)	3 (1.7%)	61 (7.2%)
- Other	1 (0.4%)	2 (0.5%)	2 (1.1%)	5 (0.6%)
- Other hospital- normal ward	4 (1.4%)	0 (0.0%)	0 (0.0%)	4 (0.5%)
- Home	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
- Total	276	402	174	852
- Missing	24	9	3	36
Hospital discharge destination				
- Deceased’	78 (29.0%)	178 (44.8%)	115 (65.3%)	371 (44.1%)
- Home	88 (32.7%)	108 (27.2%)	32 (18.2%)	228 (27.1%)
- Transfer to rehab	38 (14.1%)	65 (16.4%)	21 (11.9%)	124 (14.7%)
- Transferred to another hospital	63 (23.4%)	43 (10.8%)	8 (4.5%)	114 (13.5%)
- Other	2 (0.7%)	3 (0.8%)	0 (0.0%)	5 (0.6%)
- Total	269	397	176	842
- Missing	31	14	1	46

Overall, most patients were discharged from ICU to the ward (427 (50.1%)), but 354 (41.5%) were deceased and 61 (7.2%) were discharged to the ICU in another hospital. After hospital discharge, only 228 (27.1%) were discharged home while 124 (14.7%) were transferred to a rehabilitation facility.

Survival

We have shown survival to 180-days in Kaplan-Meier plots stratified by type of ECMO (Figure 10) and by type of ECMO and retrieval status (Figure 11). Patients receiving VV-ECMO are most likely to survive overall and patients receiving ECPR are least likely to survive.

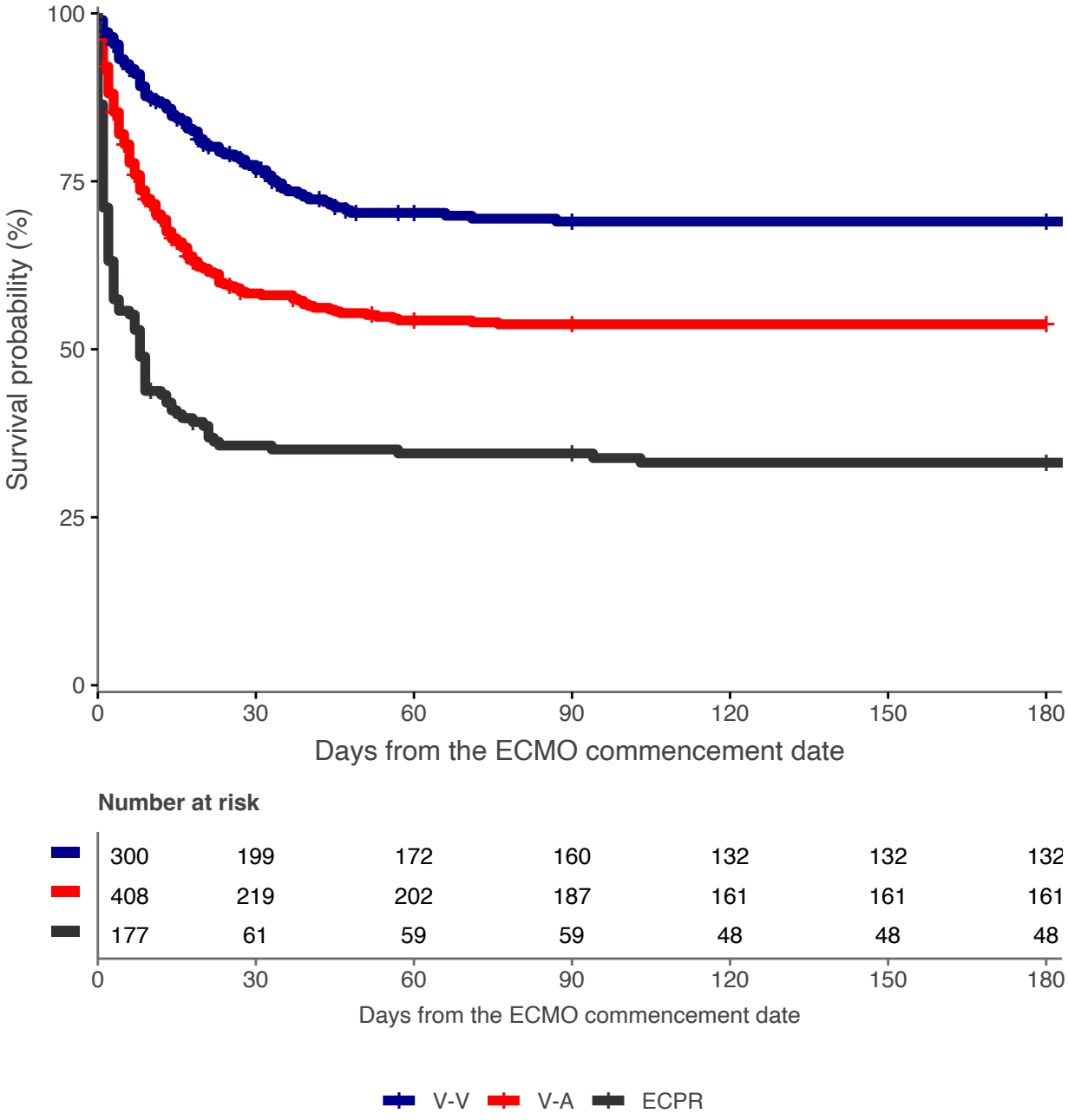


Figure 10: Kaplan-Meier plot of survival stratified by ECMO type

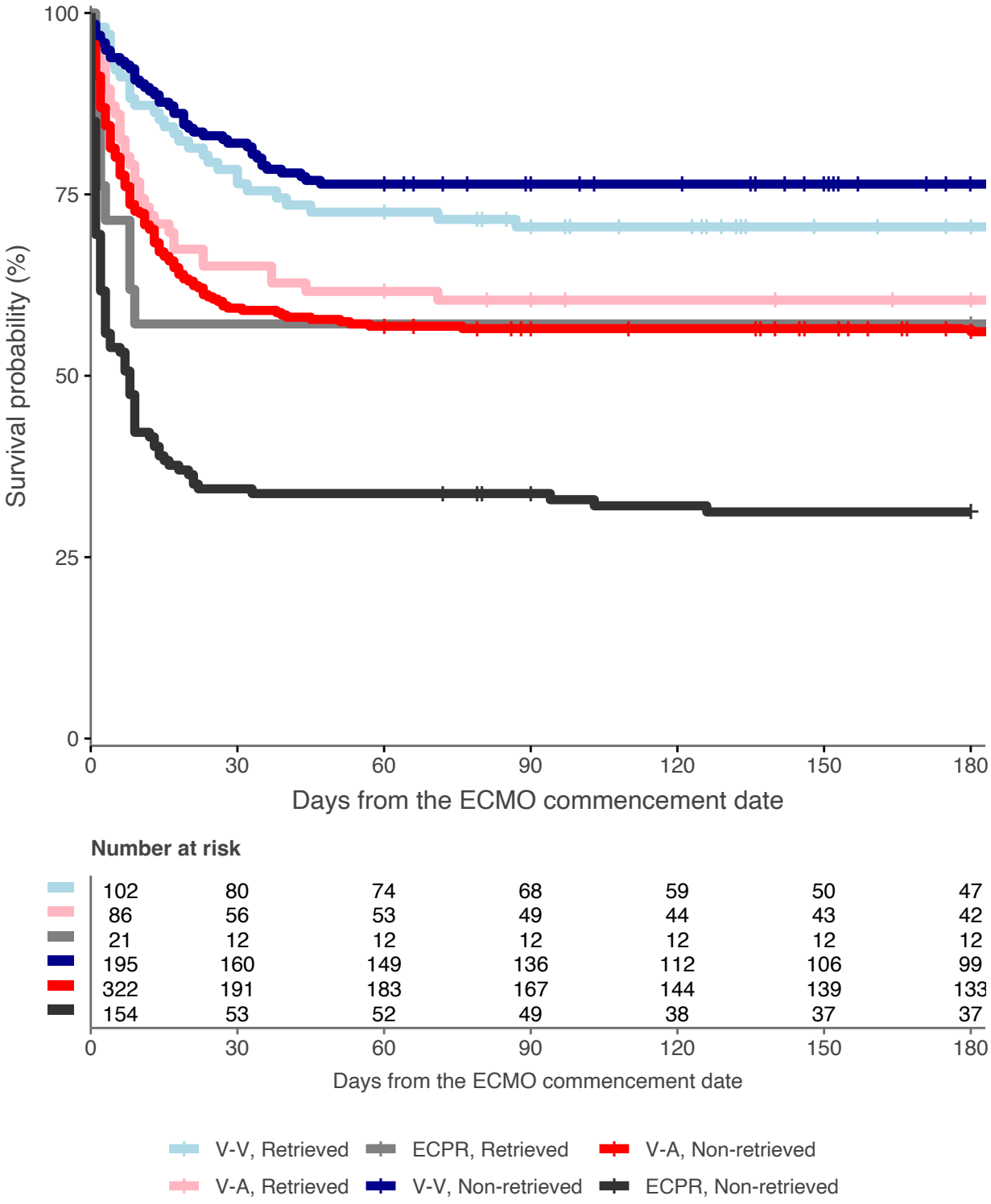


Figure 11: Kaplan-Meier plot of survival stratified by transfer status and ECMO type

Funnel plots

We provide risk-adjusted mortality for VV-patients (using the RESP score), for VA-patients (using the SAVE score) and for ECPR patients (also using the SAVE score). Each dot represents a site, and the shaded areas represent the 95% and the 99.8% control limits. In reports to each site biannually, the site is identified using a different colour to allow interpretation of outliers.

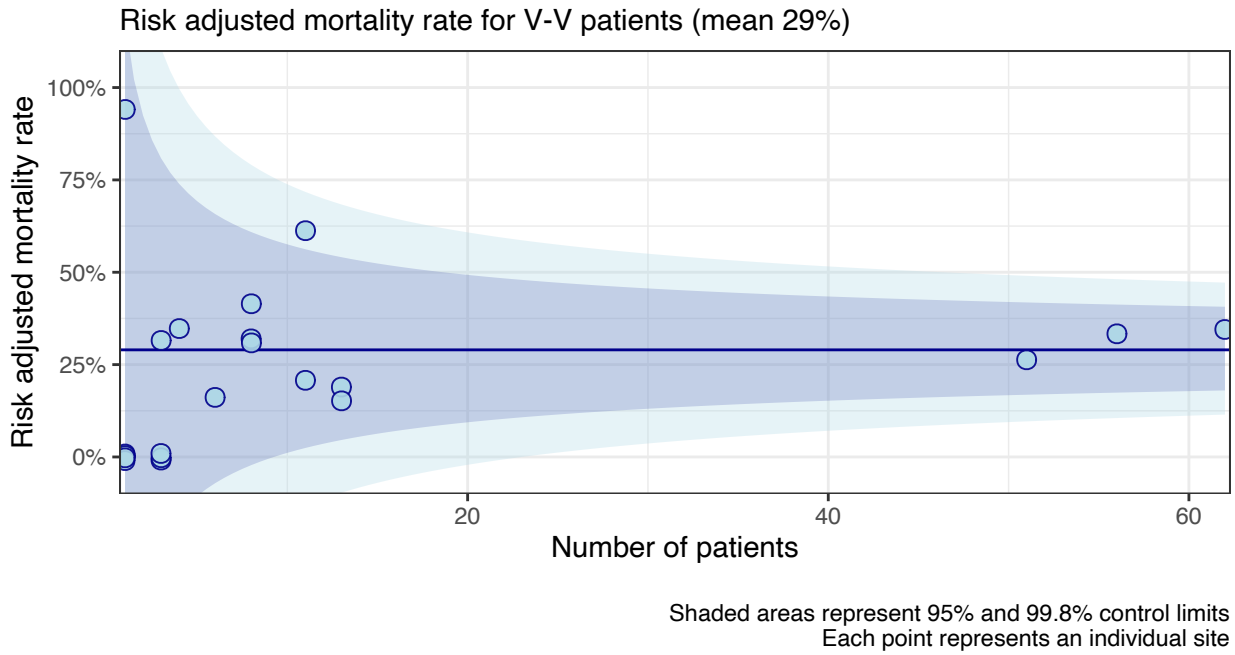


Figure 12: Risk adjusted mortality rate for V-V patients

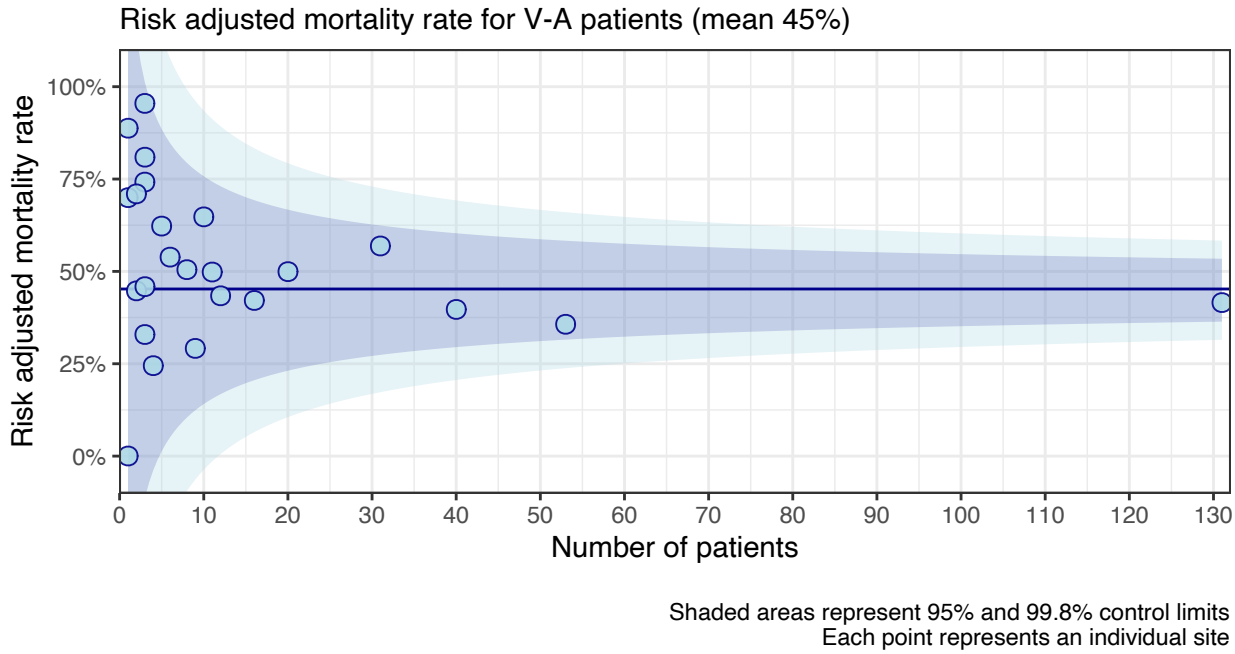


Figure 13: Risk adjusted mortality rate for V-A patients

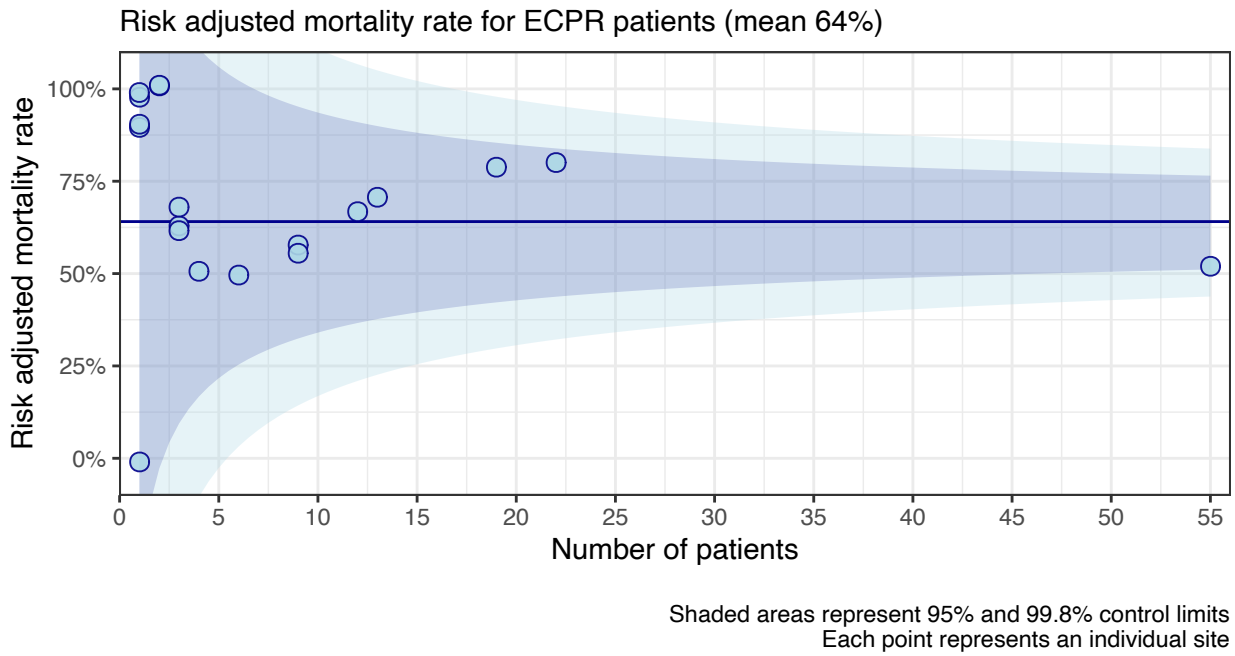


Figure 14: Risk adjusted mortality rate for ECPR patients

FOLLOW-UP (6 months post ECMO)

We follow-up each surviving patient at 6 and 12 months by telephone from the Australian and New Zealand Intensive Care Research Centre using trained personnel. Each call is monitored for quality purposes. The patient reported outcome measures (PROMS) used include:

- The Lawton IADL Scale is a valid and reliable functional assessment instrument which assesses independent living skills across 8 domains of function. A summary score ranges between from 0 and 8 with higher scores indicating greater levels of independence.
- The Barthel Index measures functional disability in 10 ADLs by quantifying patient performance. 5-point increments are used in scoring, with a maximal score of 100 indicating full independence in physical functioning whilst a lowest score of 0 indicating a patient with a complete bed-bound state.
- The EQ-5D-5L is a generic preference-based instrument that measures health related quality of life. It is comprised of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ Visual Analogue Scale provides a single global rating of self-perceived health and is scored on a 0 to 100 scale representing “the worst…” and “the best health you can imagine”, respectively
- The 12-item WHODAS 2.0 score scores from 0 (no difficulty) to 4 (extreme difficulty) for each item and a total WHODAS score ranges from 0 to 48, with higher scores representing greater disability. The total score is divided by 48 and multiplied by 100 to convert it to a percentage of maximum disability.

Table 15: Follow-up functional outcome measures and ECMO mode

	V-V (N=129)	V-A (N=173)	ECPR (N=51)	Total (N=353)
WHODAS 2.0 12L				
- Mean (SD)	19.9 (19.9)	19.2 (17.1)	20.1 (18.7)	19.6 (18.4)
- Median (IQR)	14.6 (4.2, 29.2)	14.6 (4.2, 27.1)	12.5 (4.2, 35.4)	14.6 (4.2, 29.2)
- Range	0.0 - 91.7	0.0 - 75.0	0.0 - 75.0	0.0 - 91.7
- Missing	18	24	6	48
IADL				
- Mean (SD)	6.8 (1.8)	6.5 (2.0)	6.6 (1.8)	6.6 (1.9)
- Median (IQR)	8.0 (6.0, 8.0)	7.0 (5.5, 8.0)	7.0 (6.0, 8.0)	8.0 (6.0, 8.0)
- Range	0.0 - 8.0	1.0 - 8.0	1.0 - 8.0	0.0 - 8.0
- Missing	17	22	5	44
Barthel index				
- Mean (SD)	94.5 (13.3)	94.9 (11.0)	92.7 (15.8)	94.4 (12.6)
- Median (IQR)	100.0 (95.0, 100.0)	100.0 (95.0, 100.0)	100.0 (95.0, 100.0)	100.0 (95.0, 100.0)
- Range	30.0 - 100.0	35.0 - 100.0	30.0 - 100.0	30.0 - 100.0
- Missing	17	22	5	44
Health related quality of life				
- Mean (SD)	73.7 (18.3)	70.3 (19.9)	72.1 (18.9)	71.8 (19.2)
- Median (IQR)	75.0 (60.0, 90.0)	75.0 (60.0, 85.0)	75.0 (60.0, 90.0)	75.0 (60.0, 90.0)
- Range	20.0 - 100.0	8.0 - 100.0	25.0 - 100.0	8.0 - 100.0
- Missing	17	23	6	46

While recovery at 6-months is variable, the majority of survivors report mild to moderate disability. This is despite being able to independently manage their daily activities. Health related quality of life is similar to other survivors of critical illness.

Distribution of 6-month follow-up functional outcome measures

Vertical lines illustrate 25th, 50th, and 75th percentiles

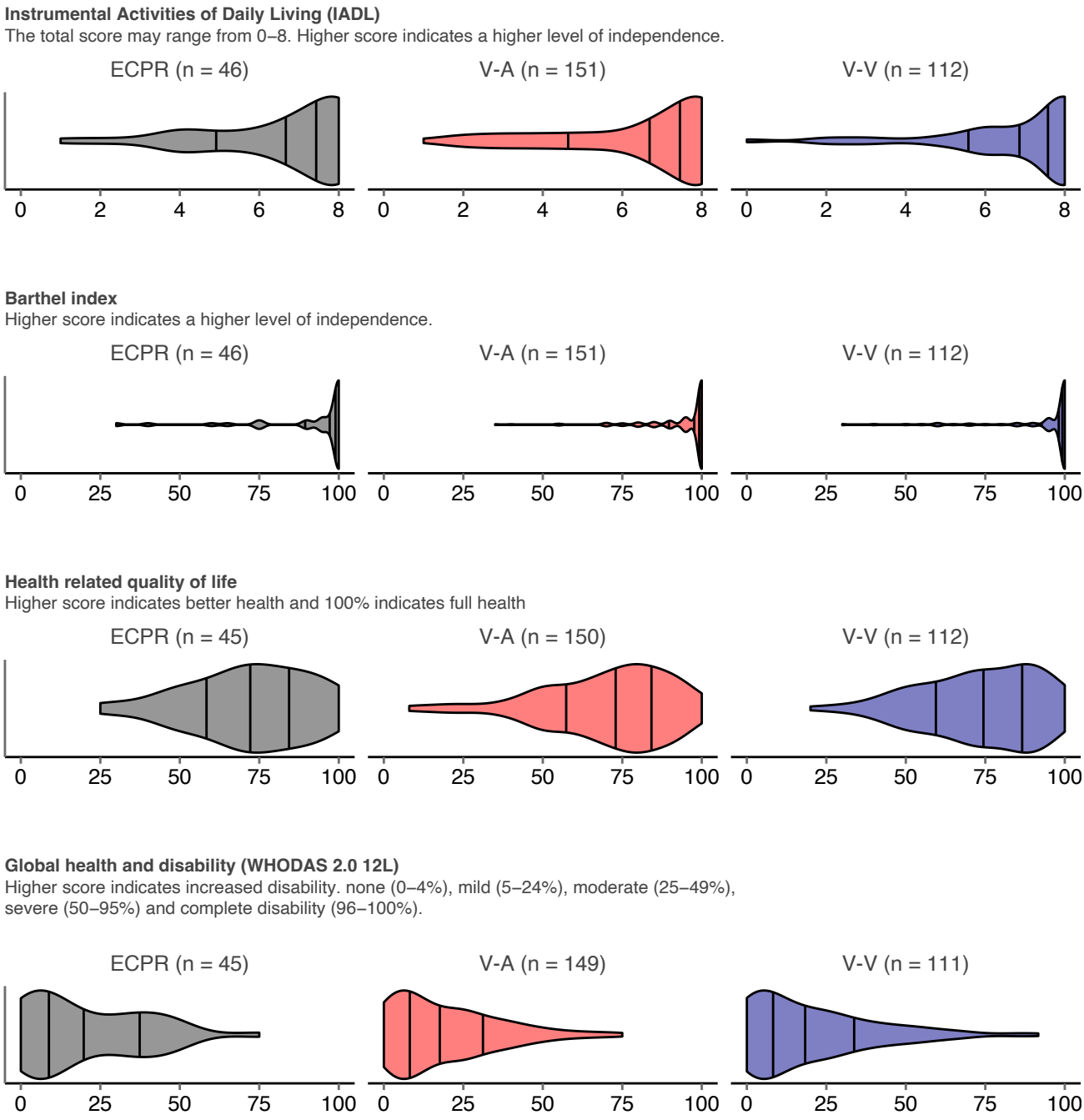


Figure 15: Distribution of follow-up functional outcome measures and ECMO mode

COVID-19 PATIENTS

In 2020 we added additional data points to determine the use of ECMO in patients with COVID-19, aligned with the data in the international registry (ELSO). There were 94 (11%) patients who were diagnosed with COVID-19 who received ECMO in this period. Patients with COVID-19 had a longer duration of ECMO, longer ICU and hospital length of stay (Figure 17). Survival of patients with COVID-19 was lower than other patients on VV-ECMO (Figure 19).

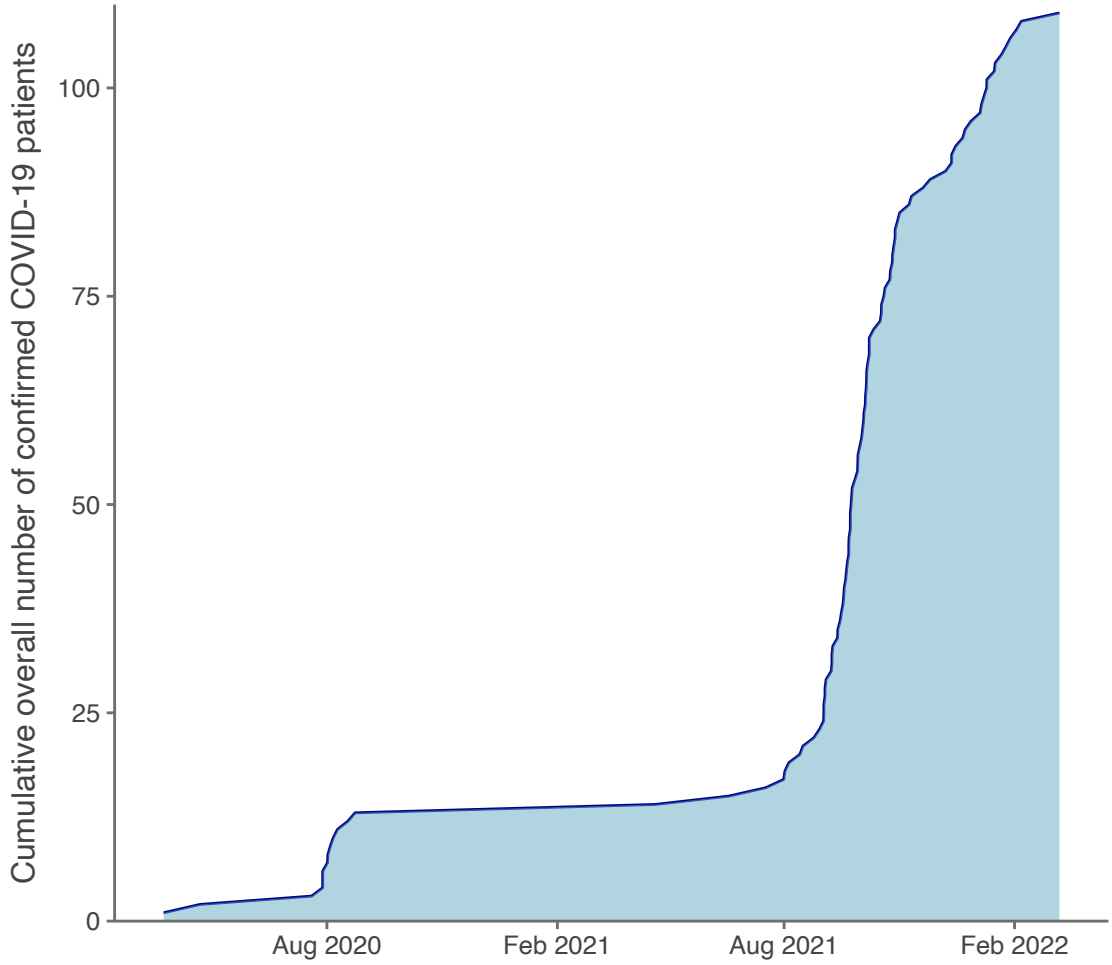


Figure 16: Cumulative overall confirmed COVID-19 patients

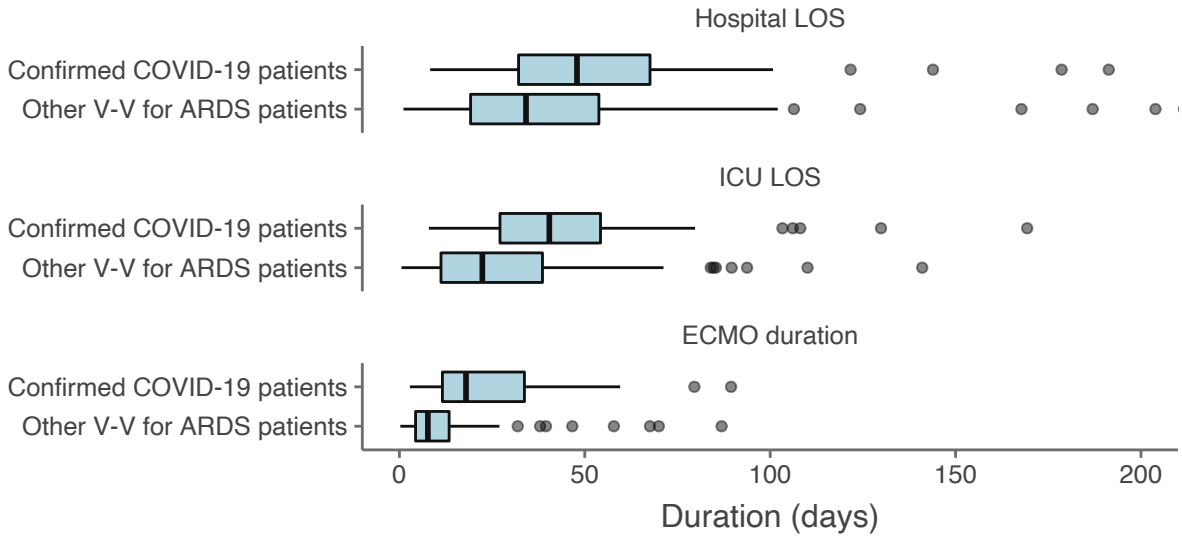


Figure 17: Distribution of length of stay stratified by COVID-19 status

Table 16: Discharge destination post-ECMO stratified by COVID-19 status

	Confirmed COVID-19 patients (N=94)	Other V-V for ARDS patients (N=112)	Total (N=206)
ICU discharge destination			
- Ward	31 (41.9%)	56 (51.4%)	87 (47.5%)
- Deceased	30 (40.5%)	33 (30.3%)	63 (34.4%)
- Other hospital ICU	12 (16.2%)	16 (14.7%)	28 (15.3%)
- Other hospital- normal ward	1 (1.4%)	2 (1.8%)	3 (1.6%)
- Home	0 (0.0%)	1 (0.9%)	1 (0.5%)
- Other	0 (0.0%)	1 (0.9%)	1 (0.5%)
- Total	74	109	183
- Missing	20	3	23
Hospital discharge destination			
- Deceased’	31 (44.3%)	34 (31.5%)	65 (36.5%)
- Transferred to another hospital	17 (24.3%)	32 (29.6%)	49 (27.5%)
- Home	11 (15.7%)	24 (22.2%)	35 (19.7%)
- Transfer to rehab	11 (15.7%)	16 (14.8%)	27 (15.2%)
- Other	0 (0.0%)	2 (1.9%)	2 (1.1%)
- Total	70	108	178
- Missing	24	4	28

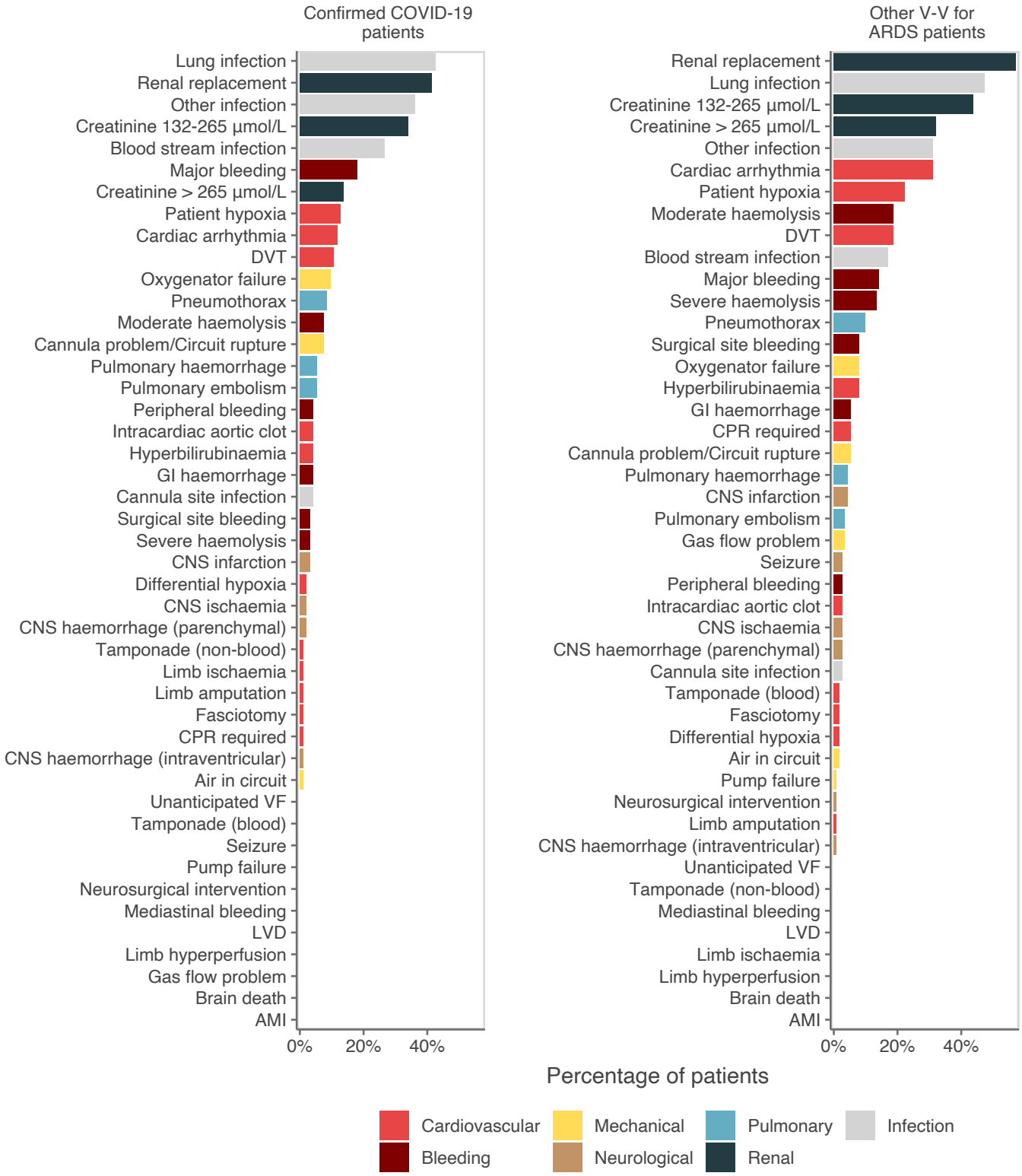


Figure 18: Distribution of post-ECMO complications stratified by COVID-19 status

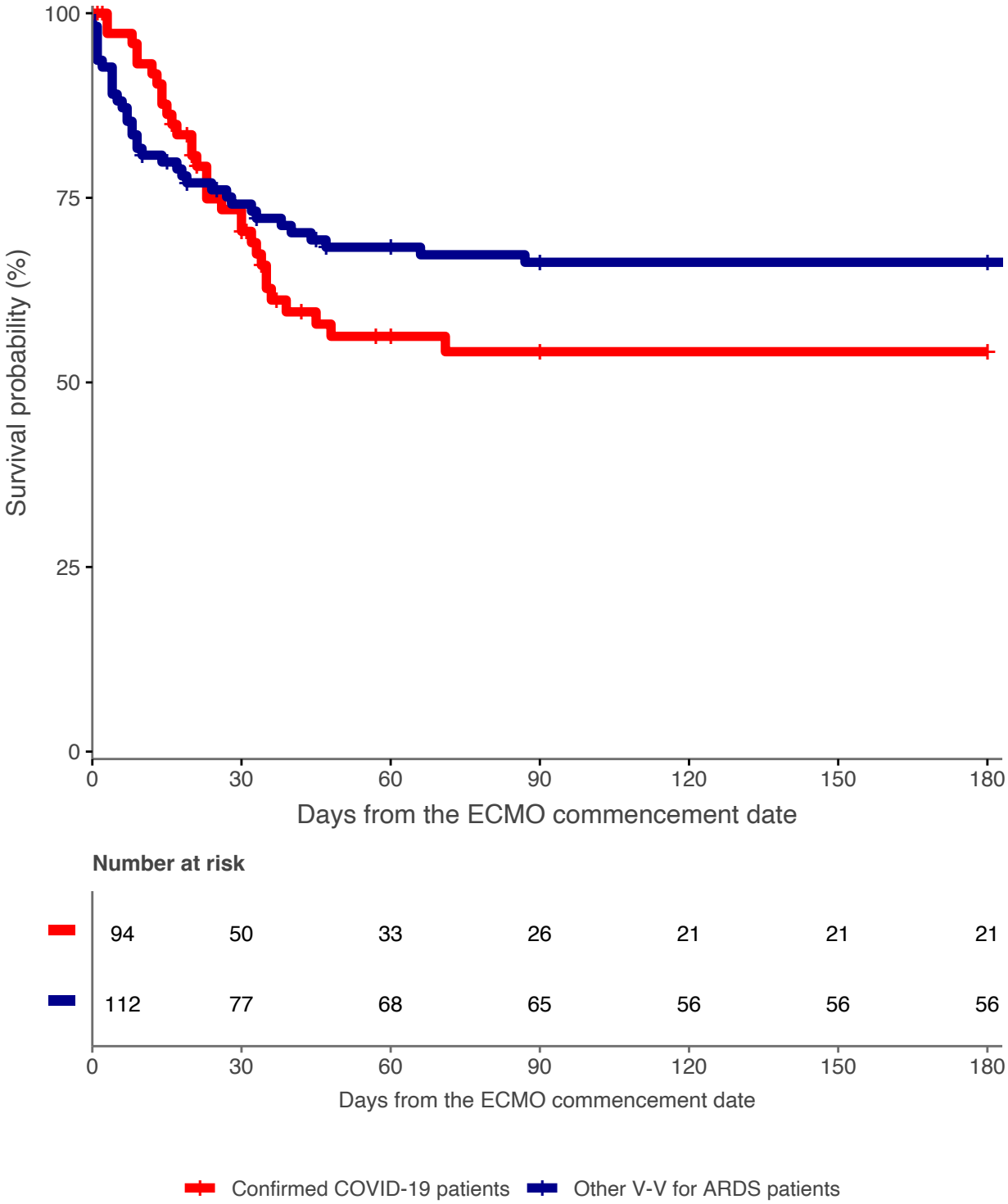


Figure 19: Kaplan-Meier plot of survival stratified by COVID-19 status

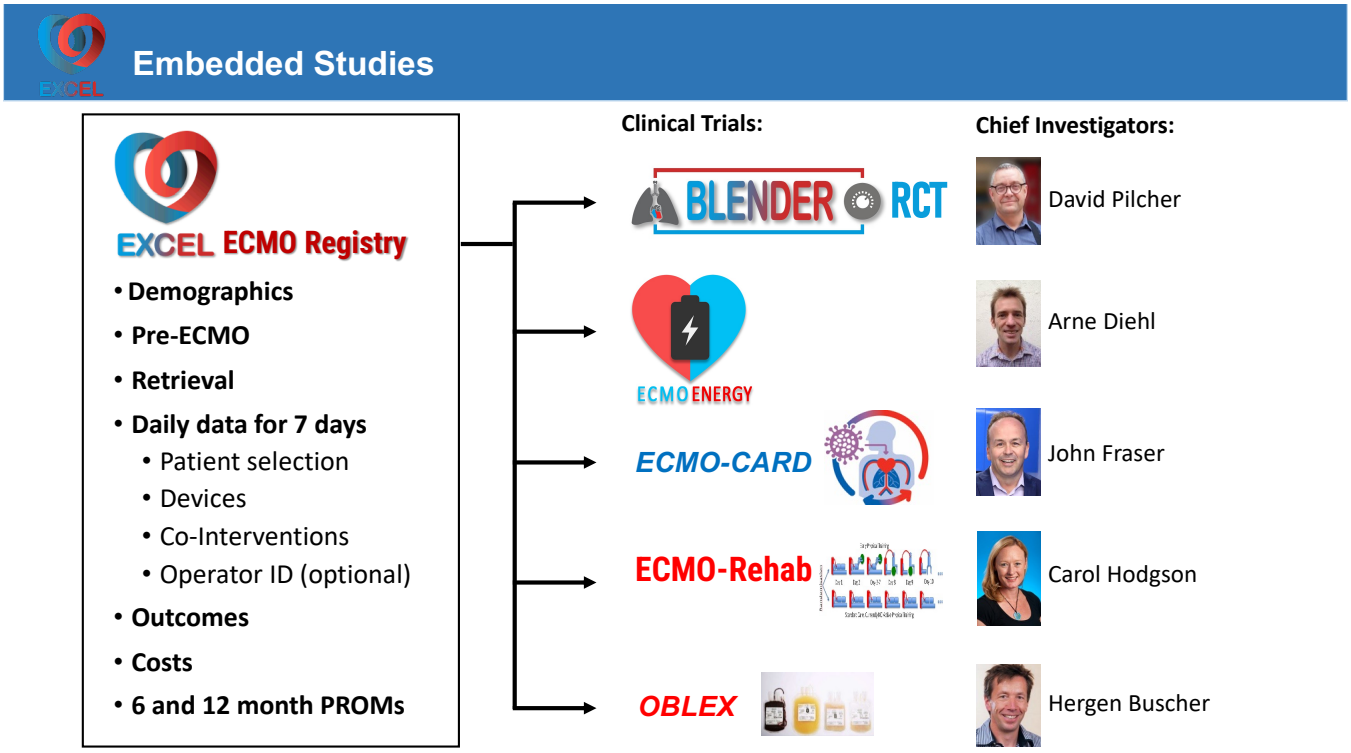
FUTURE INITIATIVES

As the EXCEL Registry moves towards maturity, the data are becoming more valuable for monitoring ECMO in Australia. We will be undertaking further work on testing and refining algorithms to identify outliers, device performance, safety signals, risk prediction and patient outcomes.

We anticipate that data from the EXCEL Registry will become increasingly important to drive continuous quality improvement in healthcare. We plan more detailed reports back to sites and funders including their choice of process measures of care. We will continue to work with stakeholders, including consumers, to raise awareness about the registry within Australia. This report is designed to provide feedback to Australian and New Zealand ECMO sites about patient outcomes and to inform healthcare providers about the national use and outcomes of ECMO.

We have been fortunate to receive partnership funding from the NHMRC, Heart Foundation, the International ECMO Network, The Dicker Family, Critical Care Research Group (CCRG), and major Australian ECMO sites including The Prince Charles Hospital, The Alfred, St Vincent's Hospital Sydney, The University Hospital Geelong, and Royal Prince Alfred Hospital. We will be exploring alternate funding models within the Commonwealth, and look forward to engaging with stakeholders to measure and report on new models of care.

The EXCEL Registry will continue to work with our research collaborators, including the existing studies that are embedded within the registry:



We have five completed publications (see below) and several planned publications on retrievals, decannulation, long term outcomes and costs. We have presented our data at The World Congress of Intensive Care (2019) and the ANZICS Conference on Safety and Quality (2019), with over 20 national and international presentations completed over this three year period. Work is also being done with the INDEX Registry in North America, and a planned annual report may eventuate.

On behalf of the EXCEL Management Committee, we look forward to another active year ahead, working with clinicians, hospitals, patients and other stakeholders to improve the health of Australians on ECMO.

PUBLICATIONS

1. Linke NJ, Fulcher BJ, Engeler DM, et al; EXCEL Investigators. A survey of extracorporeal membrane oxygenation practice in 23 Australian adult intensive care units. Crit Care Resusc 2020;22(2):166-70. PMID: 32389109

2. Hodgson, C. L., Fulcher, B., Mariajoseph, F. P., Burrell, A., Pellegrino, V., Brodie, D., Fan, E., & SCOPE Study Investigators on behalf of the International ECMO Network (2021). A Core Outcome Set for Research in Patients on Extracorporeal Membrane Oxygenation. Critical care medicine, 49(12), e1252–e1254. https://doi.org/10.1097/CCM.0000000000005110

3. Fulcher BJ, Nicholson AJ, Linke NJ, Berkovic D, Hodgson CL; EXCEL Study Investigators and the International ECMO Network. The perceived barriers and facilitators to implementation of ECMO services in acute hospitals. Intensive Care Med. 2020;46(11):2115-7. PMID: 32705292

4. Hodgson CL, Burrell AJC, Engeler DM, Pellegrino VA, Brodie D, Fan E, International ECMO Network. Core Outcome Measures for Research in Critically Ill Patients Receiving Extracorporeal Membrane Oxygenation for Acute Respiratory or Cardiac Failure: An International, Multidisciplinary, Modified Delphi Consensus Study. Crit Care Med 2019;47(11):1557-63. PMID: 31389837

5. ECMO-PT Study Investigators; International ECMO Network. Early mobilisation during extracorporeal membrane oxygenation was safe and feasible: a pilot randomised controlled trial. Intensive Care Med 2020;46(5):1057-9. PMID: 32179935

APPENDIX

Complications

The EXCEL Registry currently collects a range of complications that both clinicians and researchers feel is important to know when a patient undergoes ECMO. This data will help to drive both improvement and identification of complications that present most notability within specific ECMO populations, as well as the ECMO cohort as a whole. The definitions for these complications have recently been updated with regard to new research evidence decided upon by the international ECMO community (e.g. core outcome set - Hodgson et al, Crit Care Med, 2021).

The captured complications are listed below.

Mechanical Complications

Relates directly to components within the ECMO circuit that are used to deliver extracorporeal support. This can include things such as:

- Oxygenator and pump failure requiring exchange of these components
- Cannula problems and circuit rupture.
- Formation of clots within the circuit's components (connectors, bridges, pigtails) or within the haemofilter itself
- Disruption of gas flow and air within the circuit
- Heat exchanger malfunction

Haemorrhagic Complications

Due to the high acuity and often post-operative status of these patients, we collect an extensive range of bleeding complications. These include:

- GI haemorrhage (upper or lower GI)
- Peripheral and mediastinal site bleeding.
- Surgical site bleeding (other than the cannulation sites)
- Major bleeding which can include fatal or symptomatic bleeds within critical areas or regions, as well as whether a fall in haemoglobin or transfusion has been performed.

Renal Complications

- Creatinine serum measurement of >132.
- Use of renal replacement therapy

Cardiovascular Complications

A large proportion of ECMO patients undergo the intervention based upon a cardiovascular related diagnosis. The following complications seek to elucidate the further development of cardiac conditions following institution of ECMO.

- Cardiac arrest requiring CPR
- Cardiac arrythmia requiring antiarrhythmic medications, overdrive pacing, cardioversion or defibrillation
- Tamponade.
- Acute myocardial infarction.
- Left ventricular distension requiring decompression of the left ventricle after initiation of VA-ECMO
- Unanticipated ventricle fibrillation.
- Intracardiac/aortic clot confirmed by echocardiography

Pulmonary Complications

- Pneumothorax requiring insertion of chest drain
- Pulmonary haemorrhage requiring a packed red blood cell transfusion
- Pulmonary embolism diagnosed with contrast angiography, ventilation perfusion scan, isotope scanning or CTPA.

Metabolic Complications

ECMO patients are also noted to undergo serious metabolic changes and complications during the intervention.

- Hyperbilirubinemia – Based on total bilirubin or conjugated bilirubin, or the need for extracorporeal purification
- Moderate and severe haemolysis – Peaks in plasma haemoglobin sustained for 2 recordings 4 hours apart
- Patient hypoxia – With an oxygen saturation level below 80% lasting more than 5 minutes or requiring an emergency response.
- Differential hypoxia – Lower oxygen saturation readings on one side of the body when compared to the other

Limb Complications

Extended stays within ICU as well as peripheral limb cannulation sites can develop into a number of limb complications for the ECMO patient.

- Fasciotomy – Performed secondary to compartment syndrome from ECMO cannulation
- Pressure injury – Localised damage to the skin and underlying tissue caused by pressure or shearing force
- Limb amputation – Secondary to complications experienced during ECMO run
- Limb ischaemia requiring limb perfusion cannula – Post peripheral cannulation, requiring addition of limb reperfusion cannula within 6 hours of cannulation
- Deep vein thrombosis – Diagnosed with imaging (ultrasound or venography)
- Limb hyper-perfusion – Caused by the ECMO cannula, causing increased blood flow in a limb

Neurological Complications

- Brian death or neurological determination of death
- Seizures clinically determined
- Seizures confirmed by EEG
- CNS diffuse ischaemia – CT or MRI demonstrating ischaemic changes
- CNS infarction (US or CT or MRI) OR thrombotic/embolic CVA
- Intracranial haemorrhage – Acute neurological deficit attributable to intracranial haemorrhage
- Neurological intervention performed – For example, intracranial pressure monitor or external ventricular drain inserted

Other Complications

This is a free text field within the database in which we give clinicians the ability to enter in any other complication they believe are a result of the patient being on ECMO. This has assisted in identification and addition of new complications that were not previously available, but that have been found to occur frequently within this patient cohort.