

February 2020

# Implementing the Victorian ECMO Service

Part two: Appendices





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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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ISBN 978-1-76069-207-0 (print) ISBN 978-1-76069-207-0 (online)

Available at Safer Care Victoria www.safercare.vic.gov.au (1709046)



# **About this report**

Safer Care Victoria (SCV) is working with the Department of Health and Human Services (the department) to refine and implement a new delivery model for extracorporeal membrane oxygenation (ECMO) in Victoria. This report should be read in conjunction with *Implementing the Victorian ECMO Service: Part one*.

While part one gives a high level overview of our proposed structure for the new statewide service, this report (part two) explores in detail the clinical and operational data, feedback and experience surveys, pathways of care, selection criteria, credentialing, training and accreditation.

# **HOW TO READ THIS REPORT**

This report is divided into eight appendices:

# **Appendix 1**

covers what clinical and operational data should be collected and reported to support the ongoing operation the Victorian ECMO Service and drive quality and safety improvements.

# **Appendix 2**

details how we will collect feedback from clinicians working within the Victorian ECMO Service and consumers undergoing treatment, to learn from their experiences and improve the service.

# **Appendix 3**

outlines our proposed pathways of care, including consultation and coordination between services.

# **Appendix 4**

covers things you should consider when deciding on ECMO for a patient, including the eligibility criteria and diagnostic groups for each type of ECMO.

# Appendix 5

outlines what each health service will need to do to participate in the Victorian ECMO Service as an initiation site, intermedia centre, or comprehensive centre.

# **Appendix 6**

covers the credentialing requirements for staff participating in the Victorian ECMO Service, including what's required for specific roles within the service.

# **Appendix 7**

outlines our plan for a statewide training program for the Victorian ECMO Service.

# **Appendix 8**

details our approach to testing different elements of the service including referral and retrieval pathways, clinical criteria and hospital accreditation requirements.

# **Appendix 1: Data collection and reporting**

This section covers the clinical and operational data that should be collected and reported to support the ongoing operation of the Victorian ECMO Service and drive quality and safety improvements. We've included data collection processes for Adult Retrieval Victoria, Ambulance Victoria and clinical quality registries, as well as reporting processes for operations and performance data.

# 1.1 DATA COLLECTION

# 1.1.1 Adult Retrieval Victoria, Ambulance Victoria

Ambulance Victoria should help monitor the Victorian ECMO Service by reporting on clinical and operational data about coordination, retrieval and bed management including existing quality assurance reports.

Additional data points can be added to Ambulance Victoria's clinical information software platform for Adult Retrieval Victoria (ARVIS) to capture ECMO patients (Table 1). These new data points will ideally be dropdown boxes or toggle buttons to avoid free text.

Table 1: Additional data fields for ARVIS to support monitoring of the Victorian ECMO Service

Data field	First level response	Second level response	Third level response
ECMO case	Advice only – not retrieved	Too well for ECMO Disease process too advanced	
		Lack of destination therapy	
		Out of criteria	
		Other (allow free text)	
	Retrieval	Off ECMO	ARV only
			ARV + ECMO retrieval
			team
		On ECMO	VV
			VA
			ECPR
Destination site (ECMO)	Comprehensive		
	Intermediate: Hospital A		
	Intermediate: Hospital B		
Retrieval timing (ECMO)	Date/time of presentation to referring hospital		
	Date/time of referral (first teleconference)		

Date/time of retrieval decision (second teleconference)	Delayed decision (allow free text)	
Date/time of ECMO initiation		
Date/time of retrieval dispatch		
Date/time of arrival at receiving site		
Date/time of retrieval return		

# 1.1.2 Clinical quality registry and administrative data

A combination of data sources should be used to monitor the Victorian ECMO Service, including the Australian and New Zealand Intensive Care Society (ANZICS) clinical registries and Victorian Admitted Episode Dataset (VAED) administered by the Department of Health and Human Services (Table 2).

In July 2019 the ANZICS clinical registries launched the ANZICS ECMO dataset for use in Australia and New Zealand. This dataset is a subsidiary of the adult and paediatric intensive care clinical registries. A patient does not have to be admitted to an intensive care unit to be included in the ECMO dataset. The intent is that all patients who are established on ECMO or undergo an attempt to initiate ECMO, are included in this dataset.

The VAED is submitted by all Victorian health services on a monthly basis. The dataset already includes information on patients receiving ECMO and can be used without any modifications. In future we would support differentiating between the types of ECMO used. By using the VAED data to monitor the Victorian ECMO Service we hope to reduce the data collection burden for health services. Some resources will be required to extract and analyse data and prepare and interpret reports.

Table 2: Variables from clinical registry and administrative data for monitoring the Victorian ECMO Service

Variable	Data source	Comments
ECMO type	ANZICS	
Duration of ECMO	ANZICS	
Length of stay:	ANZICS	
Length of stay: hospital	ANZICS and VAED	
Patient outcome: survival	ANZICS and VAED	Minimum requirement is survival to hospital discharge

		Ideally linked to Victorian / National Death Index for survival beyond hospital discharge
Predicted survival at ECMO initiation	ANZICS	SAVE and RESP scores
Common	ANZICS	Gastrointestinal tract bleeding
selected		Intracranial bleeding
complications		Other bleeding
		Limb ischaemia (including. fasciotomy or amputation)
		Thrombotic/embolic stroke
		ECMO circuit exchange due to clot / failure
		Failed cannulation

## **1.2 REPORTING**

Monitoring the performance, quality and safety of the Victorian ECMO Service will require us to prepare and review reports of operational and patient data. This will occur on a six-monthly basis and rely on Ambulance Victoria, ANZICS and VAED data to be extracted and analysed against statewide access and delivery of the service and clinical factors. This process should involve clinicians, SCV, VAHI and the department. Reports will be publicly available.

# 1.2.1 Operations and performance data

# Service volume

- Number of patients referred to the service
- Number of patients retrieved on ECMO
- Number of patients retrieved off ECMO
- Number of retrievals where the team dispatched but a decision was made on site not to commence ECMO, or patient died before transfer
- Number of each ECMO type (VV, VA, ECPR)
- Minutes spent for coordination advice (total, median and IQR/range per patient)
- ours spent on retrieval (per retrieval) (total, median (IQR)

### **Patient outcomes**

- Duration of ECMO run
- Length of ICU stay
- Length of hospital stay
- Survival rate (by site and by patient to account for transfers)

- Predicted number of survivors (calculated using appropriate prediction models: RESP and SAVE)
- Six and 12 months long term outcomes

# 1.2.2 ECMO site comparative reports

These will be presented as 'your identified site' compared to all other ECMO sites aggregated and according to tier.

# Service volume and performance

- Number of patients referred for ECMO (initiation sites) / number of patients considered for ECMO (comprehensive and intermediate centres)
- Number of patients initiated on ECMO (VV, VA, ECPR)
- Number of patients transferred in for ECMO (VV, VA, potentially ECPR) (intermediate and comprehensive sites only)
- Number of failed cannulations
- Number of patients by cannulation location:
- ICU, operating theatre, emergency department, coronary catheter laboratory, other hospital, other
- Frequency table by diagnosis
- Time from referral to decision (mean, median, IQR)
- Time from referral to retrieval activation (mean, median, IQR)

# **Patient outcomes**

- Duration of ECMO run (mean, median, IQR)
- Length of ICU stay (mean, median, IQR)
- Length of hospital stay (mean, median, IQR)
- Number (%) of survivors
- Predicted number (%) of survivors (calculated using appropriate prediction models: RESP and SAVE)
- Number (%) of patients with:
  - gastro-intestinal tract bleeding
  - intracranial bleeding
  - other bleeding
  - limb ischaemia including fasciotomy or amputation
  - thrombotic or embolic stroke
  - ECMO circuit exchange due to clot / failure (reported per patient day)

# **Appendix 2: Feedback and experience**

This section details how we will collect feedback from clinicians working within the Victorian ECMO Service and consumers undergoing treatment, to learn from their experiences and improve the quality and safety of the service.

### 2.1 SERVICE FEEDBACK

## 2.1.1 Referral unit to Victorian ECMO Service

After each patient retrieval the ECMO coordinator at the receiving site (comprehensive and intermediate sites only) contacts the referring hospital (ECMO lead, clinician, head of unit, nurse unit manager or hospital coordinator) to complete the service feedback questionnaire. This focuses on the experiences of clinicians from the referring hospital.

The ECMO program director and coordinator at comprehensive and intermediate centres should be responsible for reviewing and discussing local data and any actions required. The program director should report aggregate and exceptional feedback to the Victorian ECMO Service governance committee.



See 2.4.1. for the service feedback: referral unit to Victorian ECMO Service questionnaire.

# 2.1.2 Victorian ECMO Service to referral unit

Following each patient retrieval, on behalf of the retrieval team, Adult Retrieval Victoria should provide the referring hospital with feedback on communication, preparation and handover of the patient. Feedback should be directed to the program director, coordinator, lead or an appropriate head of unit or nurse unit manager.

Adult Retrieval Victoria should report aggregate and exceptional feedback to the Victorian ECMO Service governance committee. At times organising case discussion and follow-up, including de-briefing, with members the referring unit team, may be required. The ECMO coordinator at the receiving unit will be responsible for arranging this. Discussions should include clinical staff responsible for patient management during the referral, retrieval and receiving of the patient.



See 2.4.2. for the service feedback: Victorian ECMO Service to referral unit questionnaire.

# 2.3 EXPERIENCE FEEDBACK

### 2.3.1 Consumer to Victorian ECMO Service

The patient, carer or medical treatment decision maker (MTDM) could provide feedback on consumer experience to the Victorian ECMO Service. Feedback should be requested at two stages during a patient's care to assess initial ECMO related communication, decision making and transfer, as well as the hospital stay at the comprehensive or intermediate ECMO centre.

The ECMO program coordinator should set the timing and collection process of feedback at the hospital level. The program director and coordinator at comprehensive and intermediate centres should review and discuss local data and any actions required. The program director or coordinator from each comprehensive and intermediate centres will present aggregated and exceptional feedback at the Victorian ECMO Service governance committee.

# Stage one: Retrieval

After transfer from a referring unit to a comprehensive or intermediate centre, the patient, carer or MTDM will be provided with a modified version of the Australian Hospital Patient Experience Question Set.

At stage one, the survey should assess communication and the retrieval process and be given to the patient, carer or MTDM in the days following transfer, generally during the patient's ICU stay. This ensures that the consumer perspective is included in the quality assurance process of the transfer.



See 2.4.3. for the experience feedback: patient to Victorian ECMO Service form related to the retrieval process.



See 2.4.5. for the experience feedback: carer to Victorian ECMO Service form related to the retrieval process.

# Stage two: Hospital stay

In stage two, the patient, carer or MTDM are invited to provide feedback about the ECMO treatment and related hospital stay. The survey should be given close to patient discharge from the receiving hospital.



See 2.4.4. for the experience feedback: patient to Victorian ECMO Service form related to the ECMO hospital stay.



See 2.4.6. for the experience feedback: carer to Victorian ECMO Service form related to the ECMO hospital stay.

# 2.3 LONGER TERM FOLLOW-UP

ECMO is a resource intensive and expensive treatment for patients with life threatening illness. Along with immediate outcome, it is important to measure longer term physical and mental health, quality of life and socioeconomic recovery to assess the overall success of the Victorian ECMO Service.

Longer term follow-up of patients treated by the Victorian ECMO Service was one of the most important elements identified by ECMO consumers. However, due to time delays, loss to follow-up and decentralised initiatives, the capacity for this remains a challenge.

There are two possibilities to explore these outcomes:

# 2.3.1 Data linkage

VAHI is working with clinical quality registries to maintain linkages with department datasets. Data from the VAED and ANZICS clinical registry has been successfully linked and analysed to answer outcome questions for intensive care patients.

ANZICS clinical registries are currently working with the Australian Institute of Health and Welfare to link adult intensive care clinical registry data to the National Death Index to provide longer term mortality data for intensive care patients.

Linkage to some primary care provider datasets, including general practitioners, is also being explored. These data linkage could be used to monitor the longer term outcomes of Victorian ECMO patients on a regular or intermittent basis.

# 2.3.2 EXCEL ECMO research registry

EXCEL is a national research registry on the treatment and outcomes of patients requiring ECMO administered through the Australia and New Zealand Intensive Care Research Centre at Monash University. This or similar registries could be used to provide long-term follow-up of Victorian ECMO patients.

# 2.4 FEEDBACK QUESTIONNAIRES

# 2.4.1 Service feedback: Referral unit to Victorian ECMO Service

Question	Rating (circle)	Comments
Please rate the professional	Excellent	
support and communication	Good	
	Poor	
Was the advice prior to retrieval	Yes	
adequate?	No	
Was the retrieval timely?	Yes	
	No	
Was the checklist easy to follow?	Yes	
	No	
How can the Victorian ECMO		
Service improve?		

# 2.4.2 Service feedback: Victorian ECMO Service to referral unit

Question	Rating (circle)	Comments
Was the internal escalation	Yes	
appropriate?	No	
Was the referral timely?	Yes	
	No	
Was the checklist adhered to?	Yes	
	No	
Was the patient prepared for	Yes	
retrieval?	No	
Was the family/MTDM prepared	Yes	
and available?	No	
Were senior staff present?	Yes	
	No	
What can improve for the next referral?		

# 2.4.3 Transfer experience feedback: Patient to Victorian ECMO Service

# Patient survey: ECMO communication, decision making and transfer

You were recently referred to the Victorian ECMO Service because you needed a specialised form of life support treatment. This may mean you were transferred from another hospital to this hospital.

Please think about the service and transfer and answer the following questions.

	In relation to the ECMO service and transfer	Please circle or comment
1	My views and concerns were listened to	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
2	My individual needs were met	Always
		Mostly

		Sometimes
		Rarely
		Never
3	When a need could not be met, staff explained why	Always
		Mostly
		Sometimes
		Rarely
		Never
4	I felt cared for	Always
		Mostly
		Sometimes
		Rarely
		Never
5	I was involved as much as I wanted in making decisions	Always
	about my treatment and care	Mostly
		Sometimes
		Rarely
		Never
6	I was kept informed as much as I wanted about my	Always
	treatment and care	Mostly
		Sometimes
		Rarely
		Never
7	As far as I could tell, the staff involved in my care	Always
	communicated with each other about my treatment	Mostly
		Sometimes
		Rarely
		Never

		Didn't apply
8	I received pain relief that met my needs	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
9	When I was in the hospital, I felt confident in the safety of my	Always
	treatment and care	Mostly
		Sometimes
		Rarely
		Never
		Never
10	I experienced unexpected harm or distress as a result of my treatment or care	Yes, physical harm
		Yes, emotional distress
		Yes, both
	[if answer is no, skip to Q12]	No
11	My harm or distress was discussed with me by staff	Yes
	.,,,,	No
		Not sure
		Didn't want to discuss it
12	Overall, the quality of the treatment and care I received was:	Very good
		Good
		Average
		Poor
		Very poor
13	What could the service do to improve the care and services it provides to better meet the needs of patients and families?	

# 2.4.4 Hospital stay experience feedback: Patient to Victorian ECMO Service

# Patient survey: ECMO hospital stay

You recently needed a specialised form of life support treatment called ECMO. You were in the intensive care unit at this hospital to receive this treatment.

Please think about your hospital stay for ECMO and answer the following questions.

	In relation to your hospital stay for ECMO	Please circle or comment
1	My views and concerns were listened to	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
2	My individual needs were met	Always
		Mostly
		Sometimes
		Rarely
		Never
3	When a need could not be met, staff explained why	Always
		Mostly
		Sometimes
		Rarely
		Never
4	I felt cared for	Always
		Mostly
		Sometimes
		Rarely
		Never

5	I was involved as much as I wanted in making decisions about my	Always
	treatment and care	Mostly
		Sometimes
		Rarely
		Never
6	I was kept informed as much as I wanted about my treatment and	Always
	care	Mostly
		Sometimes
		Rarely
		Never
7	As far as I could tell, the staff involved in my care communicated	Always
	with each other about my treatment	Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
8	I received pain relief that met my needs	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
9	When I was in the hospital, I felt confident in the safety of my	Always
	treatment and care	Mostly
		Sometimes
		Rarely
		Never

10	I experienced unexpected harm or distress as a result of my	Yes, physical harm	
	treatment or care	Yes, emotional distress	
		Yes, both	
	[if answer is no, skip to Q12]	No	
11	My harm or distress was discussed with me by staff	Yes	
		No	
		Not sure	
		Didn't want to discuss it	
12	Overall, the quality of the treatment and care I received was:	Very good	
		Good	
		Average	
		Poor	
		Very poor	
13	What could the hospital do to improve the care and services it		

# 2.4.5 Transfer experience feedback: Carer to Victorian ECMO Service

# Carer survey: ECMO communication, decision making and transfer

provides to better meet the needs of patients and families?

Your relative or friend was recently referred to the Victorian ECMO Service because they needed a specialised form of life support treatment. This may mean they were transferred from another hospital to this hospital. Please think about the service and transfer and answer the following questions.

In relation to the ECMO	service and transfer	Please circle or comment
My views and concerns	were listened to	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply

2	My individual needs were met	Always
		Mostly
		Sometimes
		Rarely
		Never
3	When a need could not be met, staff explained why	Always
		Mostly
		Sometimes
		Rarely
		Never
4	I felt cared for	Always
		Mostly
		Sometimes
		Rarely
		Never
5	I was involved as much as I wanted in making decisions about their	Always
	treatment and care	Mostly
		Sometimes
		Rarely
		Never
6	I was kept informed as much as I wanted about their treatment and	Always
	care	Mostly
		Sometimes
		Rarely
		Never
7	As far as I could tell, the staff involved in their care communicated	Always
	with each other about their treatment	Mostly
		Sometimes

		Rarely
		Never
		Didn't apply
		Біан с арріу
	They received pain relief that met their needs	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
-		
	When they were in the hospital, I felt confident in the safety of their	Always
	treatment and care	Mostly
		Sometimes
		Rarely
		Never
)	I/they experienced unexpected harm or distress as a result of their	Yes, physical harm
	treatment or care	Yes, emotional distress
		Yes, both
	[if answer is no, skip to Q12]	No
	My/ their harm or distress was discussed with me by staff	Yes
		No
		Not sure
		Didn't want to discuss it
2	Overall, the quality of the treatment and care they received was:	Very good
		Good
		Average
		Poor
		Very poor

13 What could the service do to improve the care and services it provides to better meet the needs of patients and families?

# 2.4.6 Hospital stay experience feedback: Carer to Victorian ECMO Service

# Carer survey: ECMO hospital stay

Your relative or friend recently needed a specialised form of life support treatment called ECMO. They needed to be in the intensive care unit at this hospital to receive this treatment.

Please think about their hospital stay for ECMO and answer the following questions.

In relation to their ECMO hospital stay	Please circle or comment
My views and concerns were listened to	Always
	Mostly
	Sometimes
	Rarely
	Never
	Didn't apply
My individual needs were met	Always
	Mostly
	Sometimes
	Rarely
[if answer always/mostly, skip to Q4]	Never
When a need could not be met, staff explained why	Always
	Mostly
	Sometimes
	Rarely
	Never
I felt cared for	Always
	Mostly
	Sometimes
	Rarely
	My individual needs were met  [if answer always/mostly, skip to Q4]  When a need could not be met, staff explained why

		Never
5	I was involved as much as I wanted in making decisions about their treatment and care	Always
		Mostly
		Sometimes
		Rarely
		Never
6	I was kept informed as much as I wanted about their treatment and care	Always
		Mostly
		Sometimes
		Rarely
		Never
7	As far as I could tell, the staff involved in their care communicated with each other about their treatment	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
В	They received pain relief that met their needs	Always
		Mostly
		Sometimes
		Rarely
		Never
		Didn't apply
9	When they were in the hospital, I felt confident in the safety of their treatment and care	Always
		Mostly
		Sometimes
		Rarely
		Never

10	I/they experienced unexpected harm or distress as a result of their treatment or care	Yes, physical harm
		Yes, emotional distress
		Yes, both
	[if answer is no, skip to Q12]	No
11	My/ their harm or distress was discussed with me by staff	Yes
		No
		Not sure
		Didn't want to discuss it
12	Overall, the quality of the treatment and care they received was:	Very good
		Good
		Average
		Poor
		Very poor
13	What could the hospital do to improve the care and services it	

# **Appendix 3: Consultation and coordination** pathways

This section covers our proposed pathways of care, including consultation and coordination between services. We've outlined all possible pathways of care for a patient who may potentially benefit from ECMO.

The tiered and networked nature of the Victorian ECMO Service enables patients to be referred from any acute care hospital in Victoria. The statewide coordination service should be a single point of access to the service.

# 3.1 PATHWAYS

At a statewide level, these pathways require staff, infrastructure and other logistics to ensure access and outstanding care.

Flowchart 1: Referral and retrieval pathways for the Victorian ECMO Service.

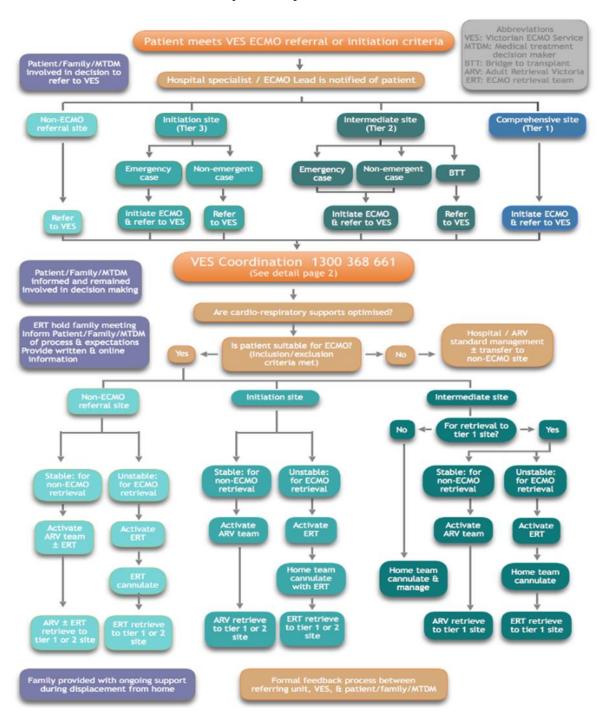
Flowchart 2: Operational communications pathway for consultation and coordination within the Victorian ECMO Service.

Flowchart 3: Referral and retrieval pathway for patients referred from a hospital not accredited to provide ECMO.

Flowchart 4: Referral and retrieval pathway for patients referred from an ECMO initiation site.

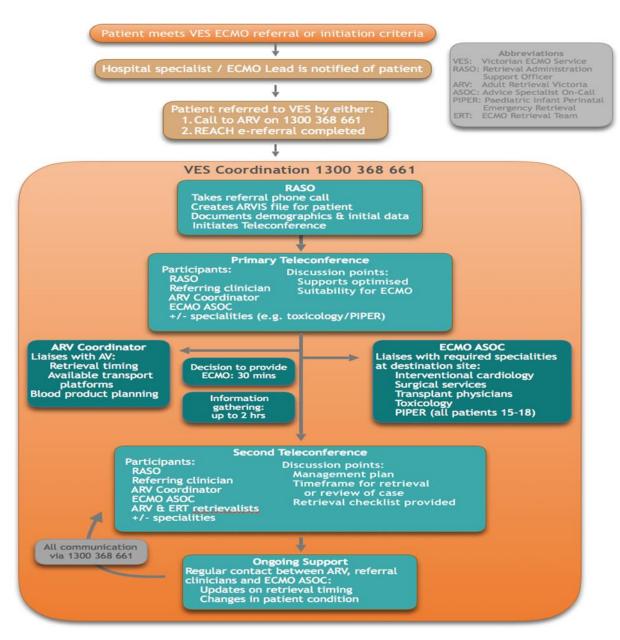
Flowchart 5: Referral and retrieval pathway for patients referred from an ECMO intermediate centre.

# Flowchart 1: Referral and retrieval pathways

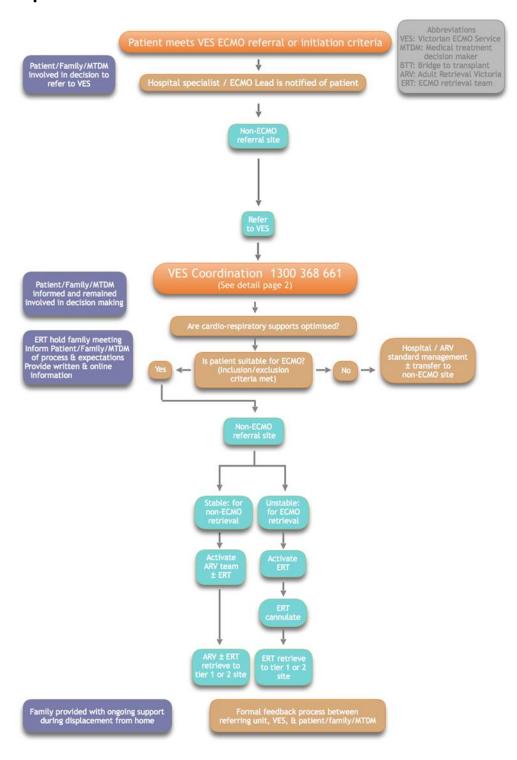


The patient, family members or medical treatment decision makers form an essential component of the care of patients. The purple boxes show involvement of these consumers throughout the treatment pathway.

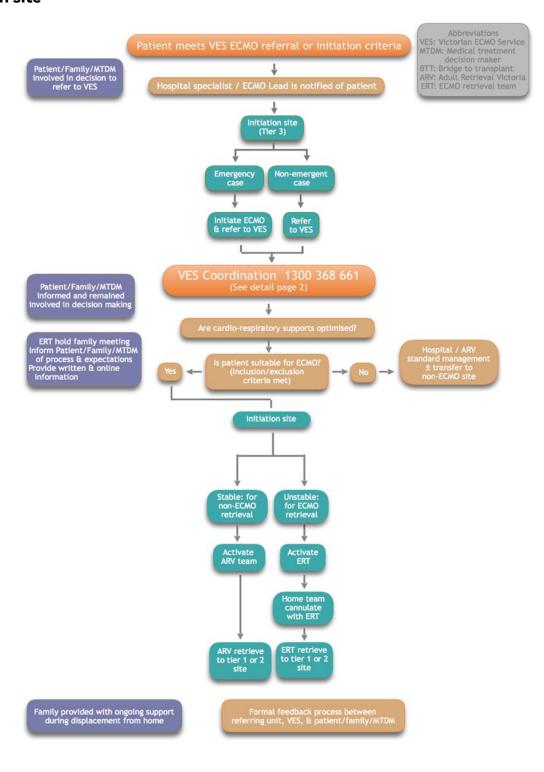
# Flowchart 2: Operational communications pathway for consultation and coordination



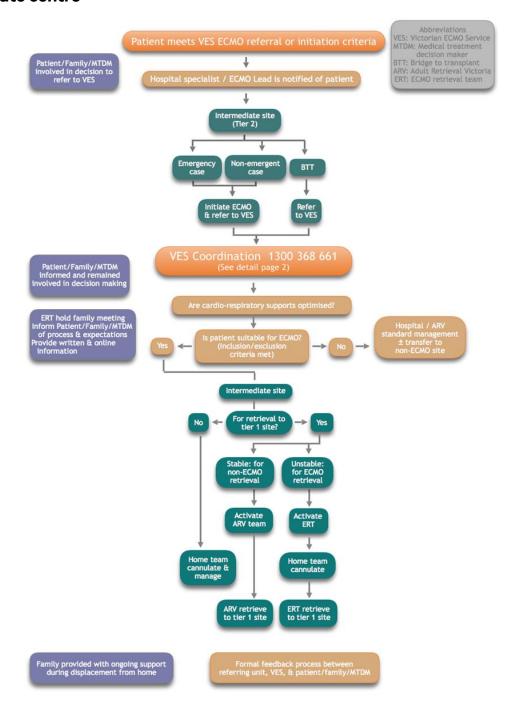
# Flowchart 3: Referral and retrieval pathway for patients referred from a hospital not accredited to provide ECMO



# Flowchart 4: Referral and retrieval pathway for patients referred from an ECMO initiation site



# Flowchart 5: Referral and retrieval pathway for patients referred from an intermediate centre



# 3.2 PATIENT REFERRAL AND CLINICAL ADVICE

Patients who meet referral or initiation criteria are first brought to the attention of the hospital ECMO lead. For hospitals without a designated ECMO lead, the most senior person responsible for the care of the patient and in charge of the management would fulfil this role. The ECMO lead/senior clinician must involve the patient, family/carer or MTDM in decision making at all times. These steps are important to ensure patients are escalated firstly within the referral hospital and the treating teams and patient, family/carer, or MTDM are aware of the intention and decision to refer.

If indicated, there are two pathways to refer to the Victorian ECMO Service via the current Ambulance Victoria infrastructure:

- Directly call Adult Retrieval Victoria (ARV) via the hotline.
- Complete an e-referral form online via the REACH website https://reach.vic.gov.au/#/portal/home.
- Submission of the e-referral form will trigger a call from the ARV coordination staff to the referring clinician.

Once a patient is referred to Victorian ECMO Service (Flowchart 2):

- A teleconference (first ARV teleconference) is initiated between the referring clinician, ARV coordinator and ECMO advice specialist on call.
- Cardio-respiratory supports are discussed and optimised.
- Eligibility for ECMO and/or retrieval to a comprehensive or intermediate centre is determined with the referring clinician.
- Patients who are determined not to benefit from ECMO will follow existing standard treatment pathways. These may include remaining at the referring hospital for treatment, commencing a palliation pathway or being retrieved for a higher level of support that does not include ECMO.
- The ECMO lead or senior clinician ensures the patient, family/carer or MTDM remain involved and informed in the decision-making process.

A significant proportion of ECMO calls may require advice from speciality services including:

- heart and lung transplant physicians
- cardiothoracic surgeons
- interventional cardiologists
- respiratory physicians
- toxicologists
- Paediatric Infant Perinatal Emergency Retrieval service.

For most cases, advice and discussion will occur between the ECMO advice specialist and the speciality services after the initial ARV teleconference. Information will be relayed to ARV coordination staff by the ECMO advice specialist. Occasionally it will be necessary to have specialty services participate in the primary teleconference with the referring clinician, for example in toxicology cases.

In line with the guiding principles of the Victorian ECMO Service, the aim should be to decide on ECMO eligibility within 30 minutes of a referral. The process of gathering additional information and planning for a retrieval should not take more than two hours.

## 3.3 COORDINATION TEAM MEMBER ROLES AND ROSTERING

# 3.3.1 Retrieval administration support officer

Retrieval administration support officers would be the first point of contact for all referrals as they would receive and process all Victorian ECMO Service consultation and coordination calls. They collect document basic clinical and logistic information related to a retrieval in ARVIS and organise the primary teleconference between the referring clinician, Adult Retrieval Victoria (ARV) Coordinator and the ECMO Advice specialist on-call. The retrieval administration support officer would then coordinate all further teleconference communications.

# 3.3.2 Adult Retrieval Victoria coordinator

As part of the Victorian ECMO Service, the ARV coordinator's primary role is to provide coordination and logistical support. The role will include:

- completing any coordination documents
- providing clinical advice in conjunction with the ECMO advice specialist on-call
- determining required retrieval team
- determining platform to be used, in conjunction with Ambulance Victoria staff
- determining timing of retrieval stages
- coordinating blood product and other clinical equipment or product requirements for the retrieval.

# 3.3.3 ECMO advice specialist

The primary role of the ECMO advice specialist is to provide clinical advice and support decision making related to ECMO. This advice will include:

- how to optimise cardio-respiratory supports
- appropriateness of ECMO initiation and likely patient trajectory and destination therapy
- ECMO modality and cannulation technique
- need for retrieval
- appropriate disposition of patient with the aim of getting the patient to the right place the first time

An ECMO advice specialist requires a significant amount of ECMO experience. Given the time critical nature of the decisions, it is vital that clinical expertise is provided quickly. In addition, many of the referrals are complex, so it is important that the ECMO advice specialist works in an environment where they have access to support from colleagues if needed.

In the initial phase of the Victorian ECMO Service it is expected that the ECMO advice specialist role will be filled by The Alfred team who currently provide a similar role informally. As experience develops at intermediate sites, intensivist ECMO specialists at those sites should begin participating in the advice speciality role to increase capacity.

# 3.3.4 Rostering of coordination team members

Ambulance Victoria will be responsible for rostering existing ARV roles including the retrieval administration support officer and ARV coordinator.

Given the challenges of rostering and the need for immediate access to an ECMO advice specialist at a statewide level it may be preferable to allocate the ECMO advice specialist role to a hospital for a rostered period, for example a day or a week. That hospital could then allocate appropriately accredited intensivists to fill the roster. It is vital that ARV are always aware who the ECMO advice specialist on-call is.

As described, in the initial phase of the Victorian ECMO Service this role should be filled by The Alfred team. In future, the plan would be to rotate the roster between The Alfred and intermediate sites on a regular basis, for example weekly.

At any point if there is a delay contacting the ECMO specialist, the default will be to contact the comprehensive centre's rostered ECMO lead via the hospital switchboard.

### 3.4 PATIENT RETRIEVAL

Once a decision is made to retrieve a patient, the composition of the retrieval team required is determined both by the stability of the patient and the tier of the referring hospital.

Patients should always be retrieved to a comprehensive or intermediate centre as these hospitals are capable of managing an ECMO patient throughout their treatment pathway. The principle is that patients are moved only once to the hospital able to provide the care they require.

If it is determined that a patient is stable for retrieval not on ECMO, the standard ARV team will be dispatched.

For patients who are likely to require ECMO prior to transport or for who it would be safer to move on ECMO, the ECMO retrieval team will be dispatched. The ECMO retrieval team will consist of the standard ARV retrieval team with the addition of ECMO specific team members (appendix 3.7).

Where urgent cannulation is not required prior to retrieval from an initiation site, including most VA ECMO patients, cannulation should be undertaken with the ECMO retrieval team present.

Cannulation in the presence of the ECMO retrieval team provides many benefits. In the initial phases of the service, it is expected that ECMO volumes will remain low. Exposure to cannulations at initiation sites for individual clinicians will remain minimal. The presence of the ECMO retrieval team will increase the quality and safety for these infrequent events.

Credentialing of ECMO cannulators will be required on a two-yearly basis. Observation of cannulation by the ECMO retrieval team members could form part of assessment for re-credentialing purposes.

## 3.5 REFERRING UNIT PROCESSES AND PREPARATION REQUIREMENTS

# 3.5.1 Internal escalation process

When a patient is identified to potentially benefit from ECMO, you should discuss with the most appropriate senior member of local staff as part of the referral process. Hospitals accredited to participate in the Victorian ECMO Service as a comprehensive, intermediate or initiation site should have a designated ECMO lead on-call who should be notified, discuss the case with the treating team and coordinate multidisciplinary and patient and family discussion and referral to the service.

Ideally this discussion should take place prior to starting cannulation to determine the suitability and benefit to the patient. This includes patients flagged as potentially benefiting from ECMO in the emergency department, operating theatre, cardiac catheter laboratories or ICU. This also includes patients who are high-risk for longer term mechanical support.

Suitability for ECMO should be discussed prior to starting a procedure, for example in the cardiac catheter laboratories or operating theatre. In elective cases these discussions should also form part of the pre-admission planning and consent process.

# 3.5.2 Family member and carer preparation

As part of the Victorian ECMO Service patients will be transferred to comprehensive and intermediate ECMO centres for ongoing care. Family members may be displaced from home during a period of significant emotional stress. It is important that referral hospitals request that family members or the MTDM be present for the arrival of the retrieval team.

As part of the retrieval process a member of the retrieval team will facilitate a family meeting to explain the need for retrieval, the basics of ECMO support and the likely outcomes to expect. If required, informed consent for ECMO support can be obtained during this meeting.

The retrieval team should offer written information about ECMO that includes:

- basic description of ECMO
- information about comprehensive and intermediate centres (receiving sites)
- parking
- accommodation options
- ICU location
- support available and important phone numbers (e.g. intensive care unit and social worker)
- opportunity to provide feedback on the service

This information should be developed by the Victorian ECMO Service in conjunction with consumers and clinicians. The governance committee will make sure this information is maintained.

# 3.5.3 Patient preparation for retrieval

Once it is decided a patient needs ECMO and retrieval, planning and preparation is required. An ECMO retrieval preparation checklist should be available, preferably online, to assist referring hospitals in this process (Appendix 3.5.4). In line with the guiding principles of the Victorian ECMO Service, the aim of this checklist is to lighten the load on the referring team.

The checklist outlines equipment and preparation required for all patients retrieved by the Victorian ECMO Service. It also outlines specific requirements for patients who will be cannulated by the ECMO retrieval team at the referring hospital.

# 3.5.4 ECMO retrieval preparation checklist

# Victorian ECMO Service: Referring hospital retrieval checklist

ECMO retrievals can be lengthy but the referring team can assist to make sure the patient receives outstanding care.

The ECMO cannulation procedure itself takes between 30 to 60 minutes. Assessment of the patient, discussion with family and stabilisation of the patient post cannulation usually involves an additional few hours. Often extra nursing staff are needed to assist with preparation of the patient for retrieval.

Most of the equipment required will be supplied by the retrieval team. The referring team can assist by making the following preparations while awaiting retrieval team arrival:

# General requirements for all patient retrievals

## Patient and family preparation

0	Explain to the patient (if possible) and patient's family / carer the need for retrieval Encourage family / carer to be available to meet the retrieval team on arrival for discussion and consent Insert arterial line (preference for right radial)
	Insert central venous line (preference for left internal jugular)
	Insert urine catheter
	All notes photocopied / printed
	All imaging on disk or electronically transferred to receiving site
Equipm	nent
	Small procedure trolley and IV pole available for ECMO console
	Access to two oxygen outlets or two full oxygen bottles available (one for transport ventilator and one for ECMO circuit)

Medic	ations
	Sedation, inotropes, vasopressors and muscle relaxants drawn up to meet <u>ARV standard infusion</u>
	concentrations. ARV team will provide pumps and compatible syringes
	o Morphine 50mg / 50ml NS
	o Midazolam 50mg / 50ml NS
	o Propofol 200mg x 2 syringes
	o Noradrenaline 3mg / 50ml D5W
	o Adrenaline 3mg / 50ml D5W
	o Muscle relaxants
	Antibiotic dosing up to date (if indicated). Additional antibiotic doses available if required for
	expected prolonged retrieval
nvest	igations
	FBE, UEC, LFT
	ABG
	Coagulation screen (INR, APTT, fibrinogen)
	CXR
	CT brain if indicated. All OHCA require a CTB.
	ECG and echocardiography (if available)
	Pregnancy test if appropriate
	Microbiology results
Blood	bank
	Welled accessor and healed
	3 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
	platelet count < 80
dditi	onal requirements for patients not already on ECMO support
atier	nt preparation
	Ensure patient is in single room or large area able to be screened off for cannulation procedure
	Ensure femoral access sites are clean and hair clipped
erso:	nnel required
	Consultant responsible for patient management present
	Consultant responsible for patient management present Two nursing staff available to assist

# Equipment □ Large procedure trolley available for cannulation □ Resuscitation trolley and airway trolley available □ Ultrasound machine(s) with both cardiac and vascular probes available □ Two sterile ultrasound covers □ 1 litre of 0.9% saline □ 10,000 units of heparin □ Betadine (povidone–iodine 10%) (200mls)

# ☐ Personal protective equipment: surgical gowns x2, masks with face shields x2, sterile surgical gloves, surgical hats

# 3.6 RETRIEVAL LOGISTICS

# 3.6.1 Information platforms and tools

☐ Local anesthetic (1 or 2% lignocaine)

### **Adult Retrieval Victoria Information System (ARVIS)**

ARVIS is a real time case management system designed to capture ARV cases. ARVIS is linked to the REACH (Retrieval and Critical Health) website and provides some decision support for ARV staff.

The system has been designed to accommodate various case types. Each form contains a slightly different data set and/or mandatory fields which are customised per case type to ensure appropriate data is captured given the nature of the referral.

The ARV retrieval administration support officer creates a case by capturing basic details about the referrer and the patient. Cases may also be initiated by online e-referral. Once the case is created, it appears on the open cases dashboard and the ARV coordinator works through the form and continues to capture all of the clinical information related to the patient transfer.

Upgrades to ARVIS, as detailed in Appendix 1.1, would be required to facilitate the Victorian ECMO Service. Currently only patients who are retrieved on ECMO are stored under the ECMO case type. To ensure appropriate monitoring and governance of the service, all patients referred to the Victorian ECMO Service should be captured in the data set. This will include patients who:

- are referred, but only advice is given to the referring team
- are referred, but retrieved before ECMO is initiated
- are referred and retrieved on ECMO

# Retrieval and Critical Health (REACH)

The REACH (Retrieval and Critical Health) Information System is a real time, web-based bed occupancy reporting tool used by ARV, health services and the Department of Health and Human Services. It provides a statewide and hospital level view of specific bed capacity, based on regular hospital data

input. REACH was developed by Ambulance Victoria in partnership with the department. ARV is responsible for its management.

Upgrades to REACH will be required to facilitate ECMO bed management across the Victorian ECMO Service. It is important that the capacity at each ECMO receiving hospital is known in real time by the service coordination staff. The REACH platform should show 'ECMO beds' occupied, available or patient awaiting retrieval.

# 3.6.2 Bed management

In the Victorian ECMO Service patients requiring ECMO should be transferred to a comprehensive or intermediate centre. Depending on credentialed staffing numbers, hospitals will have a certain capacity to manage patients on ECMO. In particular, the number of ECMO patients an ICU will have capacity to manage will depend on the number of nurse and/or perfusionist ECMO specialists trained and credentialed to manage each patient. As detailed above, upgrades to REACH will allow a statewide view for ECMO bed management.

It is expected that an intermediate centre have capacity to manage three patients on ECMO simultaneously, whereas the comprehensive centre will have capacity to manage up to ten.

If no ECMO beds are available at any comprehensive or intermediate centre, the Victorian ECMO Service coordination staff, with ARV, will be able to perform a 'defined transfer' and allocate the patient to one of these centres. This will ensure that a patient who requires retrieval and high level support is not left waiting at a referring hospital. The requirement for initiation sites to be able to manage ECMO patients for up to 48 hours should minimise the need for this override.

# 3.6.3 Retrieval equipment

Retrieval equipment will be standard for all ECMO retrievals as part of the Victorian ECMO Service.

Adult Retrieval Victoria should be responsible for providing standard equipment for managing a critically unwell patient in transit. This equipment includes, but is not limited to:

- transport monitor and defibrillator
- transport ventilator
- portable ultrasound
- adequate oxygen supply for both ventilator and ECMO circuit
- electrical outlets
- sufficient pumps and syringes for drug delivery
- airway management equipment
- intravenous access equipment
- emergency medications
- handheld blood analyser.

ECMO retrieval team members are responsible for ensuring all ECMO-specific equipment – including equipment required for cannulation – is packed, checked and ready for use prior to travelling to the referring hospital. This equipment includes, but is not limited to:

- ECMO console
- ECMO cannulas of varying sizes and spares
- circuit clamps
- cannulation equipment.

Ambulance Victoria as the retrieval service provider should participate in the exchange of short-dated consumable stock and statewide procurement processes to reduce waste.

As the Victorian ECMO Service develops there may be a need for a more centralised stock of equipment and consumables to be held at either Ambulance Victoria or the comprehensive centre.

## 3.6.4 Retrieval platforms

The selection of retrieval platforms used for ECMO depends on the referring location, patient needs, clinical urgency, weather conditions and capacity within the Ambulance Victoria system. The decision-making process is the responsibility of the Adult Retrieval Victoria coordinator in conjunction with Ambulance Victoria staff.

Logistics and platform options for transporting retrieval team members to a referral hospital or rendezvous site needs to be considered. Currently a combination of Ambulance Victoria platforms or public taxis are used. While access to Ambulance Victoria resources to attend a retrieval is ideal, this would depend on available platforms at the time of coordinating the retrieval. A backup transport system such as taxis would always be required. There should not be an expectation that retrieval team members use their own private transport to or from a referring hospital.

#### 3.7 RETRIEVAL TEAM MEMBER ROLES AND ROSTERING

An ECMO retrieval team varies depending on the retrieval platform used. It may also vary depending on whether the patient has already been initiated on ECMO prior to retrieval. All team members will need to be credentialed in retrieval via Ambulance Victoria. According to the current standard of care, five team members are required for an ECMO retrieval:

- Adult Retrieval Victoria retrievalist
- critical care nurse or flight paramedic
- pilot or second AV paramedic / patient transport officer
- two FCMO retrievalists

## 3.7.1 Adult Retrieval Victoria (ARV) retrievalist

The ARV retrievalist is the expert clinical interface with the equipment and the practicalities of the retrieval process. The ideal skillset for an ARV retrievalist attending an ECMO transfer is a pre-hospital and retrieval medicine consultant with current annual credentialing in ECMO retrieval.

They are responsible for managing the following aspects of patient care in conjunction with the ECMO retrievalist but also independently during the cannulation process:

- initiating or maintaining a secure airway
- complex ventilatory requirements including optimising oxygenation and ventilation prior to cannulation and then lung protective strategies post cannulation
- assessing, diagnosing and optimising haemodynamic state including use of multiple inotropes/vasopressors, blood products and fluids.
- managing resuscitation during ECMO cannulation.

# 3.7.2 Critical care nurse or Ambulance Victoria flight paramedic

The critical care nurse must be an experienced registered nurse with post graduate skills in either emergency, intensive care or critical care specialities. Both critical care nurse and flight paramedics will need to complete annual ECMO credentialing. This team member needs to

- have a high degree of platform familiarity
- have a high degree of familiarity with all retrieval equipment and processes
- provide clinical support to the ARV and ECMO retrievalists as well as interface with clinical staff at the referring hospital.

## 3.7.3 Pilot or second Ambulance Victoria paramedic or patient transport officer

If rotary or fixed wing transport is used for retrieval a pilot will be part of the team. During air missions the pilot is responsible for the overall safety and management of logistics. In flight the pilot is in control of all resources and is responsible for all decisions in relation to the aircraft, flight path, safe altitude etc as per current Ambulance Victoria policy.

If road transport is used a second paramedic or a patient transport officer will be involved as a driver and to provide logistical support.

## 3.7.4 ECMO retrievalist

The ECMO retrievalist will be a consultant ECMO specialist with cannulation credentialing. They will be responsible for ensuring proper function of the ECMO circuit and in collaboration with the ARV retrievalist determine clinical management. They will also work with and support the clinical staff at the referring hospital and lead the communication about ECMO and retrieval with the patient, family/carer or MTDM.

#### 3.7.5 Second ECMO retrievalist

If a patient requires or is likely to require ECMO cannulation as part of the retrieval process, this team member will be a second ECMO cannulator. If the patient is already on ECMO prior to the retrieval, this role may be filled by a nurse ECMO specialist credentialed for retrievals. Retrieval credentialed perfusionists may also participate in the role. This role provides an important interface with nurses/perfusionists at the referring site.

It is expected that unless emergency cannulation is required, cannulation at initiation centres should be performed in the presence of the ECMO retrieval team. Cannulation episodes are likely to be low for individual cannulators at initiation sites. This planned process will enable ECMO retrieval teams to assist with difficult cannulation if required. Observation of cannulation by the ECMO retrieval team could also be included as part of a re-credentialing program at initiation sites.

# 3.7.6 Rostering of retrieval team members

Rostering of existing Adult Retrieval Victoria and Ambulance Victoria roles including the ARV retrievalist, critical care nurse, paramedic, pilot and patient transport officer will remain the responsibility of these organisations.

Rostering of the ECMO retrievalists will require a coordinated process between hospitals participating in the Victorian ECMO Service. This roster will need to be separate to the ECMO advice specialist. Two ECMO retrievalists are required to be available 24 hours a day, probably via an on-call arrangement.

The deployment arrangement for ECMO retrievalists may be flexible.

## **Potential models**

**Single hospital model**: Both team members are from the same hospital. Familiarity of team members may improve efficiency in cannulation, communication and retrieval. The challenge of this model is in removing two ECMO trained staff members from one hospital and the potential for expertise limited to in-house scenarios. This model limits collaboration and knowledge sharing between hospitals participating in the service.

**Rendezvous model**. Team members from two different hospitals participate in the retrieval. The main advantages of this approach are collaboration between hospitals and less dilution of local expertise. The challenge of this model is determining which service is responsible for providing the equipment and also where to rendezvous - at the referral hospital, retrieval facility, airport etc.

**Training model**: Use the single hospital model above but have a member from another hospital participate as the third ECMO retrievalist. This would allow team members to learn the retrieval process and to develop skills required for ECMO retrievals. The challenge of this model is that many transport platforms do not have capacity for another staff member. Alternative transport options would need to be sought.

Initially the Alfred team will continue to fulfil the retrievalist roles based on the single hospital model. As experience develops at intermediate and initiation sites, participation in the retrieval service will be encouraged. Similar to rostering of the ECMO advice specialist role, one option for rostering retrieval staff between hospitals may be to have individual hospitals responsible on a week to week basis.

While the rendezvous model involves a more complex rostering arrangement, it could include one team member from the Alfred in addition to one team member from another hospital on a rotating basis

Depending on bed availability and the need patients to the home hospital of the retriev and family members.	

# **Appendix 4: Clinical criteria for ECMO**

This section covers things you should consider when deciding on ECMO for a patient. We've outlined the eligibility criteria and diagnostic groups for each type of ECMO. You'll also find referral triggers, initiation criteria, withdrawing and weaning procedures for patients considered for or already on ECMO. These recommendations are based on best evidence and expert opinion at the time of writing and may be subject to change in future.

#### **4.1 BENEFIT OF ECMO**

When considering ECMO, the individual situation of the patient and their family should be taken into account.

Use the following five statements to assess each request for ECMO before going into specific clinical criteria.

- 1. ECMO is a broad term that covers multiple forms of physiological support for cardiac and respiratory failure. In cases of severe respiratory or cardiac failure, ECMO can provide physiological stability and prolong life where less invasive forms of support cannot.
- 2. ECMO can provide an enduring benefit to the patient when its use results in patient survival with a level of function consistent with the patient's preferences and values.
- 3. ECMO may benefit the patient by providing physiological support, preventing additional organ damage, and prolonging immediate survival. It can facilitate:
  - recovery and return to health
  - bridging to long term mechanical support or organ transplantation
  - definitive investigation for prognostication
  - disease specific treatment
- 4. ECMO should only be offered where there is a realistic possibility of achieving one of these outcomes.
- 5. ECMO may harm the patient through improper patient selection, the burden of general intensive care and support, and ECMO specific complications, such as:
  - discomfort, pain and loss of dignity and privacy
  - prolonged sedation and immobility
  - extending the dying process without realistic prospect of recovery to quality of life acceptable to the patient
  - delayed delivery of palliation
  - ECMO specific complications, including bleeding, leg ischaemia and worsened left ventricular failure
  - post ECMO complications including muscle weakness, chronic pain, pressure injury and neuro-psychiatric disorder.

The balance between benefit and harm depends on patient specific factors such as presenting illness, age, and chronic health problems as well as ECMO related factors such as timing, method and duration of ECMO.

When a patient presents with severe life-threatening cardiac or respiratory failure, timely initiation of ECMO may occur in the absence of specific disease diagnosis or prognosis, knowledge of patient's chronic health and functional ability, and understanding of the patient's preferences and values. The decision to continue ECMO should be guided by this information as it becomes available.

ECMO should not be provided where the sole anticipated benefit is to extend the dying process for family or medico-legal reasons.

#### 4.2 CRITERIA FOR PATIENT SELECTION FOR ECMO

The criteria for initiating ECMO is complex and needs to cover multiple components at the time of decision making. These include patient specific factors (age, comorbidities, and acute physiological derangements) and diagnostic category of the cause of the acute illness. Each of these factors will influence the likely benefit and success of ECMO for the patient.

For both venovenous (VV) and venoarterial (VA) ECMO, these influencing factors are grouped by severity to support decision making. Tools and decision-making algorithms are also provided for each type of ECMO and specific influencing factors.

## 4.2.1 Venovenous (VV) ECMO

VV ECMO is a form of respiratory support for patients with respiratory failure that are not responding to conventional mechanical ventilation and rescue therapies. It is a highly invasive therapy.

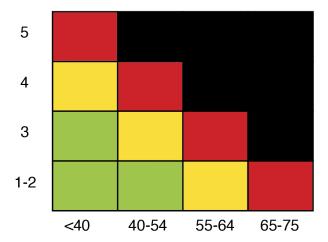
One of the most important things to consider before initiating VV ECMO is the potential for reversal of the condition causing the respiratory failure. Native lung function recovery is required to wean from ECMO once initiated. VV ECMO is often required for several weeks to allow this recovery to occur.

#### **Eligibility chart**

## **Steps**

- Determine diagnostic group (score = 1, 2 or 3)
- Determine presence/absence of modifying acute (score = +1) and chronic illness (score = +1)
- Calculate combined score (1-5)
- Make sure there are no absolute contraindications
- Use chart to observe eligibility and expected benefit from ECMO

# **Eligibility chart**



The chart indicates eligibilty and expected outcome for VV ECMO according to patient age and risk score (1-5) which is the diagnostic group 1, 2 or 3 plus presence of acute (+1) and/or chronic modifers (+1)

GREEN YELLOW RED BLACK Good expected outcome Uncertain expected outcome Poor expected outcome Negligible benefit

## **Diagnostic groups**

Diagnoses are categorised according to commonly associated outcomes with VV ECMO into 'Favourable', 'High risk' and 'Unfavourable' pathologies (Table 3). These relate to the condition's potential for reversal and treatability. Chronic respiratory failure is addressed separately (See next section).

Table 3: Diagnoses categorised by commonly associated outcomes with VV ECMO

Favourable (score = 1)	High risk (score = 2)	Unfavourable (score = 3)
Community acquired pneumonia (infective cause)	Necrotising pneumonia	Acute respiratory distress syndrome (ARDS) from non-pulmonary cause (e.g. pancreatitis)
Status asthmaticus	Pulmonary vasculitis (Goodpasture's, ANCA-associated, other autoimmune)	Invasive aspergillosis
Aspiration pneumonitis	Lung transplant recipient 7-30 days post-transplant	Pneumocystis jirovecii pneumonia
Primary graft dysfunction following lung transplant within 7 days	Traumatic injuries:	Lung transplant recipients >30 days and suitable for re-

	Moderate TBI, hypoxia from chest injury to allow assessment	transplantation (see also bridge to transplant)
	Bronchial tear with air leak and hypoxia	
ARDS from primary pulmonary pathologies (but excluding traumatic)	ARDS from direct chest trauma	

#### **Clinical modifiers**

A patient's comorbidities can have a significant effect on the success of ECMO. Some comorbidities in isolation, for example hypertension, have a minimal effect, but can greatly impact reversibility of disease and survival when present in combination with others.

Common comorbidities are categorised according to their influence on ECMO associated mortality. The impact of comorbidities that are not categorised should be assessed by the treating clinician prior to the initiation of ECMO. Advice should be sought from the local ECMO lead or the ECMO advice specialist on call.

Acute physiological derangements also have an influence on the success of ECMO. ECMO should be initiated before established multi-organ failure occurs, as if initiated afterwards the chance of success is limited.

Table 4: Influence of co-morbidities on outcomes of VV ECMO

Acute Clinical Conditions (score +1)	Chronic Clinical Conditions (score +1)
Lactate >5 (type A lactic acidosis despite resuscitation)	Known ischaemic heart disease or prior revascularisation
Noradrenaline (norepinephrine) >0.3 mcg/kg/min and/or adrenaline (epinephrine) ≥0.1mcg/kg/hr	Peripheral vascular disease (symptomatic or requiring interventions)
Acute liver dysfunction (bilirubin ≥33μmol, or AST/ALT ≥70UI/L)	More than one of hypertension, dyslipidaemia
Acute kidney Injury (creatinine ≥133umol with or without renal replacement therapy)	≥ Moderate COPD (GOLD Stage II, FEV150-80%)
Cardiac arrest prior to ECMO with uncertain neurology	Chronic renal failure (stage 3 or 4 CKD eGFR<60)
Prolonged unsafe mechanical ventilation for more than 7-10 days prior to ECMO  Plateau pressures >30cmH20	Chronic liver disease

Driving pressures >15cmH2O	
	Chronic immunosuppression (≥7.5mg prednisolone for >3 months or equivalent
	Advanced frailty (e.g Charlson comorbidity index score 3)

#### **Contraindications to VV ECMO**

- Lung diseases
  - Severe chronic lung disease (see below Bridge to transplant)
  - Pulmonary fibrosis likely cause of respiratory failure (acute or subacute)
  - Previous known/treated systemic lupus erythematosus, extra-articular rheumatoid arthritis, scleroderma, dermatomyositis, sarcoidosis
  - Clinical of pathological investigations suggestive of irreversible process, for example bleomycin lung injury
  - Obliterative bronchiolitis is the likely cause of respiratory failure
  - Graft versus host lung disease.

Severe acute restrictive lung disease with relatively clear chest x-ray (early) is suggestive of cryptogenic organising pneumonia (bronchiolitis obliterans with organising pneumonia) and biopsy should be performed if safe to do so, prior to instituting ECMO if this condition is suspected.

#### **Patient factors**

- Age >75 years
- Child-Pugh B liver cirrhosis or acute liver failure / asities / encephalopathy
- Severe brain injury, for example intracranial haemorrhage, large ischaemic stroke, traumatic brain injury
- Chronic renal failure (chronic kidney disease grade 5 or dialysis)
- Severe cardiac disease, cardiomyopathy (ventricular assist device or inotropes)
- Chronic respiratory failure / requiring home oxygen and not a lung transplant candidate
- Solid organ or bone marrow transplant recipient
- Consider autologous bone marrow transplantation on a case by case basis
- Non-treatable malignancy.

## **Acute conditions**

- Pulmonary oedema due to left ventricular failure consider VA ECMO instead
- Septic shock with hypoxia predominant presentation rather than pulmonary infiltrates
- Advanced microcirculatory failure with severe mottling or established purpura
- Advanced multiorgan failure ≥4 days

#### **Anatomical consideration**

Inability to safely cannulate patient, for example multiple stenosed or thrombosed vessels.

#### **Patient wishes**

 ECMO initiation would not be in keeping with known patient wishes and/or values or those of the patient's MTDM.

## 4.2.2 Venoarterial (VA) ECMO

#### Eligibility criteria

Venoarterial (VA) ECMO can provide patients with mechanical circulatory support to allow for either reversal of a pathology which causes acute haemodynamic compromise or for the evaluation and planning of durable/long-term support pathways in the context of an established irreversible process.

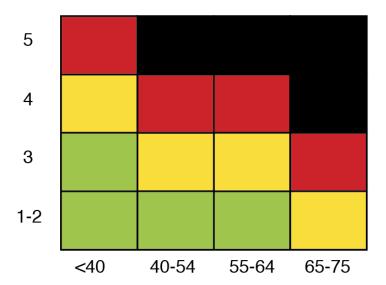
Patients considered for long term mechanical circulatory support (left or right ventricular assist device or biventricular assist device) should be discussed with the transplant unit to inform decisions about transplant and ECMO selection. For some patients, long term mechanical circulatory support is not appropriate either due to complications of ECMO or due to other factors which rule out eligibility for long term support or transplant.

## **Eligibility chart**

## **Steps**

- Determine diagnostic group (score 1, 2 or 3)
- Determine presence of modifying acute (score +1) and chronic illness (score +1)
- Calculate combined score (1-5)
- Make sure there are no absolute contraindications
- Use chart to observe eligibility and expected benefit from ECMO.

# **Eligibility chart**



The chart indicates eligibilty and expected outcome for VA ECMO according to patient age and risk score (1-5) which is the diagnostic group 1, 2 or 3 plus presence of acute (+1) and/or chronic modifiers (+1).

GREEN Good expected outcome
VELLOW Uncertain expected outcome
Poor expected outcome
BLACK Negligible benefit

# **Diagnostic groups**

Diagnoses are categorised according to commonly associated outcomes with VA ECMO into 'Favourable, 'High risk' and 'Unfavourable' pathologies (Table 5). These are related to the reversibility and treatability of the condition. Chronic cardiac failure is addressed separately (See next section).

Table 5: Diagnoses categorised by commonly associated outcomes with VA ECMO

Favourable (score = 1)	High risk (score = 2)	Unfavourable (score = 3)
Fulminant myocarditis	Acute myocardial infarction complicated by cardiogenic shock including vasospasm	Chronic cardiomyopathy (ejection fraction ≤40%) without the prospect of ventricular assist device / transplant
Pulmonary embolism with cardiogenic shock	Ischaemic ventricular septal defect or papillary muscle rupture post acute myocardial infarction	Congenital heart disease

First presentation acute cardiomyopathy	Failure to wean off cardiopulmonary bypass	Septic shock (see 4.2.3)
Primary arrhythmogenic cardiomyopathy, for example ventricular tachycardia storm	Heart transplant recipient with chronic rejection suitable for ventricular assist device / retransplant (depending on comorbidities)	
Drug overdose with cardiac depression and no long-term sequelae		
Primary graft dysfunction post heart transplant		

#### **Clinical modifiers**

A patient's comorbidities can have a significant effect on the success of ECMO. Some comorbidities in isolation, for example hypertension, have a minimal effect, but can greatly impact reversibility of disease and survival when present in combination with others.

Common comorbidities are categorised according to their influence on ECMO associated mortality. The impact of comorbidities that are not categorised should be assessed by the treating clinician prior to starting ECMO. Seek further advice from the local ECMO lead or the ECMO advice specialist on-call.

Acute physiological derangements can also influence the success of ECMO. ECMO should be initiated before established multi-organ failure occurs as if initiated afterwards the chance of success is limited.

Table 6: Clinical modifiers in VA ECMO (if present add +1 to score)

Acute Clinical Conditions (score +1)	Chronic Clinical Conditions (score +1)
Lactate >10 (type A lactic acidosis despite resuscitation)	Peripheral vascular disease (symptomatic or requiring interventions)
adrenaline (epinephrine) ≥0.5mcg/kg/hr (or equivalent inotrope dose)	Known ischaemic heart disease or prior revascularization
Ischaemic hepatitis (AST/ALT > 1000, or INR >2.0)	Prior valve surgery, coronary artery bypass graft or aortic surgery
Acute kidney Injury (creatinine ≥133umol with or without renal replacement therapy)	≥ Moderate COPD (GOLD Stage II, FEV1 50-80%)
Onset of shock >12 hours	Chronic renal failure (stage 3 or 4 CKD eGFR<60)

Intubation >30 hours prior to ECMO	Chronic liver disease
Cardiac arrest prior to ECMO with uncertain neurology	Chronic immunosuppression (≥7.5mg prednisolone for >3 months or equivalent
CNS dysfunction (Neurotrauma, stroke, encephalopathy, seizure syndromes)	Advanced frailty (Charlson comorbidity index score 3)

#### **Contraindications to VA ECMO**

#### **Patient profile**

- Age >75 years
- Terminal illness or non-treatable malignancy
- Liver cirrhosis ≥Child-Pugh B
- Irreversible CNS injury
- Chronic renal failure (chronic kidney disease grade 5 or dialysis)
- End stage COPD
- Chronic symptomatic cardiac failure (NYHA 3 or 4) and not a ventricular assist device or transplant candidate.

#### **Acute condition**

- Cardiogenic shock with advanced microcirculatory failure with severe mottling or established peripheral purpura
- Septic shock without evidence of ventricular impairment
- Cerebral deficit with fixed dilated pupils

#### **Anatomical consideration**

- Inability to safely cannulate patient for example multiple stenosed or thrombosed vessels
- ≥Moderate aortic regurgitation with no potential for correction.

## **Patient wishes**

• ECMO initiation would not be in keeping with known patient wishes and/or values or that of the patient's MTDM.

# 4.2.3 ECMO for septic shock

## **Key messages**

ECMO is unlikely to benefit patients with septic shock, particularly where a vasoplegic picture predominates.

In severe right ventricular or left ventricular failure accompanying sepsis, ECMO may be considered in selected younger patients.

ECMO does not have an established role in adults with worsening vasoplegic shock ('distributive shock') from sepsis, and is not likely to improve the patient's outcome in this situation. However, there are two situations in which ECMO may potentially provide benefit to patients with septic shock, when refractory to standard therapy:

- 1. For patients with acute right heart failure due to hypercarbia, hypoxia and acidosis, who are deteriorating despite conventional supports, where VV ECMO may be considered. These patients almost all have bacterial pneumonia as the cause for their septic shock.
- 2. For patients with severe left ventricular depression in the setting of sepsis, refractory to inotropic support, where VA ECMO may be beneficial in selected patients.

Case series reporting the use of ECMO in situation 2 come from single-centre retrospective studies from several large units, therefore are open to potential biases. Patients with severe sepsis-induced LV failure constituted a very small percentage of the ECMO patients overall in these centres. Common to these series were the generally young age of patients (median age 40-54 years), a left ventricular ejection fraction of about 15-30 per cent, with confirmation of poor cardiac output (left ventricular outflow tract time-velocity integral on echocardiography), and very high inotrope supports at initiation. Long-term survival is quoted between 70-90 per cent, although in carefully selected patients.

Note that an echocardiogram is essential to understand any cardiac pathologies that may be present, and their severity.

It may therefore be reasonable to consider ECMO use in younger patients with septic shock where the following features are all present:

- echo-confirmed severe left ventricular and/or right ventricular failure
- measures confirming a low cardiac output state (e.g. low left ventricular outflow tract time-velocity integral on echocardiography) and clinical markers of poor end-organ perfusion (i.e. oliguria, rising lactate)
- shock refractory to moderate to high dose inotrope/vasopressor support
- before the development of anuric acute kidney injury or severe ischemic hepatitis

The use of ECMO for predominantly vasoplegic shock associated with sepsis in the absence of severe cardiogenic shock, is unlikely to be beneficial and is not recommended.

The use of ECMO for sepsis-related cardiac arrest should be considered futile.

# 4.2.4 ECMO Cardiopulmonary Resuscitation criteria

## **Definition**

ECMO Cardiopulmonary Resuscitation (ECPR) is defined as the rapidly-deployed application of VA ECMO in patients with cardiac arrest, during cardiopulmonary resuscitation before the return of spontaneous circulation.

ECPR can be initiatied for patients who have an in-hospital cardiac arrest. Protocols can be developed to transfer patients from the community with cardiopulmonary resuscitation ongoing (out of hospital cardiac arrest).

Survival rates from ECPR in experienced centres is significantly lower than that of either VA or VV ECMO. Expected survival ranges in experienced centres are:

- in-hospital cardiac arrest 25-40%
- out of hospital cardiac arrest 15-30%.

#### **Indications**

- Cardiac arrest > 15 minutes duration
- Presumed cardiac origin
- Ability to establish ECMO flow prior to 60 minutes of arrest (=low flow time < 60 minutes)</li>
  - Patient arrival to hospital and ECPR team available to commence cannulation by 45 minutes of arrest.

#### **Exclusion criteria**

- Age > 65
- Unwitnessed arrest
- Initial rhythm asystole
- No flow (arrest to cardiopulmonary resuscitation) > 5 minutes
- Low flow (arrest to ECMO) > 60 minutes
- ECPR team not available to commence by 45 minutes of arrest
- End-tidal CO2 < 10mmHg</li>
- Known symptomatic chronic organ failure
- Multiple past coronary revascularisations
- Liver cirrhosis with jaundice, ascites or encephalopathy
- End stage renal failure on dialysis
- Cardiomyopathy (ventricular assist device or inotropes)

- Chronic lung disease (NYHA 3 or 4)
- Chronic pulmonary arterial hypertension
- Aortic regurgitation ≥ moderate.

## 4.3 CLINICAL CRITERIA FOR INITIATING ECMO

It is important to establish ECMO at an appropriate time in the course of an acute illness.

Although ECMO itself has significant complications, starting a patient on ECMO should not be delayed until organ dysfunction, such as renal failure, is established. Once multiorgan dysfunction has started the likelihood that ECMO will alter the clinical outcome significantly decreases.

#### **4.3.1 VV ECMO**

The main indications for starting VV ECMO are:

- refractory hypoxia and hypercapnia despite optimal protective ventilation strategies
- unsafe non-protective ventilation settings required to support gas exchange with or without barotrauma
- air leaks or bronchopleural fistulas (e.g. due to trauma).

A trial of high positive end expiratory pressure is often indicated prior to considering ECMO, for example 18-24cmH2O. Similarly volume overload should be considered and fluid removal strategies should be used. Echocardiography is important to exclude a cardiovascular cause of refractory hypoxia for example intra-cardiac shunt.

Rescue therapies may be trialled prior to a decision to start VV support.

- neuromuscular blockade
- prone positioning
- recruitment manoeuvres

Nitric oxide may be used to allow time to prepare for ECMO or the arrival of a retrieval team, but should not be used to delay the institution of VV ECMO.

Table 7 outlines the parameters and threshold values for indication for VV ECMO. When a patient meets the values for two parameter categories VV ECMO may be indicated.

**Table 7: Indications for starting VV ECMO** 

Parameter	Clinical definition
Hypoxaemia	O2 saturations < 88%
	PF ratio < 100
	FiO2 > 0.8
PEEP	Trial of high PEEP 18 – 24 cmH2O

Hypercarbia	PH < 7.25	
	PaCO2 > 60	
Ventilation	Plateau pressures > 30cmH2O	
	Tidal volumes > 6ml/kg predicted body weight	
	Driving pressure (Vt/C) >15cmH2O	

## Indications for earlier use of VV ECMO

Earlier use of VV ECMO may be indicated in specific scenarios:

- progressive barotrauma
- rapidly progressive (6-12 hour) lung injury due to a fulminant process
- early onset of secondary organ failures
- requirement of safe inter-hospital transport
- inability to tolerate hypercarbia for example traumatic brain injury or right heart failure

## Respiratory extracorporeal membrane oxygenation survival prediction score

The respiratory extracorporeal membrane oxygenation survival prediction score (RESP score) is a validated tool to predict survival for patients receiving VV ECMO for respiratory failure.

The RESP score incorporates:

- age
- immunocompromised status
- duration of mechanical ventilation before ECMO
- diagnosis group
- central nervous system dysfunction
- acute non-pulmonary infection
- neuromuscular blocking drugs or nitric oxide use pre-ECMO
- bicarbonate infusion pre-ECMO
- cardiac arrest pre-ECMO
- PaCO2 level and peak inspiratory pressures.

Total scores range from -22 to 15 with a score of 0 approximately representing a survival of 50 per cent (Table 8).

Access a RESP score calculator at http://www.respscore.com/

Table 8: Respiratory extracorporeal membrane oxygenation survival prediction score: hospital survival by risk class

RESP score	Risk class	Survival
≥ 6	ı	92%
3-5	II	76%
-1 to 2	III	57%
- 5 to - 2	IV	33%
≤ - 6	V	18%

## **4.3.2 VA ECMO**

The indication for VA ECMO is a persistent low cardiac output state as defined in Table 9 despite adequate supports.

Table 9: Indications for initiation of VA ECMO

Indication	Clinical definition
Hypotension	Systolic BP < 90mmHg on inotropes (see table below)
Lactate	> 5 mmol/l
Echocardiogram	Confirmation of low cardiac output state
Evidence of malperfusion	Skin mottling, altered conscious state, oliguria > 4 hours

Most patients are on inotropic support prior to starting VA ECMO. It is important not to delay cannulation while continuing to escalate these supports. Delay in starting ECMO is likely to result in multiorgan dysfunction and a lower chance of survival.

Table 10 outlines the maximum infusion rates that should be reached prior to starting ECMO. It is important to stress that ECMO may be instituted before these limits are reached. If a combination of inotropic and vasopressor agents are used, consider half these infusion rates as the maximum prior to initiation of VA ECMO.

Table 10: Maximal inotrope / vasopressor threshold for ECMO initiation

Inotrope or vasopressor	Threshold infusion rate	
Adrenaline	> 0.2 mcg/kg/min	
Dobutamine	> 5 mcg/kg/min	

Milrinone	> 0.5 mcg/kg/min
Noradrenaline	> 0.5 mcg/kg/min
Vasopressin	> 2 units/hr

#### Indications for earlier use of VA ECMO

The earlier use of VA ECMO may be indicated in specific scenarios:

- progressive barotrauma
- rapidly progressive (4-6 hours) hypotension with severe echocardiography changes suggestive of fulminant course for example pulmonary embolus, myocarditis
- early onset of secondary organ failures, especially respiratory failure
- requirement for safe inter-hospital transport

#### Survival after venoarterial ECMO score

The survival after venoarterial ECMO score (SAVE score) is a validated tool to predict survival for patients receiving VA ECMO for cardiogenic shock.

The SAVE score incorporates:

- age
- diagnostic group
- weight
- haemodynamic parameters
- cardiac arrest pre-ECMO
- inspiratory pressures
- duration of ventilation
- renal failure
- bicarbonate level
- central nervous system dysfunction
- liver failure.

Total scores range from -35 to 17 with a score of 0 approximately equivalent to 50 per cent survival (Table 11).

Access a SAVE score calculator at http://www.save-score.com/

Table 11: SAVE score: Hospital survival by risk class

Total SAVE Score	Risk class	Survival
≥ 5	I	75%
1-5	II	58%
-4 to 0	III	42%
- 9 to - 5	IV	30%
≤ 10	V	18%

## 4.4 TRIGGERS FOR REFERRAL TO VICTORIAN ECMO SERVICE

One of the guiding principles of the Victorian ECMO Service is to aim for early referral of patients to ensure that the institution of ECMO for eligible patients is not delayed.

The service should aim to transfer patients to comprehensive or intermediate centres prior to the patient needing ECMO. Therefore, the criteria or clinical triggers used to refer a patient to the Victorian ECMO Service should be set below the criteria for the initiation of ECMO.

# 4.4.1 VV ECMO referral triggers

Referral for VV ECMO should occur where:

- The treating team are unable to maintain adequate oxygenation or ventilation with optimal safe ventilation settings.
- There is evidence of barotrauma.

Table 12 outlines the patient physiological and ventilator parameters to trigger a referral to the Victorian ECMO Service. If any of the described categories are met the patient should be referred to the Victorian ECMO Service.

Table 12: Criteria for referral to the Victorian ECMO Service: VV ECMO

Criteria	Clinical definition	
Hypoxaemia (>3 hours)	Oxygen saturation < 90%	
	PF ratio < 150	
	FiO2 > 0.7	
Hypercarbia (> 3 hours)	pH < 7.25	
	PaCO2 > 60 mmHg	
Ventilator settings		
PEEP	>10 cmH <sub>2</sub> O	
Vt	> 6mL/kg	
Plateau Pressure	> 30 cmH <sub>2</sub> O	

Driving Pressure (Vt/C)	> 15 cmH₂O
Considering rescue therapies	Recruitment manoeuvres
	Prone positioning

# 4.4.2 VA ECMO referral triggers

Referral for VA ECMO should occur for patients who are developing cardiogenic shock despite resuscitation and on low dose inotrope support and have:

- persisting hypotension or
- evidence of malperfusion (low cardiac output state)

Table 13 outlines the patient physiological parameters and support requirements to trigger a referral to the Victorian ECMO Service. If any three of the criteria are met the patient should be referred to the Victorian ECMO Service.

Table 13: Criteria for referral to the Victorian ECMO Service: VA ECMO

Criteria	Clinical definition	
Hypotension (>3 hours)	Systolic BP < 90 mmHg	
Inotrope support	More than low dose	
Acute pulmonary oedema	Requiring positive pressure	
Blood gas derangement	Lactate > 4 mmol/L	
Malperfusion	Skin mottling	
	Oliguria > 4 hours	
	Altered conscious state	
	Deranged ALT/AST	
Cardiac Index (CI)	< 2.2 l/min/m2	

# 4.4.3 Post-cardiotomy shock as an ECMO referral trigger

# **Key messages**

Survival outcomes of VA ECMO in the post-cardiotomy group are low compared to the overall VA ECMO cohort.

A multi-disciplinary consensus on the suitability for post-operative ECMO should be reached before any planned high-risk procedures.

The option of post-operative ECMO in this patient group should be discussed with the patient (or medical treatment decision maker) as part of the consent process for surgery.

Decision about ECMO for emergency cases or unexpected intra-operative events should ideally be made before the patient leaves the operating room in discussion with another experienced cardiac surgeon and intensivist ECMO specialist. This may be via the Victorian ECMO Service coordination

The success of the surgical procedure in addressing the underlying pathology is an important consideration for the initiation of ECMO in addition to the patient's age and comorbidities.

Post-cardiotomy shock (PCS) is a term loosely used to refer to a group of patients who are unable to be weaned from cardiopulmonary bypass following open heart surgery. Although this is a relatively uncommon event (~1% of all cardiopulmonary bypass cases), VA ECMO for PCS constitutes a significant proportion of all VA ECMO cases.

A recent meta-analysis pooling data from 20 observational studies (1996-2017) involving 2877 patients, showed a very high mortality in this subgroup of ECMO patients with 34 per cent surviving to hospital discharge, and 24 per cent surviving to one year.

Factors that have been shown to predict mortality include:

- older age
- rising lactate
- duration of ECMO support
- organ failures

Despite advances in technology, the outcome in this group of patients has not significantly improved over time.

As ECMO support is costly and resource intensive, it is important to define the patient population who are most likely to benefit. Unfortunately, there has not been any specific risk models developed for these patients, partly due to the inherent heterogeneity within the group. Several distinct contexts of PCS can be identified, and this has bearing on the appropriateness and timing of VA ECMO.

## **High-risk procedures**

Planned high-risk procedures are encountered increasingly by cardiac surgeons. Examples include:

- multiple valve replacements in the setting of significant RV dysfunction
- coronary artery bypass grafts for significant ischemic cardiomyopathy.

For these patient groups we recommend a multi-disciplinary approach to reach a pre-operative consensus on the suitability for ECMO in the post-operative setting. These discussions could be held as part of a case conference and should involve representatives from:

- cardiac surgery
- cardiology
- intensive care including an intensivist ECMO specialist
- anaesthetics

#### Factors to be taken into consideration include:

- age of the patient,
- co-morbidities,
- frailty
- underlying cardiac function
- left and right ventricular function
- presence of pulmonary hypertension

Patients often do not fully appreciate the degree of risk involved in these operations. A frank multidisciplinary discussion will help the patient to make a more informed decision. It is appropriate for the patient to decide whether they want VA ECMO once the various potential outcomes and complications are discussed openly.

#### **Risk scores**

Risk scores for example STS score or EuroSCORE II, may be used to define the risk of a cardiothoracic procedure. An STS score above 8-10 per cent, or EuroSCORE II >15-20 per cent should trigger a multidisciplinary discussion.

These scores have recognised limitations. The scores were not derived for the Australian setting and at the extremes of risk scores tend to be less accurate.

## **Emergency situations**

Emergency operations – for example aortic dissection, post-infarct ventricular septal defect or coronary artery bypass grafting for cardiogenic shock – are increasingly resulting in use of VA ECMO. Due to the time critical nature of the procedure, no pre-operative multi-disciplinary discussion can take place.

Unexpected intraoperative events that lead to significant myocardial injury are potential reasons to consider VA ECMO without prior discussion. Examples include:

 multiple cross-clamp periods to fix a valve lesion, for example planned repair turned into replacement

- prolonged cross-clamp time
- hypothermic arrest for intra-operative complications, for example iatrogenic aortic dissection.

In these scenarios, another experienced cardiac surgeon as well as the ICU team, including an intensivist ECMO specialist, should be involved in making a decision about ECMO in the perioperative period.

Ideally, a consensus on the suitability for ECMO should be reached before the patient leaves the operating room. Factors such as age and comorbidities are once again important to consider. But, more importantly, the success of the primary operation to deal with the underlying pathology is a vital part of the decision-making process.

Significant residual defects make the likelihood of a successful outcome with VA ECMO low. Examples include:

- non-revascularisable myocardium
- significant residual valvular pathology.

## Timing of VA ECMO for post-cardiotomy shock

Patients who are eligible for ECMO should have the support started early. Patients who have support delayed with rising inotrope requirements tend to develop multi-organ dysfunction and have poor survival outcomes.

Anecdotal evidence and small series studies have shown that early ECMO implementation before escalation of inotropic support is more likely to produce a favourable outcome.

ECMO allows reduction in inotropic requirement and may minimise the deleterious effects of high inotropic and vasoconstrictive agents. It rests the ventricles and allows time for "resuscitation" to correct metabolic derangements that contribute to cardiac dysfunction. The amount of inotropic support required will also inform the likelihood of success.

#### Complications from VA ECMO for post-cardiotomy shock

One of the preventable complications of VA ECMO unique to PCS is postoperative bleeding. Due to prolonged cardiopulmonary bypass, PCS patients are often coagulopathic and the massive transfusions that may be required can lead to activation of the clotting cascade, thromboembolic events and failure of the ECMO circuit oxygenator.

It is strongly encouraged that haemostasis is controlled in the operating room, or that plans are made to re-explore the surgical site early after a period of resuscitation. The secondary complications resulting from bleeding and transfusion may add significantly to the mortality and morbidity associated with PCS ECMO.

## **Predicting outcome**

These factors have been shown independently to be associated with increased ECMO mortality:

inotropic score

- lactate level
- pH levels on ECMO
- sequential organ failure assessment (SOFA) score
- duration of FCMO.

However, these predictors are more relevant to the 'survivability of ECMO' rather than the appropriateness of ECMO initiation. The decision to start ECMO should be based on the completeness of surgical repair and the likelihood of ongoing myocardial injury. This requires significant experience from both the cardiac surgical and ICU teams.

In patients where there are uncertainties about myocardial recovery, a short period (24-48 hours) of ECMO may serve as a bridge to decision. In this situation, the trends of important physiological parameters should be followed. A rising lactate level or continued organ dysfunction while on ECMO may indicate poor prognosis and suggest withdrawal and palliative care may be appropriate.

## Left ventricular assist device bridge to decision therapy

Important consideration should be given to patients who are potential candidates for left ventricular assist device (LVAD) or transplant destination therapy. In these patients, it may be reasonable to refer the patient to the comprehensive ECMO centre for their primary cardiac surgery.

In patients that are stabilised on ECMO and myocardial recovery does not appear imminent but without any significant residual pathology, referral to the comprehensive ECMO centre for ongoing management and consideration of LVAD or transplant destination therapy.

## 4.4.4 High risk interventional cardiology as an ECMO referral trigger

The Cardiac Society of Australia and New Zealand has position statements on percutaneous coronary intervention (PCI) in Australia. Accreditation processes rely on local hospital scope of practice policies.

ECMO in PCI with cardiogenic shock and cardiac arrest are well described. However there is little evidence on elective ECMO in high risk stable PCI patients. The concept of preemptive ECMO to facilitate PCI in complex anatomy is unique to The Alfred and a few international ECMO centres.

High risk patients include those with left ventricular ejection fraction < 30% requiring complex PCI such as:

- unprotected left main PCI
- single or multiple target lesions that in aggregate jeopardise over 50% of the remaining viable myocardium.

In these scenarios transferring the patient for treatment at an intermediate or comprehensive ECMO centre should be considered.

Centres embarking on other forms of temporary mechanical circulatory support for high risk patients should make a pre-procedure evaluation of the likelihood of successful weaning post PCI. If the patient is at high risk of failing to wean, it should be discussed with the Victorian ECMO Service.

# 4.4.5 Poisoning as an ECMO referral trigger

VA ECMO is an intervention that may be appropriate for selected patients who do not respond to conventional therapy, rather than a first line treatment. In-hospital mortality following poisoning is less than one per cent.

You should seek advice about risk assessment and medical management of clinical toxicity from a clinical toxicologist via the state poisons information centre (telephone 13 11 26).

## Pathway for ECMO referral in cases of poisoning

You should consult the state poisons information centre for all cases of poisoning.

Suspected poisoning occurs in a heterogeneous group of patients with varying degrees of symptom severity and time courses. Many factors make it hard to determine the expected clinical progression:

- potential for synergy / drug interactions meaning dose thresholds quoted for single ingestions may not apply
- confirmation of exposure difficult until cardiovascular instability occurs
- onset of cardiovascular instability will vary based on exposure

It is difficult to determine those that require transfer and the ideal timing of transfer if indicated. Occasionally patients post poisoning may require ECMO support until the effects of the toxicity abate. Ideally these patients would be moved to an ECMO capable centre prior to meeting ECMO initiation criteria.

There are two possible pathways that a patient with suspected poisoning should be referred to the Victorian ECMO Service:



## Indications for ECMO referral in cases of poisoning

A patient may benefit from VA ECMO following any exposure where life-threatening cardiovascular system dysfunction develops. VA ECMO is more likely to benefit those exposures that lead primarily to cardiovascular systemic dysfunction, rather than exposures that lead to systemic toxicity with multiorgan failure.

Table 14 outlines common exposures for patients in Victoria who may benefit from VA ECMO if life-threatening toxicity resistant to medical therapy occurs. The list is not exhaustive. Dose thresholds are of limited benefit as most suspected poisonings involve multiple drugs or substances. Many drugs or substances interact to produce greater degrees of clinical toxicity. In addition, there is individual variation in response to exposures.

Table 14: Exposures that may benefit from VA ECMO support in refractory cardiac failure

Calcium channel blockers	Beta-blockers	Antipsychotics	Tricyclic antidepressants	Other pharmaceuticals
Verapamil Diltiazem Amlodipine Lercanidipine Nifedipine Felodipine In combination with angiotensin converting enzyme inhibitor In combination angiotensin receptor blocker	Propranolol Sotalol Metoprolol Atenolol Bisoprolol Nebivolol Carvedilol	Quetiapine Amisulpride Ziprasidone Chlorpromazine	Amitriptyline Dothiepin Nortriptyline Imipramine Clomipramine Doxepin	Flecainide Cardiac glycosides (acute digoxin toxicity) Venlafaxine Desvenlafaxine Lamotrigine Carbamazepine Quinine Chloroquine Hydroxychloroquine Buproprion Orphenadrine

Other exposures where cardiac failure may be a component of severe multi-organ clinical toxicity:

- cyanide
- recreational stimulants and illicit drugs
- organophosphorus pesticides
- herbicides

There is little evidence to support VA ECMO in these cases, but where life-threatening cardiac dysfunction is present clinicians should undertake further discussion with a clinical toxicologist and the Victorian ECMO Service.

# Evidence for poisoning as an ECMO referral trigger

Every year, a wide range of pharmaceutical, recreational and non-drug products are responsible for exposures that have the potential to cause adverse health effects. It is not possible to list all exposures that may produce life-threatening physiological dysfunction that may benefit from VA ECMO. The proposed indications for referral are based on the following information:

- A review of Victorian Poisons Information Centre referrals from Victorian Hospitals over the past 10
  years. Exposures to drugs or substances with the potential to cause cardiac failure that were most
  commonly reported were identified.
- A review of poison information sources including TOXINZ and ToxBase. These organisations are staffed by specialists in poisons information and clinical toxicologists.
- A literature search and review (see poisoning folder in resources file) using the terms [poison\*] OR [toxic\*] AND [ECMO] OR [extracorporeal membrane oxygenation].

## **4.5 WITHDRAWING ECMO SUPPORT**

International overall survival to discharge of patient post ECMO is reported as:

- VV ECMO ~ 60%
- VA ECMO ~ 45%
- ECPR ~ 30%

With the implementation of the Victorian ECMO Service, overall survival between 50-60 per cent is anticipated. A significant proportion of ECMO patients will not survive to discharge from hospital. Patients who die during the course of an illness where ECMO is used fall into three main groups:

- Failure to improve: Progressive deterioration despite ECMO support due to progression of the primary disease, establishment of multiorgan dysfunction, or due to complications of ECMO support
- 2. **Lack of destination** therapy: Patients who stabilise on ECMO, but cannot be weaned from support and are not eligible for destination therapy
- 3. **Out-of-criteria** ECMO: Patients where the use of ECMO was not likely to alter the course of disease and therefore would not benefit the patient.

## 4.5.1 Failure to improve

ECMO is a support therapy not a treatment option. Although ECMO has the ability to improve physiological parameters, the support itself has no effect on the progression of the acute illness.

Many patients continue to deteriorate despite the institution of ECMO. The ECPR group are an example where many patients develop rapidly progressive and irreversible multiorgan failure following prolonged cardiopulmonary resuscitation. Patients often develop progressive hyperlactaemia and escalating inotrope/vasopressor requirements over several hours despite ECMO.

In these scenarios the Victorian ECMO Service coordinating team should provide advice for ongoing management. Retrieval would not be initiated until the situation stabilises. If withdrawal of care is indicated the Victorian ECMO Service coordination team will support the referring hospital team through the decision and process of withdrawal of ECMO.

In current practice, discussions about ECMO are often only started late in the course of a disease. Patients often develop secondary organ dysfunctions during this period, for example renal failure, liver

impairment. These secondary organ dysfunctions have a significant impact on the recovery potential for the patient.

The Victorian ECMO Service and use of a single set of statewide referral triggers are designed to enable patients to be referred earlier and ECMO, when indicated, commenced prior to multiorgan involvement.

# 4.5.2 Lack of destination therapy

Patients are often placed on ECMO in the setting of advanced progression of an acute illness or in an emergency situation. All the information needed to make a fully informed decision on the benefit to the patient is often missing at the time of ECMO initiation. Although many of these patients have undiagnosed chronic health conditions, some have diagnoses that need to be considered when deciding to start ECMO.

When possible you should refer patients to the Victorian ECMO Service prior to starting ECMO. Part of the early assessment and coordination process involves discussions with transplant physicians when indicated. If patients fall outside of destination therapy options, the benefit of commencing ECMO should be re-assessed.

The workup for transplantation is complex and often quite prolonged. Patients can wait months for organs, even once listed for transplant. The process of referring a patient, not previously known to the transplant teams, increases the complexity of the process.

Many patients supported on ECMO to a decision about transplantation (bridge-to-decision) are deemed ineligible for transplantation. This is obviously a very difficult and distressing process for families and patients if they are awake while on ECMO. If withdrawal of care is indicated the Victorian ECMO Service coordination team will support the local hospital team through the decision and process of withdrawing ECMO.

# 4.5.3 Out-of-criteria ECMO

ECMO is sometimes initiated as a rescue therapy when other supports have been exhausted. Although clinicians are trying to offer the patient a chance at survival, these decisions can be made without considering the realistic benefit ECMO has to offer.

Examples may include a septic shock patient with escalating vasopressor requirements and progressive distributive shock. Another example is an elderly patient in theatre who is unable to separate from bypass following a prolonged attempt at valve replacement.

Wherever possible you should refer difficult cases to the Victorian ECMO Service prior to starting ECMO. The expected benefit to the patient can be discussed and if ECMO is deemed appropriate the retrieval process can begin. If it is determined that there is no expected benefit for the patient, ECMO should not be initiated.

If a patient on ECMO is referred to the Victorian ECMO Service with no expected benefit from ECMO, the Victorian ECMO Service should not be obliged to retrieve the patient. The Victorian ECMO Service

coordination team will continue to offer support to the referring hospital site as needed including to assist with the decision and process of withdrawing ECMO.

## **4.6 WEANING OF ECMO SUPPORT**

## 4.6.1 VV ECMO Weaning

Most patients who require VV ECMO need the cause of the respiratory failure to be determined and native lung recovery to occur before weaning of VV ECMO support can be considered.

Only a small per cent of patients on VV ECMO will have lung transplantation as a destination therapy and there are currently no medium-term bridge supports for respiratory failure. The dependence on native lung function recovery as a criterion for weaning highlights the importance of appropriate patient selection for VV ECMO support.

## Assessing readiness to wean

Weaning from VV ECMO can occur once lung recovery has started and lung rest is no longer considered necessary. The timing of lung recovery varies and will depend on the original pathology and severity of lung injury.

Most patients will require VV ECMO support for 2-4 weeks. It is not unusual for longer periods of ECMO support to be needed for more severe acute respiratory distress syndrome cases.

A variety of weaning strategies are reported in the literature and no consensus exists on the correct approach. Weaning from VV ECMO should not be rushed. Unsafe ventilation strategies during the weaning phase or following ECMO removal may lead to a recurrent episode of lung injury due to barotrauma, ventilator induced lung injury or patient self-inflicted lung injury.

Assessing readiness to wean VV ECMO should be prompted by:

- resolving primary disease state
- clearing chest x-ray
- improvement in lung compliance >20mL/H2O

Weaning can start once the chest x-ray begins to clear and the compliance state of the lungs improves. An arbitrary value for compliance used in some centres to signify readiness to wean is >20mL/cmH2O.

A change in the patient's tidal volumes on ventilator rest settings may be a guide to improvement in compliance. Assessing compliance states during ventilation modes other than full mandatory ventilation, for example assisted or pressure supported modes, is difficult without the use of devices such as oesophageal balloons. Assessment may require intervals of paralysis to accurately determine the compliance state.

## Commencing the weaning process

VV ECMO support should be weaned through reducing the fresh gas flow (sweep gas) to zero.

Once full ECMO support, for example blood flow of >5L/min, is no longer required, blood flow can be reduced to a safe level (e.g. 3L/min) to facilitate diuresis and prevent episodes of access insufficiency. Weaning to below 1.5L/min is not recommended due to the increased risk of thrombus formation in the oxygenator.

Weaning can then occur with staged reductions in the fresh gas flow by 1L/min increments. Concurrent increase in mechanical ventilation to ensure adequacy of CO2 removal as the fresh gas flow is being weaned is required. It is not required to separately reduce the fraction of inspired oxygen to the blender. Once the fresh gas flow is reduced to zero the patient is essentially off ECMO support and assessment for decannulation can begin.

There is no agreed standard as to whether the patient should be separated from VV ECMO on mandatory ventilation or spontaneously breathing, however ventilator support should provide adequate gas exchange at non-injurious ventilator settings to the recovering lungs. The benefits of spontaneous breathing include reduced disuse myopathy, ability to de-sedate, early gentle mobilisation and possible beneficial haemodynamic effects.

Early application of spontaneous modes may not be protective in the recovering severe acute respiratory distress syndrome population. Tachypnoea, high minute ventilation (tidal volume > 6mL/kg) and generation of large negative pleural pressures can result in recurrent episodes of lung injury. Close attention to the work of breathing and delivered tidal volume is essential. Work of breathing is difficult to determine from the bedside. Assessment may require intervals of short acting sedatives and paralysis to truly estimate the compliance state. Alternatively, devices such as oesophageal balloons may help with assessment.

The ideal timing for tracheostomy in patients on VV ECMO is not clear. Younger patients requiring high dose sedation to facilitate safe ECMO support and endotracheal intubation, may benefit from earlier tracheostomy prior to weaning ECMO with a view to de-sedation and commencing gentle mobilisation. However, the benefits of this strategy need to be weighed against the ongoing need for anticoagulation.

Patients with severe acute respiratory distress syndrome with a relatively prolonged requirement for ECMO may require a tracheostomy to facilitate weaning from mechanical ventilator support post ECMO decannulation. In some circumstances, in highly specialised centres, patients on VV ECMO support may be extubated prior to weaning of their VV ECMO.

## Assessing readiness for decannulation

Fresh gas flow should be left off for a period of >12 hours prior to proceeding to decannulation. Parameters in Table 15 should be met before proceeding to VV ECMO decannulation.

Currently, most institutions leave the fresh gas flow off for a period of 4-24 hours to ensure there is no slow deterioration in gas exchange or haemodynamics (heart rate, blood pressure, cardiac filling pressures) and no increase in minute ventilation. Slow progressive increase in PaCO2 can occur and it is important to allow adequate time for this to happen.

It is not universal practice to perform an echocardiogram around the time of weaning, however you should investigate any change in haemodynamics with an echocardiogram to exclude cor pulmonale or pulmonary hypertension as a cause.

Table 15: Parameters required for decannulation of VV ECMO

Parameter	Clinical definition
Disease process	Significant improvement
Oxygenator fresh gas flow	0 L/min for >12hours
Ventilator settings	
Fraction of inspired oxygen (FiO <sub>2</sub> )	≤ 50%
Plateau Pressure	≤ 25
Positive end expiratory pressure	≤ 12
Tidal volumes	<8 mL/kg
Respiratory rate	< 20
Extubated ventilation respiratory rate	< 20
O <sub>2</sub> Saturation	> 92%
PaCO <sub>2</sub>	< 50
На	> 7.35

## **Decannulation process**

Decannulation of VV ECMO can be performed at the bedside. Cannulae inserted via cut-down procedure should be removed in the operating room by surgical teams. The process should be explained to the patient or medical treatment decision maker with plans around weaning failure explored prior to the procedure.

Heparin should be ceased 2-4 hours prior to cannula removal and coagulation profile checked prior to removal. Both limbs of the ECMO circuit should be clamped and cannulae withdrawn. To prevent entrainment of air into the venous system, a valsalva manoeuvre should be performed by the patient or performed with the ventilator. Alternatively, a neuromuscular blocking agent can be used.

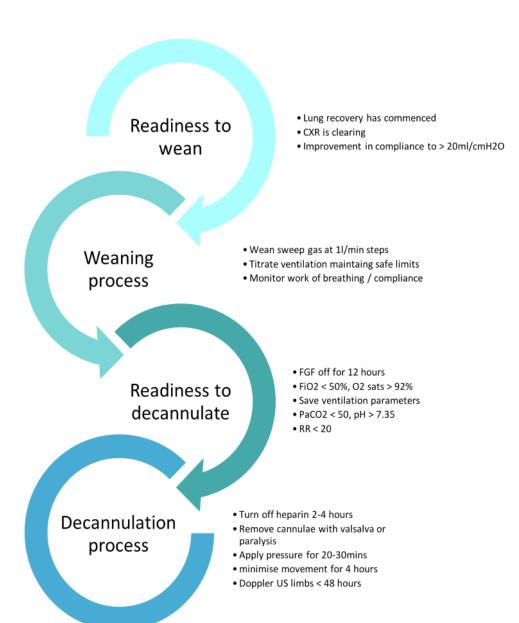
You should maintain pressure over the cannulation sites for 20-30 minutes. Some institutions insert a purse string suture under sterile conditions around the cannula prior to removal. Alternatively, an interrupted stitch may be placed at the exit sites post removal.

You should ensure that the patient has minimal movement at the cannulae sites for a further 2-4 hours to maintain haemostasis. Limiting coughing is also important during this period. Loss of haemostasis will require a further period of manual pressure. On occasion surgical intervention may be required to achieve haemostasis.

You should obtain vascular ultrasounds within 48 hours of decannulation to exclude the possible formation of venous thrombi.

Once the patient has been successfully decannulated from VV ECMO they can proceed with routine weaning from mechanical ventilation. In patients who have required high dose sedation during their ECMO run careful daily incremental reduction in the doses of sedative drugs may be required.

Figure 1: VV ECMO weaning flowchart



# 4.6.2 VA ECMO weaning

## Assessing readiness to wean

Many factors impact the timing of weaning from VA ECMO, including the natural history of the underlying disease, time required for treatments to work, and the development of ECMO related complications.

You should assess each day whether a patient can be weaned from VA ECMO. A weaning study itself rarely has adverse consequences, whereas remaining on ECMO longer than necessary may lead to increased complications.

Consider weaning from VA ECMO once the following prerequisites have been met:

- The conditions which necessitated the institution of ECMO should have resolved.
  - Adequate time should be allowed for recovery based on the natural history of the disease
- Pulsatile waveform, for example pulse pressure >20mmHg, for greater than 24 hours
  - Briefly pause intra-aortic balloon pump, if present
- Baseline mean arterial pressure > 60 mmHg with low or no vasoactive agents
- Stable or improving organ failures
- Minimal or no pulmonary impairment for example fraction of inspired oxygen on ventilator <0.6, chest x-ray clear or clearing
  - Consideration of converting to VV ECMO is discussed below

## **VA** weaning study

Assessing cardiac function is challenging while under the altered loading conditions of ECMO. A weaning study involves decreasing ECMO flow rates, for example to 50 per cent then 25 per cent of adequate cardiac output. This allows increased blood flow through the heart and for cardiac function to be assessed more accurately.

The weaning study is usually performed using a transthoracic echocardiogram, although transoesophageal echocardiography may be required if adequate views are not possible. The intensivist ECMO specialist +/- perfusionist should be present to assist with assessment and to ensure haemodynamic stability is maintained.

Note that low ECMO flows predispose circuits to thrombus formation. Hence, a weaning study should ideally be performed with the patient anticoagulated and should not last any longer than 10-15 minutes at flows <1.5L/min.

There are several ways of performing a VA ECMO weaning study. A suggested approach is:

- prepare inotropes to support heart during the weaning study
- ensure the patient is anti-coagulated (APTT 50-70 seconds)

- if APTT <50, give a bolus of intravenous heparin, for example 2500-5000units, depending on the most recent APTT and bleeding risk of the patient
- gradually wean ECMO flows by 1L/min every 5-10 minutes until flows are 0.5 -1L/min as tolerated, while increasing inotropic/vasopressor support as necessary
- assess both the haemodynamic and echocardiographic response at each stage
- Satisfactory cardiac function (as reflected by stable blood pressure and stable or increased cardiac output on echocardiography), on no or stable low dose inotropic support is predictive of successful weaning. A degree of cardiac reserve is desirable prior to ECMO decannulation.
- After the weaning study is complete increase ECMO blood flows back to above 2.0 L/min until decannulation.

## Assessing readiness for decannulation

Along with a successful weaning study, the parameters in Table 16 should be met before proceeding to VA ECMO decannulation.

Table 16: Parameters predictive for successful decannulation of VA ECMO

Parameter	Clinical definition			
ECMO blood flow	Able to tolerate an ECMO blood flow 0.5-1L/min (10-15ml/kg/min) for a period of > 10mins with at most mild inotrope requirements and minimal alteration in haemodynamic parameters.			
Haemodynamics and	Stable haemodynamics			
blood pressure	Arterial pulse pressure (S	Arterial pulse pressure (SBP-DBP) of > 25 mmHg		
Inotropic supports	Low dose inotropic or	Adrenaline	< 0.1mcg/kg/min	
	vasopressor supports	Milrinone	< 0.25mcg/kg/min	
		Noradrenaline	< 0.2mcg/kg/min	
		Dobutamine	< 2.5mcg/kg/min	
Echocardiography	LV and RV size	and RV size No significant ventricular dilatation during		
	LVOT VTI	>12 cm		
	LVEF	> 20-25%		

#### Transition from VA to VV ECMO

Some patients on VA ECMO may require transition to VV ECMO after cardiac recovery due to significant concomitant lung pathology. This should be considered if the ventilator fraction of inspired oxygen (FiO2) is unable to be weaned below about 0.6 during the VA ECMO weaning study to achieve an oxygen saturation (SpO2) of > 90%, giving a PF ratio < 100.

#### **Decannulation of VA ECMO**

You should confirm timing of removal with the surgeon or intensivist. Heparin is usually stopped 1-2 hours prior to decannulation.

Surgical removal with repair of the artery is the usual practice for the removal of peripheral VA ECMO cannulae. This is performed in the operating room by the cardiothoracic or vascular team. Central ECMO must be removed by the cardiothoracic team in the operating theatre.

An ultrasound should be performed within 48 hours of decannulation to exclude thrombosis of the cannulated vein.

Thromboprophylaxis with heparin may be resumed 6-8 hours post decannulation if there are no signs of active bleeding.

Figure 2: VA ECMO weaning flowchart

Readiness to wean

- Resolving primary process
- Pulsatile arterial waveform
- MAP > 60 with minimal vasoactive agents
- Improving organ failures

Weaning study

- Ensure adequate anticoagulation
- Baseline echocardiographic study
- Wean ECMO blood flow in stages
- Monitor and record echocardiographic and haemodynamic changes at each stage

Readiness to decannulate

- Stable haemodynamics at 0.5-1L/min blood flow
- Minimal change to inotrope/vasopressor supports
- No significant LV/RV dilation during wean
- Other echocardiographic weaning indices met
- If ventilator FiO2 > 60% for O2 sats >90% consider VV ECMO

Decannulation process

- Arrange theatre time with surgeons and perfusion
- Turn off heparin 2-4 hours
- Surgically remove cannulae and repair vessels
- Doppler US limbs < 48 hours

# **Appendix 5: Hospital accreditation**

This section covers our proposed hospital accreditation processes and capability requirements. We've detailed what each service will need to do to participate in the Victorian ECMO Service as an initiation site, intermediate centre, or comprehensive centre. This includes staffing requirements, hospital capability and equipment needed.

#### **5.1 ACCREDITATION PROCESS AND FREQUENCY**

#### 5.1.1 Initial accreditation

Hospitals will need to meet the requirements set out for the tier of service to be delivered including staff credentialing. Hospital capability requirements should be met before specific requirements for each tier of ECMO service are considered.

The Department of Health and Human Services will designate the number of hospitals at each tier. This may be revised from time to time in line with statewide needs, geography and projected patient numbers.

The accreditation process should involve a site visit, potentially by peer review. Consumers should participate in all accreditation processes.

#### 5.1.2 Maintaining and renewing accreditation

Hospitals will be expected to actively participate in the Victorian ECMO Service and undertake self-audits annually to maintain accreditation.

Renewal of accreditation will be required every three years and should follow a process similar to initial accreditation while also considering information available from Victorian ECMO Service monitoring.

#### **5.2 CAPABILITY REQUIREMENTS**

# These requirements cover all Victorian ECMO Service sites, regardless of tier:

- Coronary angiography suite and high-volume interventional angiography service and emergency STEMI management capability available 24 hours a day, seven days a week
- Operating theatre and surgical services with vascular capability
- ICU with Fellow of College of Intensive Care Medicine exclusive on-call within 30 minute response time 24 hours a day, seven days a week
- Emergency department with Fellow of Australasian College of Emergency Medicine exclusive oncall within 30 minute response time 24 hours a day, seven days a week
- Blood bank and pathology services available 24 hours a day, seven days a week
- Ultrasound capable critical care clinicians available 24 hours a day, seven days a week
- Echocardiography service including reporting available 24 hours a day, seven days a week

- Radiology service including reporting available 24 hours a day, seven days a week
- Telehealth facilities available for use for ECMO patients

#### **5.3 ACCREDITATION REQUIREMENTS**

These requirements cover all Victorian ECMO Service sites, regardless of tier.

#### 5.3.1 Clinical staff – specific roles

#### **ECMO** program director

Each ECMO accredited site should have an ECMO program director. This is an Extracorporeal Life Support Organization (ELSO) defined role equivalent to a 'head of service'. In Australia generally the position is occupied by an intensivist, but alternatives could include a cardiologist, cardiac surgeon or emergency physician.

This role would be filled by a consultant ECMO specialist who also participates in the site's ECMO lead roster.

The program director is responsible for:

- education, training, service delivery and performance and quality improvement
- assuring appropriate training and performance and the credentialing of clinicians who care for ECMO patients or manage ECMO circuits
- maintaining records of credentialing and re-credentialing of staff
- directing quality improvement and projects
- assuring valid data submission as required for the program
- representing the hospital on the Victorian ECMO Service governance committee.

#### **ECMO** coordinator

Each ECMO accredited site should have an ECMO coordinator. This is an ELSO defined role to manage the operations of the ECMO program. This role is usually filled by an intensive care nurse ECMO specialist or perfusionist ECMO specialist.

The ECMO coordinator is responsible for:

- education, training, equipment management, service delivery and collection of patient and clinician experience data
- assisting the program director in maintaining records of credentialing and re-credentialing of staff
- undertaking valid data collection and submission as required for the program including patient and staff experience surveys
- being the primary contact for families and clinicians, together with the ECMO lead.

#### **ECMO** specialist

Each ECMO accredited site should have adequate ECMO specialists available to deliver care at the designated tier. ELSO defines this role as:

A technical specialist trained to manage the ECMO system and the clinical needs of the patient on ECMO under the direction and supervision of a credentialed consultant ECMO specialist.

These roles may be filled by a critical care registered nurse, perfusionist, intensivist, cardiologist, cardiac surgeon or emergency physician. The ECMO specialist is responsible for patient care and circuit management.

#### **ECMO lead**

Each ECMO accredited site should have one consultant ECMO specialist available 24 hours a day, seven days a week. A number of accredited consultant ECMO specialists would be required to fill this roster across the course of a year. The ECMO program director would participate in this roster.

Decisions around eligibility for both VV and VA ECMO may be required therefore the role is best suited to an intensive care consultant.

The ECMO lead is responsible for:

- the decisions and management of current or potential ECMO patients at the site and activation of ECMO team
- providing an escalation point for all clinicians involved in care of current or potential ECMO patients
- being the primary contact for families of ECMO patients, together with the coordinator
- communicating with the Victorian ECMO Service for the site including referrals and retrievals.

#### **ECMO** cannulator

Each ECMO accredited site should have two ECMO cannulators available 24 hours a day, seven days a week for percutaneous cannulation.

These roles may be filled by an intensivist, cardiologist, cardiac or vascular surgeon, emergency physician, anaesthetist or interventional radiologist who are trained in percutaneous or open vascular access and ECMO cannula deployment.

The ECMO cannuator is responsible for:

- correct selection and placement of ECMO cannulae including placement of backflow (reperfusion)
   cannula in VA ECMO
- when on-call must be onsite to commence cannulation within 30 minutes of activation for emergency cases.

#### 5.3.2 Bedside care model

Adequate staffing is needed to provide care for patients receiving ECMO regardless of the tier of the accredited site. Several bedside care models are described by ELSO and may be used to manage patients on ECMO support.

#### Single care-giver nursing model

A nurse ECMO specialist is responsible for patient care as well as managing the ECMO console and circuit. Perfusion services generally provide a consultation service. This is the current model used at The Alfred and Royal Children's Hospital.

#### 2:1 or 3:2 nursing model

Like the single care-giver model, nursing staff provide care for the patient and manage the ECMO console. However, the number of nursing staff providing care increases. This may be two nursing staff managing one ECMO patient or three staff managing two patients on ECMO. This is the current Barwon Health model of care.

#### 24-hour bedside perfusion model

Perfusionists provide the ECMO specialist role. Nursing staff manage the care of the patient in consultation with a perfusionist who is responsible for managing the ECMO console and circuit. This model relies on a perfusionist in attendance 24hours a day, 7 days a week while a patient is on ECMO. This is the current model of care that is provided in many private hospitals.

#### **Blended model**

Over time a hospital with limited clinical ECMO experience may transition from a perfusion model to a single-care giver model. As nursing experience and skill increases, there is likely to be a transition phase where the perfusion services offer less direct patient care hours and become more of a consultative service.

#### 5.3.3 Equipment

Each ECMO accredited site should maintain a minimum level of equipment aligned to the statewide service immediately available onsite:

- minimum two ECMO pumps
- adequate number of cannulae and associated consumables
- ultrasound for vascular access and echocardiography
- mechanical CPR device (if providing ECPR).

#### 5.3.4 Activation and escalation

#### **Escalation to ECMO lead**

Each ECMO accredited site must have a well-defined system for escalating all potential ECMO patients to the site's ECMO lead.

This supports coordinated assessment, referral and decision-making for all patients. The on-call ECMO lead should be the main communication point between the site and the Victorian ECMO Service.

You should discuss every potential ECMO patient with the on-call ECMO lead at the site. Ideally this discussion would occur prior to starting cannulation to ensure suitability and patient benefit. This includes potential patients identified in the emergency department, operating theatre, cardiac catheter laboratory and intensive care unit.

For patients who are at known high-risk for ECMO, you should discuss the suitability for ECMO with the on-call ECMO lead prior to starting a procedure, for example in the cardiac catheter laboratory or operating theatre. In elective cases these discussions should also form part of the consent process.

You should discuss patients with the hospital on-call ECMO lead and families as part of any referral to the Victorian ECMO Service.

#### ECMO team activation system

Each ECMO accredited site must have a well-defined system to notify rostered ECMO team members of a potential patient.

This may be a pager or phone system. For example, a designated phone number diverts to the on-call ECMO lead for the site who then activates the local team.

Team members should be onsite within 30 minutes of activation to commence cannulation in emergency cases.

#### 5.3.5 Quality assurance and improvement

All ECMO accredited sites will participate in statewide quality assurance and quality improvement processes, such as:

- data collection and reporting
- case reviews
- special interest group meetings for continuing education and practice development
- Victorian ECMO Service governance committee
- education provision and content maintenance
- maintenance of guidelines and policies
- collaborating to manage equipment and consumables.

#### **5.4 ACCREDITATION REQUIREMENTS FOR INITIATION SITES**

In addition to capability requirements and requirements for all accredited sites.

Initiation sites are able to cannulate patients, initiate ECMO and provide patient care until safe retrieval to a comprehensive or intermediate centre.

#### 5.4.1 Clinical staff

ECMO specialist staffing should be adequate to provide up to 48 hours of care for one patient on ECMO.

Other clinical staffing requirements should align with the site's level of capability in the relevant clinical capability framework documents.

#### 5.4.2 ECMO program

- Refers potential ECMO patients to the Victorian ECMO Service
- Ability to cannulate and initiate patients on ECMO and provide safe care for up to 48 hours while awaiting retrieval
- Provides and receives feedback to/from the Victorian ECMO Service when a patient is retrieved
- May contribute to ECMO retrieval service staffing
- Participates in statewide ECMO clinical education.

#### 5.5 ACCREDITATION REQUIREMENTS FOR INTERMEDIATE CENTRES

In addition to capability requirements and requirements for initiation sites.

Intermediate centres provide cannulation, initiation, maintenance, weaning, and post-separation care of ECMO patients from their own site and patients referred from elsewhere who do not require destination therapy.

#### 5.5.1 Hospital capability

Cardiac surgery services, including perfusion services, are required for advanced treatment options for patients on VA ECMO including:

- coronary artery bypass grafting
- left ventricular venting therapies
- repair of ischaemic complications for example ischaemic ventricular septal defect
- reconfiguration for medium term support for example subclavian cannulation to enable ambulation.

#### 5.5.2 Clinical staff

Staffing should be adequate to provide care for 20 or more patients per year and up to three patients simultaneously receiving ECMO including cannulation, initiation, maintenance, weaning, and post-separation care.

#### Intensive care nurses

Using a nursing model of bedside care, intensive care nurses provide care for patients receiving ECMO and are trained to manage ECMO circuit and pump as specialists.

Adequate nursing staff need to be trained to manage patients receiving ECMO support. The average length of ECMO support is around 10 days and therefore a patient requires care over the course of 20 twelve-hour nursing shifts. A roster of at least 10-12 intensive care nurse ECMO specialists as well as additional support staff is required to manage each patient on ECMO.

Intermediate centres with capacity to manage 20 to 30 patients per year and up to three patients simultaneously, should credential and be able to maintain at least 40 nursing staff fulltime positions at the ECMO specialist level.

#### **Perfusionists**

Perfusionists, if not participating in the bedside care model in the specialist role, play an important role at ECMO centres. They should be on-call to offer advice and assistance as required.

The role of the perfusionist may include:

- selecting suitable equipment and consumables for individual patients and the ECMO program
- consulting on the management and troubleshooting of ECMO circuits
- training of other clinical staff
- participation in retrieval teams or intra-hospital transfers
- cannulation of ECMO patients
- weaning and decannulating ECMO patients including in the operating theatre for VA ECMO patients.

#### Junior medical staff

Staffing of registrars or fellow level medical staff trained to assist in the management of emergency ECMO scenarios should be adequate to support emergency care while awaiting arrival of on-call medical ECMO specialists.

#### **Cardiac surgery services**

Cardiac surgery and cardiac anaesthetic staff with transoesophageal echocardiography skills are required to safely wean and decannulate patients from VA ECMO in theatre.

#### Social work services

Social work services are essential to assist patients and families with emotional support and unfamiliar processes such as travel, parking, accommodation and unplanned management of the patient's personal affairs. Social workers were highlighted as a vital part of a site's ECMO program staffing by consumers.

Patients will be transferred to comprehensive and intermediate centres for ECMO care. Family members will be displaced and under significant emotional stress. Formal family meetings are considered helpful in this context and should be encouraged to ensure that consistent information is shared with the family.

Social workers involved in the ECMO program must have a basic understanding of ECMO and awareness of the family situation.

#### Allied health

ECMO patients require specific assessment, planned and tailored care and monitoring from allied health clinicians. This requires a considerable investment of experienced critical care allied health clinicians trained in caring for ECMO patients. Specific disciplines that should be involved in the clinical care of ECMO patients are:

- pharmacists
- physiotherapists
- dieticians
- radiographers
- occupational therapists.

#### 5.5.3 ECMO program

- Ability to initiate, maintain and wean patients from all forms of ECMO (VA, VV and ECPR)
- Ability to manage more than 20 patients per year and up to three patients simultaneously
- Accepts retrievals from other hospitals of patients who do not require destination therapies
- Refers complex patients or those requiring destination therapies to comprehensive centre
- Coordinates patient follow-up and feedback for own patient cohort
- Contributes to ECMO retrieval service staffing
- May contribute to ECMO advice specialist staffing
- Contributes to statewide ECMO clinical education, for example:
  - hosting statewide case review or morbidity and mortality meetings
  - teaching at training courses for other institutions such as competency training at initiation sites

#### 5.6 ACCREDITATION REQUIREMENTS FOR COMPREHENSIVE CENTRES

In addition to capability requirements and requirements for initiation sites and intermediate centres.

#### 5.6.1 Hospital capability

- Adult heart failure and cardiac transplant medicine services
- Long term mechanical cardiac support services (ventricular assist device service)

- Pulmonary hypertension service
- Adult heart lung transplant surgical service.

#### 5.6.2 Clinical staff

Staffing should be adequate to provide care for more than 30 patients per year and up to ten patients simultaneously receiving ECMO including cannulation, initiation, maintenance, weaning, and post-separation care.

#### Intensive care nurses

Adequate numbers of nurses need to be trained to manage patients receiving ECMO support. The average length of ECMO support is around 10 days and therefore a patient requires care over the course of 20 twelve-hour nursing shifts. A roster of at least 10-12 intensive care nurse ECMO specialists as well as additional support staff is required to manage each patient on ECMO.

A comprehensive centre with capacity to manage up to ten patients simultaneously, should credential and be able to maintain at least 120 fulltime nursing positions at the ECMO specialist level.

# 5.6.3 ECMO program

- Ability to initiate, maintain and wean patients from all forms of ECMO (VA, VV and ECPR)
- Ability to manage failure-to-wean patients who require destination therapies
- Ability to manage more than 30 patients per year and up to ten patients simultaneously
- Accepts patients retrieved from all other hospitals including complex patients from intermediate centres
- Accepts patients destined for transplantation
- Coordinates patient follow-up and feedback for own patient cohort
- Contributes to ECMO retrieval service staffing
- Contributes to ECMO Advice Specialist staffing
- Coordinates statewide FCMO clinical education.
- Supports other sites to achieve accreditation.

#### 5.7 HOSPITAL ACCREDITATION CHECKLIST

Table 17: Requirements for all ECMO accredited sites comprehensive centre. This includes staffing requirements, hospital capability and equipment needed.

	Yes	No	Work required	Comments
Hospital clinical capability				
Coronary angiography suite and high-volume interventional angiography service				

and emergency STEMI management capability available 24/7		
Operating theatre and surgical services with vascular capability		
Intensive care unit with CICM fellow exclusive on-call within 30min response time 24/7		
Emergency department with 24hr ACEM fellow exclusive on-call within 30min response time 24/7		
Clinical support services capability		
Blood bank and pathology 24/7		
Ultrasound capable critical care clinicians available 24/7		
Echocardiography and reporting 24/7		
Radiology and reporting 24/7		
Telehealth facilities available		
Clinical staff		
ECMO program director		
ECMO coordinator		
ECMO specialists		
ECMO lead – x1 on-call 24/7		
ECMO cannulators - x2 on-call 24/7		
Bedside care model		
Appropriate care model in use		
Equipment		
Aligned with statewide service and available immediately onsite		
Minimum two ECMO pumps		
Adequate and associated consumables		
Ultrasound for vascular access and echocardiography		
Mechanical CPR device (if providing ECPR)		
Activation and escalation		
Escalation to ECMO lead system		

ECMO team activation system						
Quality assurance and improvement						
Data collection and reporting						
Case reviews						
Special interest group						
Governance committee						
Education provision and maintenance						
Guideline and policy maintenance						
Equipment management collaboration						

# Table 18: Additional requirements for Initiation centres

# In addition to capability requirements for all accredited sites (Table 17).

	Yes	No	Work required	Comments
Clinical staff				
ECMO specialist staffing adequate to provide care for up to 48hrs				
ECMO program				
Refers potential ECMO patients				
Ability to cannulate and initiate ECMO and provide safe care for up to 48 hours				
Provides and receives feedback when an ECMO patient is transferred				
Contributes to ECMO retrieval staffing (desirable longer term)				
Participates in statewide ECMO education				

# Table 19: Additional requirements for Intermediate centres

# In addition to capability requirements (Table 17) and initiation site requirements (Table 18).

	Yes	No	Work required	Comments
Hospital capability				
Cardiac surgery services				

Clinical staff		
Staffing adequate to care for 20+ ECMO patients per year and up to 3 ECMO patients simultaneously		
Credential and maintain at least 40 nurse ECMO specialists		
Perfusionists		
Junior medical staff		
Cardiac surgery services		
Social work services		
Allied health including pharmacists, physiotherapists, dieticians, radiographers and occupational therapists		
ECMO program		
Ability to initiate, maintain and wean patients from all forms of ECMO (VA, VV and ECPR)		
Ability to manage 20+ ECMO patients per year and up to 3 ECMO patients simultaneously		
Accepts ECMO retrievals		
Refers complex ECMO patients or those requiring destination therapy to comprehensive centre		
Coordinates patient follow up and feedback		
Contributes to ECMO retrieval service staffing		
Contributes to ECMO advice specialist staffing (desirable longer term)		
Contribution to statewide education		

# Table 20: Additional requirements for Comprehensive centres

In addition to capability requirements (Table 17) and requirements for initiation sites (Table 18) and intermediate centres (Table 19).

	Yes	No	Work required	Comments
Hospital capability				
Adult heart failure and cardiac transplant medicine services				
Long term mechanical cardiac support services (VAD)				
Pulmonary hypertension service				
Adult heart lung transplant surgical service				
Clinical staff				
Staffing adequate to care for 30+ ECMO patients per year and up to 10 ECMO patients simultaneously				
Credential and maintain at least 120 nurse ECMO Specialists				
ECMO program				
Ability to initiate, maintain and wean patients from all forms of ECMO (VA, VV and ECPR)				
Ability to manage ECMO patients who require destination therapy				
Ability to manage 30+ ECMO patients per year and up to 10 ECMO patients simultaneously				
Accepts ECMO retrievals				
Accept patients destined for transplantation				
Coordinates patient follow up and feedback				
Contributes to ECMO retrieval service staffing				
Contributes to ECMO Advice specialist staffing				

Coordinates statewide education		
Supports other sites to be accredited		

# **Appendix 6: Clinical credentialing**

This section covers the credentialing requirements for staff participating in the Victorian ECMO Service. We've detailed what's required for specific roles within the service, including specialists, cannulators, perfusionists, surgeons and coordination and retrieval teams.

#### 6.1 GENERAL CREDENTIALING FOR ALL ECMO CLINICAL STAFF

Each ECMO accredited site should have a well-defined program for staff training, credentialing and recredentialing.

All clinical staff providing clinical care to ECMO patients should attend the introductory sections of this training program (Appendix 7), at a minimum.

Staff members planning on undertaking a defined role in the local ECMO program, for example ECMO specialist or cannulator, should undertake the entire training program and be credentialed.

#### **6.2 HOSPITAL BASED CREDENTIALING PROGRAM**

Hospitals participating in the Victorian ECMO Service will need to develop scope of practice guidelines and will be responsible for credentialing local staff members.

The ECMO program director and coordinator are responsible for ensuring all staff members caring for patients on ECMO have met the minimum credentialing standards. This requires documentation of initial competencies being met as well as ongoing competency requirements for each two-year recredentialing cycle.



See example at 6.5.1.

Hospital ECMO programs require a process for selecting staff members to train as specialists. The program director and coordinator should ensure that enough staff are credentialed to meet the service requirements, at all times.

Developing a centralised credentialing record should be considered as part of the implementation of the Victorian ECMO Service. A state register or a passport for individual clinicians would assist mutual recognition of credentialing between services and increase mobility of a highly skilled workforce across the state. This record would not replace the need for local orientation.

#### **6.3 SPECIFIC CREDENTIALING REQUIREMENTS**

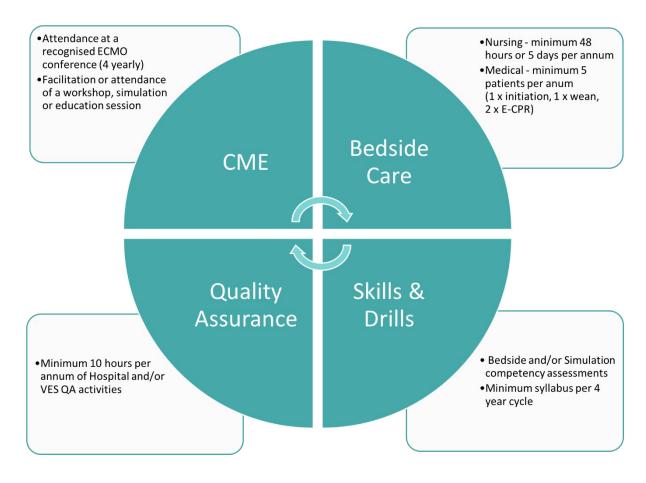
#### 6.3.1 ECMO specialist

There is currently no national or international minimum standard or benchmark for credentialing an ECMO specialist. ELSO recommends having a well-defined program for specialists including didactic teaching, laboratory training with equipment, bedside training, and testing proficiency of all team members. Documenting routine education and emergency training is also recommended.

The Victorian ECMO Service initial credentialing requirement for an ECMO specialist will include (Diagram 2):

- Attendance at an introductory ECMO course (Section 7)
  - This course should be delivered by a service with ELSO excellence pathway recognition
- Hospital based ECMO training program
  - equipment orientation
  - laboratory / simulation training
  - bedside training
- Proficiency testing
  - knowledge and skills assessment
- Sign off by the ECMO program director

#### Diagram 2: ECMO staff credentialing diagram



Re-credentialing will occur on a two-yearly basis. Components of re-credentialing will include:

- bedside care (minimum hours required)
- skills, drills and simulation

- participation in hospital quality assurance program
- ECMO based CPD
- proficiency assessment.

A traffic light system of re-credentialing should be developed and maintained at each ECMO accredited site. Monitoring of re-credentialing requirements will be performed by the ECMO coordinator on an ongoing basis.

- Green ECMO Bedside care recency < three months => continue to complete modules as per the two-yearly cycle requirements outlined below
- Yellow ECMO Bedside care recency > three months => proceed to skills and drills modules
- Red ECMO Bedside care recency > one year => proceed to initial credentialing requirements

ECMO specialists at initiation sites may have limited opportunity to provide bedside care and will require other education experiences, as part of the hospital ECMO credentialing program. This experience is likely to involve more frequent simulation and drill based training.

#### **Bedside** care

Participate in a minimum number of episodes of care of ECMO patients. This should include:

- days or hours of direct patient care
- multidisciplinary bedside 'ECMO rounds'
- bedside ECMO competency assessments

#### In addition:

- Nursing staff are required to manage patients on ECMO for a minimum of 48 hours, or five shifts, per annum
  - for education staff this may be hours spent performing competency assessments
  - for associate nurse managers this may include five shifts with ECMO patients in the unit per year
- Medical staff are required to participate in the management of a minimum of five patients per year.
  - for ICU consultants, this should include at least one ECMO initiation (all sites) and weaning at least one patient from ECMO (comprehensive and intermediate centres) per annum.

ECMO specialists at initiation sites may not be exposed to five shifts or five patients in a calendar year. They should however have the opportunity to participate in the quality assurance program to review every case as a team. They will also have the opportunity to participate in statewide case reviews, mortality and morbidity and special interest meetings hosted via a videoconferencing system.

For hospitals with an E-CPR program, ECMO specialists should also participate in at least two E-CPR scenarios. This could occur either with actual patients or in a multidisciplinary simulation scenario.

#### Skills, drills and simulation

Participate in a combination of bedside, wet-lab and simulation sessions will form an important component of credentialing and re-credentialing (Appendix 7).

Training components will include:

- routine care procedures and scenarios
- troubleshooting drills
- emergency scenarios
- E-CPR (if part of the hospital ECMO program).

Routine care scenarios are at the discretion of the hospital and may differ depending on tier of service provided.

For the purposes of credentialing and recredentialing:

- All troubleshooting drills, emergency scenarios and E-CPR scenarios (if part of the hospital ECMO program) should be covered in initial credentialing of every ECMO specialist and again across two two-year recredentialing periods.
- At least two emergency scenarios and one of each VA and VV troubleshooting scenarios should be assessed, per year.
- ECMO specialists involved in priming of ECMO circuits are required to undergo yearly credentialing
  in priming at least one ECMO circuit. If more than one type of ECMO machine is used by a hospital
  for example cardiohelp and rotaflow circuits, priming of at least one ECMO circuit for each
  platform is required.

## **Quality assurance**

- Participate in hospital or statewide ECMO quality activities, including:
  - case reviews
  - morbidity and mortality meetings
  - service performance review meetings and clinical audits
  - ECMO special interest group meetings
- Participate in hospital or Victorian ECMO Service competency assessment of other staff
  - assessor for bedside or simulation-based skills and drills.

# **Continuing Professional Development (CPD)**

- Attending an ECMO conference (ELSO, EuroELSO, APELSO) or the ECMO component of an ICU conference (CICM ASM, ANZICS ASM, ESICM) every four years is recommended
- Attend or facilitate an ECMO teaching session, workshop or simulation. This could include in-house education programs or participating in national or international conference or workshop sessions.

#### **Competency assessment**

Competency assessment programs will be developed by the ECMO program director and ECMO coordinator at a hospital ECMO program level. Assessment should include:

- theoretical knowledge: multiple choice questionnaire or oral assessments
- patient and circuit management: bedside assessments
- troubleshooting: bedside assessments
- practical skills: wet-lab or simulation-based assessments

See section 6.4 for a credentialing and recredentialing checklist for ECMO specialists.

See section 6.5 for an example of a nurse ECMO specialist credentialing program and job description.

#### 6.3.2 ECMO cannulators

Many different clinicians will have the opportunity to develop the skills required to cannulate ECMO patients, including intensivists, cardiologists, cardiac or vascular surgeons, emergency physicians, anaesthetists or interventional radiologists.

ECMO cannulators do not necessarily require credentialing as an ECMO specialist, if cannula placement is their only role as part of the ECMO program.

ECMO cannulators should attend a specifically designed ECMO cannulation course which includes practical as well as theoretical components.

Re-credentialing will be required on a two-yearly basis. ECMO cannulators will need to have peripherally cannulated at least five patients over the course of a year.

Cannulators unlikely to meet this target should make alternate arrangements, such as cannulation in theatre for cardiothoracic cases, sessions in an animal lab or simulation. Inability to meet this requirement will require re-credentialing at a cannulation course.

#### 6.3.3 Perfusionists

Perfusionists working in all ECMO accredited sites need to meet the same credentialing and recredentialing requirements for the ECMO specialist. The Australian and New Zealand College of Perfusion (ANZCP) make specific recommendations about certification and experience.

Perfusion is a science-based profession. The ANZCP education board, The Australasian Board of Cardiovascular Perfusion provides a two-year post graduate program of education and theory, with an emphasis on clinical experience for students to expose them to all aspects of cardiac surgery and its associated areas.

In addition to a two-year postgraduate education program, all perfusionists who are certified by the ANZCP receive an 11-week structured course specifically on ECMO, both adult and paediatric, and ventricular assist devices. Their training includes visiting an ECMO centre to learn about this modality of life support.

Perfusionists are trained to manage all areas of bypass and do this on a daily basis. However, ECMO comes with a different set of complications that should be considered separately when setting up an ECMO program. Experience is the key to a successful outcome and a perfusionist wishing to become an ECMO specialist should seek further learning and experience from an established program.

The ANZCP recommends that perfusionists wanting to get involved in an ECMO program must:

- be ANZCP or Australasian Board of Cardiovascular Perfusion certified or equivalent
- actively participate in ANZCP or equivalent CPD program.
- attend an ECMO training course in addition to ANZCP training.
- attend an ELSO or ECMO based conference or visit a large ECMO centre.

ANZCP recommends that all perfusionists currently involved in an ECMO program:

- must have a minimum of 10 contact hours with ECMO patients per year
- must periodically attend a conference with significant ECMO content
- should participate in hospital ECMO programs, including meetings and simulations.

ANZCP members have access to an additional online certification on extracorporeal life support for those wanting to refresh their knowledge and skills, to meet the ECMO program ongoing certification requirement.

#### 6.3.4 Surgeons

Vascular or cardiothoracic surgeons participate in ECMO programs. Depending on their role in the program they must be credentialed at either the ECMO cannulator or ECMO specialist level. They need to meet the same credentialing and re-credentialing requirements for these roles.

#### Cannulation

All surgeons intending to perform ECMO cannulation must:

- be a fellow of the Royal Australasian College of Surgeons
- have valid AHPRA registration in both general and relevant specialist categories
- have an appropriate on-call system to ensure availability 24 hours a day, seven days a week for cannulation related issues and complications

Surgical ECMO specialists involved in an ECMO program should attend an ELSO or ECMO based conference annually

All surgeons who perform **percutaneous** cannulation should meet the credentialing requirements for ECMO cannulators. This includes attending an ECMO cannulation course.

Non-cardiothoracic surgeons must meet accredited cannulation and attend an ECMO training course Cardiothoracic surgeons wishing to attempt percutaneous cannulation should complete the requirements at an ECMO specific percutaneous cannulation course.

All practicing cardiothoracic surgeons are automatically credentialed to perform open cannulation as per usual practice in their institution

For re-credentialing:

- surgeons should attend in-house cannulation simulation once every second year
- a log of all patients cannulated should be kept by the individual surgeon
- all results should be audited within an approved in-hospital morbidity and mortality forum annually.

#### **ECMO** specialist

Surgeons involved in decision making for ECMO initiation, bedside care and weaning must meet the credentialing and re-credentialing requirement for an ECMO specialist.

In addition they must:

- maintain an up to date knowledge of guidelines regarding eligibility and stop criteria
- maintain an up to date understanding of complications and management
- maintain an appreciation of suitability to wean or transition off ECMO
- work collaboratively with intensivists and other specialties to initiate weaning or transition and manage complications
- ensure any decision to wean is met with agreement of at least one other consultant ECMO specialist.

#### 6.3.5 Coordination and retrieval team

In addition to ECMO training and credentialing, coordination and retrieval team members will need to be credentialed by Ambulance Victoria. This involves online training packages related to retrieval platform orientation, lines of communication and specific role delineation.

#### **ECMO** advice specialist

To participate in the coordination of the Victorian ECMO Service the advice specialist requires a significant amount of ECMO experience. Given the time critical nature of the decisions and the last resort nature of ECMO support, it is vital that clinical expertise can be provided quickly. In addition, many of the referrals are complex, so it is important that the ECMO advice specialist works in an environment where they have access to support from colleagues if needed.

Credentialing criteria for an ECMO advice specialist will include:

- Fellow of College of Intensive Care Medicine with current and regular involvement in ECMO case management
- credentialed as an ECMO specialist
- significant ECMO experience (more than five years) including cannulation, initiation, management and weaning.

• working in a comprehensive or intermediate ECMO centre.

# **6.4 CREDENTIALING CHECKLIST: ECMO SPECIALIST**

# 6.4.1 ECMO specialist

Component	Met	Not met	Work required	Comments
Introductory ECMO course				
Hospital based ECMO training program				
Proficiency testing including at least two scenarios and one of each VA and VV troubleshooting scenarios				
Signed off by ECMO program director				

# **6.4.2 Recredentialing ECMO specialist**

Component	Met	Not met	Work required	Comments
Bedside care				
Participated in a minimum number of 'episodes' of care of ECMO patients				
<ul> <li>Nursing / Perfusion: minimum of 48 hours or 5 days per annum</li> </ul>				
<ul> <li>Medical / Surgeon: minimum of 5 patients per year</li> </ul>				
Skills, drills and simulation				
Completed hospital based ongoing training / simulation program including				
Minimum 2 emergency scenarios and 1 each of VV and VA trouble shooting scenarios each year				
ECMO specialists involved in priming of circuits: Prime at least 1 ECMO circuit for each type of platform in use				
Quality activities				

Participated in hospital or statewide quality activities		
Participated in hospital or statewide competency assessment of other staff		
Continuing professional development		
Attended an ECMO conference or the ECMO component of an ICU conference every 4 years (recommended)		
Attended, or facilitated an ECMO teaching session, workshop or simulation.		
Competency assessment		
Demonstrated competency in theoretical knowledge, daily management, troubleshooting and practical skills		

# 6.5 TRAINING AND SELECTION CRITERIA FOR NURSE ECMO SPECIALIST

# 6.5.1 Training process example from Barwon Health

	Training	Competency	Clincal Hours	Optional/ Recommended
New ICU ECMO Nurse	2 day ECMO course  Local/External provider  ECPR training  Local	ECMO emergency procedures skill Ax ECMO bedside skill Ax	24 hours supernummerary	
ECMO CCRN	4 hour ECMO update session (annual)	ECMO emergency procedures skill Ax (annual) ECMO bedside skill Ax (annual)	Minimum 48hours (annual)	External Courses ECMO Conferences Multidisiplinary SIMS ECMO SIG member
ECMO Assessors	External courses ECMO Conferences		Minimum 48 hours (annual) Including teaching hours	ECMO Management Committee member

<sup>\*</sup>A log of experience is maintained for each ECMO RN in the ICU competency folder

## 6.5.2 Selection criteria example from Barwon Health

# Selection Criteria for ECMO Nurse



#### Selection process

Expression of interest along with a paragraph on why you want the opportunity of training in ECMO to the key stakeholders (NUM, Nurse Educators and ANUMs).

Staff must meet the selection criteria as described below.

#### Selection Criteria

- · Clinical Nurse Specialist
- Minimum of rostered 48 hours per fortnight
- Critical Care qualification
- · One year of clinical experience post completion of an ICU qualification
- Sound decision-making skills
- Well-developed communication skills
- Ability to manage and take control in an emergency
- Demonstrated sound preceptorship skills
- Demonstrated advanced clinical and patient assessment skills
- Demonstrated willingness to undertake further education opportunities and involvement with change processes
- Leadership capabilities
- Competent in
  - o Advanced ventilation
  - o Pacemaker management
  - o Haemofiltration
  - o Management of the post-operative surgical cardiac patient
  - Current Advanced life support certification
  - o Transport of the critically ill patients

#### Performance Indicators

Performance will be assessed 6monthly to ensure staff are meeting the performance indictors to fulfil the role. A register of ECMO competent staff will be kept and if performance indicators are not met, the person will cease to be on the ECMO register. The following are mandatory to have continued involvement with the Collaborative ECMO service

- Must continue minimum 48 hours rostered per fortnight
- · Preceptor and foster staff who wish to undertake this role
- Maintain ALS competency
- Meet the annual education and training requirements as per the ECMO Nursing competence and training plan

# **Appendix 7: Statewide training program**

This section outlines our plan for a coordinated statewide approach to training for the Victorian ECMO Service. We've covered introductory courses, hospital based training, troubleshooting, emergency and simulation training.

#### 7.1 CURRICULUM OVERVIEW

Several levels of training are required for staff working in an ECMO program. Staff may participate in the care of patients on ECMO support (e.g. social workers, ward support), may cannulate patients (e.g. cardiothoracic surgeons) or may be involved in the selection, management and weaning components of care (e.g. critical care nurse, perfusionist, ICU consultant).

A training curriculum should have components that address the needs of all personnel working with patients on ECMO. ELSO has developed documents outlining training requirements for ECMO specialists at both new ECMO centres and those with established programs.

All ECMO accredited sites participating in the Victorian ECMO Service should develop a training and credentialing program for the development of ECMO specialists. Staff members who are not on a pathway to the ECMO specialist role, for example medical or surgical trainees, should be encouraged to participate in components of this program to optimise patient care.

The curriculum for ECMO specialists working at accredited hospitals participating in the Victorian ECMO Service will include:

- an introductory ECMO course
- an ECMO cannulation course (all ECMO cannulators)
- hospital based training program consisting of both didactic and practical components
- hospital based credentialing program with competency assessment overseen by the ECMO program director
- re-credentialing process overseen by the ECMO program director.

# 7.2 INTRODUCTORY ECMO COURSE

A number of introductory ECMO courses exist in Australia and internationally. This course should be delivered by a service with ELSO excellence pathway recognition.

An introductory course should include both didactic and practical components and cover:

- support modalities and physiology: VA and VV ECMO
- patient selection
- equipment orientation
- cannulation procedures
- coagulation management
- patient complications

emergency procedures.

#### 7.3 ECMO CANNULATION COURSE

All staff members participating in ECMO cannulations are required to attend a specifically designed ECMO cannulation course.

This course will cover:

- percutaneous approaches
- cannula selection
- circuit configuration and connections
- circuit priming
- vessel assessment
- ultrasound guidance of vascular access
- serial dilatation
- cannula placement including guided positioning
- cannula securement
- troubleshooting.

#### 7.4 HOSPITAL BASED TRAINING PROGRAM

A hospital-based training program needs to encompass all aspects of patient management to ensure the development of competent ECMO specialists.

The program should include didactic components as well as practical or 'wet-lab' training. Simulation with multidisciplinary teams is a highly effective way to practice emergency drills.

# 7.4.1 Theoretical teaching

Should include topics on:

- physiology
  - oxygen content and delivery
  - membrane gas exchange
  - haemodynamic support
- support modalities
  - VV and VA ECMO
- equipment orientation
  - ECMO consoles
  - Oxygenators
  - cannulas

- circuit components
- patient selection
  - benefit to the patient
  - diseases managed on ECMO
  - inclusion and exclusion criteria
  - timing of ECMO support
  - destination therapies
- daily patient management
  - coagulation and haematology parameters
  - fluid, electrolytes and nutrition.
  - ventilator settings and respiratory support
  - cardiac support
  - infection control
  - analgesia and sedation
  - neurologic assessment
  - psychosocial support
  - pressure care and turning
- daily circuit management
  - pump and gas flow
  - pressure monitoring
  - circuit checks
  - haemofiltration
  - aseptic technique
  - cannulation site monitoring
- patient complications and management on ECMO
  - bleeding
  - pneumothorax
  - stroke / intracranial bleed
  - cardiac arrest / arrhythmias
  - hypotension
  - hypoxia
- weaning from ECMO
  - timing
  - assessments

- weaning techniques VV and VA ECMO

### 7.4.2 Practical teaching

Education sessions should include practical training on procedures required to manage ECMO patients:

- circuit priming
- underwater seals
- cannula securing
- ECMO initiation procedure
- accessing the circuit (blood sampling, connecting haemofilter)
- decannulation (VV ECMO)
- turning ECMO patients
- transport on ECMO.

### 7.5 TROUBLESHOOTING, EMERGENCY AND SIMULATION TRAINING

Many emergency situations can arise when managing patients on ECMO. It's important to be able to recognise these situations and re-establish effective support.

You will need to continually train for these scenarios in order to be competent in management strategies. Specific troubleshooting and emergency scenarios should be included in initial and ongoing training. Emergency management is probably best taught in a simulated environment with the multidisciplinary team who will manage actual patient scenarios.

### Troubleshooting scenarios for hospital based ECMO training programs

- General
  - haemolysis
- VV ECMO
  - refractory hypoxia including recirculation
  - hypotension including recognition of right ventricular failure and cardiogenic shock
- VA ECMO
  - hypoxia including differential hypoxia
  - hypotension

#### Emergency scenarios for hospital based ECMO training programs

- Console power failure including hand cranking
- Oxygenator failure and circuit thrombosis
- Emergency circuit change
- Acute hypoxia

- Acute hypotension
- Access insufficiency
- Circuit rupture
- Accidental decannulation
- Air entrainment / embolism
- Sig alarm
- Cardiac arrest
- ECPR if part of hospital ECMO program including mechanical CPR device management.

# **Appendix 8: Testing pathways and criteria**

This section outlines our approach to testing different elements of the proposed Victorian ECMO Service including referral and retrieval pathways, clinical criteria and hospital accreditation requirements. These were tested in September and October 2019.

#### 8.1 RETRIEVAL COORDINATION

Detailed descriptions of the referral, retrieval and communications pathways (appendix 3) were tested with ARV who will play a central coordination role in the service.

The flowcharts underwent logic testing with ARV staff on site at the coordination centre. We determined that all components of the flowcharts were in the right order and the proposed communication pathways including teleconferencing were already current practice. The proposed timings for decision making were also considered appropriate.

#### **8.2 CLINICAL CRITIERIA FOR ECMO**

Our patient eligibility criteria for ECMO, including decision-making tools (appendix 4) were tested at The Alfred. As the comprehensive ECMO centre they will continue their current role of providing ECMO advice specialists for the service.

Clinical criteria and decision tools were tested in parallel to current decision-making practices during live referrals to The Alfred. A single ECMO advice specialist reviewed eight patients referred to The Alfred over ten days. In all but one case the same decision would have been made using the criteria that was made by the ECMO advice specialists at The Alfred. The patient did not survive in the case where the actual decision to initiate ECMO would have been in breach of the proposed criteria. This patient was considered for ECPR and breached the age criteria.

# **8.3 HOSPITAL ACCREDITATION**

We tested the requirements for hospital accreditation and related checklists (appendix 5) with The Alfred and Barwon Health.

The Alfred ECMO coordinator and an ECMO lead reviewed their current service against the accreditation requirements for a comprehensive centre. While Barwon Health ECMO coordinator and an ECMO lead reviewed their current service against the accreditation requirements for an intermediate site.

Both sites were able to meet the requirements. Usability was high with comments relating mainly to terminology and this feedback was used to refine the checklists.

# **Abbreviations**

**ABG** Arterial blood gas

**ACEM** Australasian College for Emergency Medicine

**AHPRA** Australian Health Practitioner Regulation Agency

**ANZCP** Australian and New Zealand College of Perfusionists

Australian and New Zealand Intensive Care Society **ANZICS** 

**APTT** Activated partial thromboplastin time

**ARDS** Acute respiratory distress syndrome

ARV Adult Retrieval Victoria

**AST** Aspartate aminotransferase

AVAmbulance Victoria

Body mass index BMI

BP Blood pressure

С Compliance

CICM College of Intensive Care Medicine

CKD Chronic kidney disease

CPD Continuing Professional Development

CNS Central nervous system

CO2 Carbon dioxide

COPD Chronic Obstructive Pulmonary Disease

**CPR** Cardiopulmonary resuscitation

CXR Chest x-ray

DBP Diastolic blood pressure

**ECG** electrocardiogram

**ECMO** Extracorporeal membrane oxygenation

**ECPR** Extracorporeal cardiopulmonary resuscitation

**ELSO** Extracorporeal Life Support Organization

**ESICM** European Society of Intensive Care Medicine EuroSCORE European System for Cardiac Operative Risk Evaluation

FBE Full blood examination

FEV1 Forced expiratory volume in 1 second

FiO2 Fraction of inspired oxygen

GFR Glomerular Filtration Rate

GOLD Global Initiative for Chronic Obstructive Lung Disease

H20 Water

ICU Intensive care unit

INR International normalised ratio

LFT Liver function tests

LV Left ventricle

LVAD Left ventricular assist device

LVEF Left ventricular ejection fraction

LVOT Left ventricular outflow tract

MTDM Medical Treatment Decision Maker

NYHA New York Heart Association

OHCA Out-of-hospital cardiac arrest:

PaCO2 Partial pressure carbon dioxide

PCI Percutaneous Coronary Intervention

PCS Post cardiotomy shock

PEEP Positive end expiratory pressure

PF Ratio of arterial oxygen partial pressure to fractional inspired oxygen

pH Hydrogen ion concentration

REACH Retrieval and Critical Health

RESP Respiratory Extracorporeal Membrane Oxygenation Survival Prediction

SAVE Survival After Venoarterial ECMO

SBP Systolic blood pressure

SCV Safer Care Victoria

SOFA Sequential Organ Failure Assessment

SpO2 Oxygen saturation of arterial blood

STS Society of Thoracic Surgery

TBI Traumatic brain injury

UEC Urea and electrolytes

VA Venoarterial

VAD Ventricular Assists Device

VAED Victorian Admitted Episodes Dataset

Vt Volume tidal

VV Venovenous

# References

#### Abrams et al. (2018)

Position paper for the organization of ECMO programs for cardiac failure in adults. Intensive Care Med. 2018 Jun;44(6):717-729.

#### **Adult Retrieval Victoria (2017)**

ARV Reference Manual. <a href="https://www.ambulance.vic.gov.au/about-us/our-services/adult-retrieval-victoria/#resources">https://www.ambulance.vic.gov.au/about-us/our-services/adult-retrieval-victoria/#resources</a>

#### Australian Commission on Safety and Quality in Health Care (2018)

Australian Hospital Patient Experience Question Set: <a href="https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/australian-hospital-patient-experience-question-set">https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/australian-hospital-patient-experience-question-set</a>

#### **BMJ best practice (2019)**

Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria: https://bestpractice.bmj.com/topics/en-us/7/criteria

#### Brechot et al. (2013)

Venoarterial extracorporeal membrane oxygenation support for refractory cardiovascular dysfunction during severe bacterial septic shock. Crit Care Med 41, 1616-1626.

#### Broman et al. (2019)

The ELSO Maastricht Treaty for ECLS Nomenclature: abbreviations for cannulation configuration in extracorporeal life support - a position paper of the Extracorporeal Life Support Organization. Crit Care. 2019 Feb 8;23(1):36. doi: 10.1186/s13054-019-2334-8.

### Cardiac Society of Australia and New Zealand (2016)

Guidelines on support facilities for coronary angiography and percutaneous coronary intervention. https://www.csanz.edu.au/resources/

#### Combes et al. (2014)

A Position paper for the organization of extracorporeal membrane oxygenation programs for acute respiratory failure in adult patients. Am J Respir Crit Care Med. 2014 Sep 1;190(5):488-96.

#### Combes et al. (2018)

Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Distress Syndrome. N Engl J Med. 2018 May 24;378(21):1965-1975

#### **Extracorporeal Life Support Organization (ELSO)**

(2010) ELSO guidelines for training and continuing education of ECMO specialists.

(2013): Guidelines for ECPR Cases.

(2013): Guidelines for Adult Cardiac Failure.

(2014): ELSO guidelines for ECMO Centres

(2017): General Guidelines for all ECLS Cases

(2017): Guidelines for Adult Respiratory Failure. https://www.elso.org/Resources/Guidelines.aspx

#### Falk et al. (2019)

Extracorporeal Membrane Oxygenation for Septic Shock. Crit Care Med. 2019 Aug;47(8):1097-1105

New Zealand Ministry of Health: Service model Extra Corporeal Membrane Oxygenation (ECMO) (2017) https://nsfl.health.govt.nz/national-services/service-models-consultation

#### **Ortuno et al. (2019)**

Weaning from veno-arterial extra-corporeal membrane oxygenation: which strategy to use? Ann Cardiothorac Surg. 2019;8(1):E1-E8.

#### Peek et al. (2009)

Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial. Lancet. 2009 Oct 17;374(9698):1351-63.

#### Riera et al. (2018)

Extracorporeal Membrane Oxygenation for Adults With Refractory Septic Shock. ASAIO J. 2018 Oct 10. doi: 10.1097/MAT.00000000000000905.

#### Schmidt et al. (2014)

Predicting survival after extracorporeal membrane oxygenation for severe acute respiratory failure. The Respiratory Extracorporeal Membrane Oxygenation Survival Prediction (RESP) score. Am J Respir Crit Care Med. 2014 Jun 1;189(11):1374-82.

(2015): Predicting survival after ECMO for refractory cardiogenic shock: the survival after veno-arterial-ECMO (SAVE)-score. Eur Heart J. 2015 Sep 1;36(33):2246-56.

#### Shaukat et al. (2018)

Outcomes of ECMO support for complex high-risk elective PCI: a single-center experience and review of the literature. J invasive cardiology 2018;30(12):456-460.

#### University of Wisconsin Hospitals and Clinics authority (2018)

Extracorporeal Membrane Oxygenation (ECMO): Initiation and Management – Adult – Inpatient – Clinical Practice Guideline. https://www.uwhealth.org/cckm/cpg/respiratory/related/

# Vogel et al. (2018) Veno-arterio-venous ECMO for septic cardiomyopathy: a single-centre experience. Perfusion. 2018 May;33(1\_suppl):57-64



