

## Service model

# Extra Corporeal Membrane Oxygenation (ECMO)

Prepared by:	Jane Potiki
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## Acknowledgements

The service model for Extra Corporeal Membrane Oxygenation, or ECMO, has been developed with consumers, family and whānau, as well as secondary care providers from a range of district health boards.

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Name	DHB/Organisation	Role
Debbie Minton	Counties Manukau	Nurse Manager, Critical Care Complex
Carl Horsley	Counties Manukau	Intensivist, Critical Care Complex
Mark Edwards	Auckland	Director, Cardiovascular Service
Andrew McKee	Auckland	Director, Cardiovascular Intensive Care
Sam Titchener	Auckland	General Manager, Cardiovascular Service
Craig Carr	Southern	Specialist, ICU
Ana Pickering		Consumer/Whānau
Alex Brown	Nelson Marlborough	Intensivist,
		Director, Surgery, CCTVS and Critical Care,
Kevin Harris	Waikato	Theatres
Pranesh Jogia	Waikato	Director, Cardiac Intensive Care
	Canterbury/West	
Ralph La Salle	Coast	Secondary Care Planning & Funding
David Closey	Canterbury	ICU consultant
Harsh Singh	Canterbury	Cardiothoracic surgeon
Kris Gagliardi	St John	National Patient Pathways Manager
Tess Moeke-Maxwell		Maori health academic

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## **Executive summary**

ECMO refers to the use of a portable modified heart-lung bypass machine to support patients whose hearts and/or lungs are failing. As such ECMO is a complex resource and infrastructure-intense modality. It is used to support organ function in a range of clinical conditions characterised by severe lung and / or circulatory failure, including support for lung transplant recipients with primary graft dysfunction in the first few days after lung transplant and after heart transplant to support heart function.

ECMO support may be veno-venous (VV) where cardiac function is adequate or mildly depressed. Veno-arterial (VA) support may be used if cardiac function is impaired and cardiac support is also required. The service requirements are the same for each type.

Auckland District Health Board (DHB) is the main provider of ECMO in New Zealand. Use of ECMO in adults is growing, in part because of increased solid organ transplant numbers. While cardiac centres in other DHBs are reportedly using VA ECMO national collection data shows only two such patients in recent years.

The adult ECMO Service is part of the Auckland DHB Cardiovascular Intensive Care Unit (CVICU) core service. Staff provide retrieval, assessment and treatment for adult patients. There are no formal referral pathways. The referral pathway is an informal one, where intensivists may contact Auckland DHB to discuss a patient, and a treatment plan will be determined.

#### **Objectives**

ECMO is a highly specialised and resource intensive input into the care of patients with complex medical conditions. Formal referral pathways will support appropriate and timely patient referral, and consistency in the use of ECMO.

An endorsed and implemented service model will improve the quality of patient care and outcomes, as well as ensuring resources are used wisely. There are six key objectives for the service model.

- 1. To have a clearly defined patient pathway to ensure patients who are clinically eligible for VV ECMO have, as far as clinically possible, equity of access to the service
- 2. To provide referrers and patients requiring ECMO within the CVICU at Auckland DHB with:
  - a. expert advice on the diagnosis and management of potentially reversible severe respiratory and/or cardiac failure, including collaboration with other tertiary providers where appropriate
  - b. a retrieval service for those patients that meet the criteria and are accepted for ECMO, including safe mobile ECMO
- 3. To support safe repatriation of patients to an appropriate hospital close to their home following ECMO
- 4. To improve patient outcomes through timely and appropriate referral to the ECMO service, as reported within the local clinical outcomes database and through submission of data to ELSO (Extracorporeal Life Support Organisation) and communicated nationally
- 5. Safe and high quality clinical care for all patients referred for ECMO
- 6. To provide cultural, as well as family and whānau support.

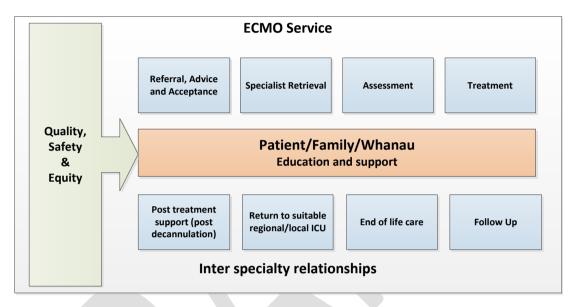
There is also an important relationship between the volume of ECMO provided in a centre and patient outcomes. ECMO is best performed when centralised to centres with a sufficient volume to develop expertise rather than being undertaken in small volume "occasional user" centres.

#### The Service Model

The ECMO service model is configured around provision of safe, high quality services to support referrers, patients and family/whānau. Elements of the service are:

- referral, retrieval, assessment and treatment
- post-treatment support, repatriation, end of life care and follow up.

Figure 1: The ECMO service model



A referral pathway has been developed for VV ECMO, with a complementary pathway for VA ECMO which may be provided in cardiac centres as a rescue procedure post cardiac surgery.

In addition to the technical expertise required for ECMO, patient and family/whānau support is important. Patients are critically ill, and families/whānau may be away from home for long periods. Families need both emotional and practical support during the treatment post treatment periods.

Intensivists referring patients for ECMO also need support so that referral to the ECMO Service is timely and appropriate, and so that patients can be safely repatriated once ECMO is discontinued.

Indicators of quality have been described to assess the clinical effectiveness of the ECMO Service, and further indicators will be developed to understand the patient and family/whānau experience, and the referrer experience.

A project group will be responsible for implementing the service model, with actions linked to achieving the six service objectives.

## **PART 1: Case for change**

#### **Background of ECMO in New Zealand**

#### What is ECMO?

ECMO refers to the use of a portable modified heart-lung bypass machine to support patients whose hearts and/or lungs are failing. As such ECMO is a complex resource and infrastructure-intense modality. It is used to support organ function in a range of clinical conditions characterised by severe lung and/or circulatory failure, including support for lung transplant recipients with primary graft dysfunction in the first few days after lung transplant and after heart transplant to support heart function.

ECMO is a form of support, rather than a treatment, for patients with severe, potentially reversible respiratory and/or cardiac failure. ECMO aims to maintain physiological homeostasis to allow organ recovery to occur. The duration of ECMO support is variable, depending on the recovery time of the patient (typically one to two weeks, although occasionally support extends beyond this time). If the patient has not recovered from their illness after a reasonable period of ECMO support, then ECMO should be stopped and the patient is unlikely to survive.

ECMO support may be VV where cardiac function is adequate or mildly depressed. VA support may be used if cardiac function is impaired and cardiac support is also required. The service requirements are the same for each type.

ECMO is used in adults for three main clinical indications:

- respiratory failure unable to be supported with conventional mechanical ventilation primarily patients with acute respiratory conditions (e.g. pneumonia)
- cardiac failure such as myocarditis or immediately after cardiac surgery for patients who are unable to maintain their circulation with medical therapy
- following heart or lung transplant if donor organ function is poor.

In some cases the requirement for ECMO following cardiac surgery can be anticipated and patients can be transferred to Auckland DHB for surgery, and ECMO if necessary.

Access for patients requiring VV ECMO for respiratory failure or VA ECMO for more uncommon conditions such as myocarditis is generally more varied. Referral is initiated by the treating intensivist at the domicile or regional DHB following patient deterioration on standard ventilation.

#### Incidence

In addition to patients with acute respiratory conditions, ECMO is also used for patients receiving heart or lung transplantation and following some cardiac surgery procedures.

National Collections data shows overall incidence of ECMO use at Auckland DHB has been relatively stable since 2012/13, but that there was an increase in adult ECMO in 2013/14 and in paediatric ECMO in 2015/16.

Table 1: Incidence of ECMO 2011/12 to 2015/16 at Auckland DHB

	2011/12	2012/13	2013/14	2014/15	2015/16
Adult	11	12	18	20	18
Transplant (adult)	2	4	5	4	7
Total adult	13	16	23	24	25
Paediatric	13	18	12	10	16
Transplant (paediatric)	О	1	О	1	1
Total paediatric	13	19	12	11	17
<b>Total ECMO at Auckland DHB</b>	26	35	35	35	41

Notes: extracted from the National Minimum Data Set (NMDS) September 2016, for Auckland DHB of service, publicly funded discharges with the ICD10 code: 9022500 - ECMO (VV and VA), for casemix included and excluded activity. Adult is classified as aged 16 years and over, in accordance with Auckland DHB's classification.

In addition to activity provided at Auckland DHB, there are a small number of other DHBs reporting use of ECMO. In total, there are 12 patients since 2011/12 with a non-Auckland DHB provider. Six of the 12 show a transfer either to or from Auckland DHB.

The other six cases show an admission where ECMO was included in the clinical codes for the admission, although only two of these are recent. In 2015 Southern and Waikato DHB reported use of ECMO for patients undergoing cardiac surgery. In general when it is known or anticipated that ECMO will be required in association with cardiac surgery the patient is likely to be referred to the Auckland cardiothoracic service for treatment.

#### **Current service configuration**

The Auckland DHB ECMO service started at the Green Lane hospital site where both adult and paediatric cases were cared for together by the Cardiothoracic Surgical Unit.

With the move to the Auckland City Hospital site in 2003 the service has been split between caring for adults (generally aged 16 and over) in the CVICU. Children (generally aged 15 and under) are cared for in Starship's Paediatric Intensive Care Unit (PICU). In general, patients receiving ECMO treatment have a long length of stay within the CVICU or the PICU, often impacting overall capacity within the units.

Nursing resource for ECMO has been shared to maximise training and support required to maintain skills in this specialised area. Caring for each ECMO patient requires two nurses, one for the patient and one for the ECMO circuit.

Because patients needing ECMO are highly complex, and are critically ill, Auckland DHB operates a national ECMO retrieval service. This involves specially trained medical and nursing staff travelling from Auckland City Hospital to the referring centre to retrieve the patient. Patients considered suitable for ECMO are likely to have ECMO commenced locally. This enables the patient to be safely transported to Auckland DHB on ECMO.

#### Referral pathways

There are currently no nationally agreed guidelines or protocols for referral. The referral pathway is an informal one, where intensivists may contact Auckland DHB to discuss a patient, and a treatment plan will be determined.

Since 2013/14 Auckland has provided ECMO for 58 adult patients, excluding transplant related ECMO. Thirty of these patients (52%) come from the Auckland metropolitan area. South Island and Midland Region DHBs have referred 10 patients each. The Central Region referred only four patients in the period, but there is open dialogue between the Capital and Coast DHB intensivists

and the Auckland ECMO provider, who support management of patients locally. A similar arrangement has been noted with Southern DHB, accounting for the low rate of referral from these two centres.

While adult patients are treated within the CVICU, they are discharged from a range of specialties, including cardiothoracic (50%), respiratory (21%), cardiology (16%) and one to two patients each from general medicine, general surgery, neurology, neurology, renal and paediatric cardiology.

Table 2: Current referral pathways for adult ECMO (non-transplant) 2013/14 - 2015/16

Region	DHB of patient domicile	People
Northern	Auckland	11
	Counties Manukau	6
	Northland	3
	Waitemata	11
Northern Total		31
Midland	Bay of Plenty	3
	Lakes	3
	Tairawhiti	1
	Taranaki	3
	Waikato	1
Midland Total		11
Central	Capital and Coast	3
	Hawkes Bay	1
Central Total		4
South Island	Canterbury	5
	South Canterbury	3
	Southern	1
South Island Total		9
Other	Overseas	1
National		56

Notes: extracted from NMDS September 2016. Extracted for Auckland DHB of service, publicly funded discharges with the ICD10 code: 9022500 (ECMO), for casemix included activity. Adult is classified as aged 16 years and over, in accordance with Auckland DHB's classification

#### **Funding**

With the exception of transplant patients, inpatient ECMO is funded by the DHB of patient domicile through casemix by Inter District Flow (IDF) arrangements. ECMO is within the Diagnostic Related Group (DRG) A4oZ.

Patient retrieval for ECMO is funded separately to the inpatient episode. Retrieval is governed by the inter-hospital transport rules and processes, with the transport funded by the DHB of patient domicile (refer to section 7.12 of the Operational Policy Framework (OPF)<sup>i</sup>, and section 6.7 of the National Travel Assistance (NTA) policy<sup>ii</sup>).

For the 18 adult ECMO patients at Auckland DHB funded through IDFs in 2015/16, the associated funding received by the service provider is identified below, along with the associated length of hospital stay. The length of stay in ICU and time on ECMO are not reported

Table 3: Caseweights, length of stay and funding - 2015/16

	Caseweights	Funding	Length of stay
Average	22.2	\$105,607	20
Median	23.3	\$110,945	15
Minimum	3.4	\$16,068	0
Maximum	44.5	\$211,506	57
Total	400.1	\$1,900,933	356

Note: Funding calculated using the 2015/16 national price of \$4715.58 per caseweight

Half of the ECMO patients (9 patients/200 caseweights) were discharged from the adult cardiothoracic service. The remainder were discharged from cardiology (4 patients/63 caseweights), general surgery (1 patient/27 caseweights), and other medical specialties (3 patients/108 caseweights).

#### Case for change

ECMO is a highly specialised input into the care of patients with complex medical conditions, and as such, it is important to ensure the service model is both effective and efficient. It is felt that formal protocols would ensure appropriate and timely patient referral, and consistency of future indications for the use of ECMO.

The experience from the United Kingdom<sup>iii</sup> is that ECMO as a treatment modality best sits within a nationally agreed pathway. There is also published evidence<sup>iv</sup> of an important volume/outcome relationship, such that ECMO is best performed when centralised to centres with a sufficient volume to allow adequate experience to develop rather than being undertaken by small volume "occasional user" centres.

There is opportunity to improve the quality of patient care and outcomes, as well as ensuring resources are used wisely. Areas of impact are:

- patient mortality the mortality rate for adult patients receiving ECMO treatment in recent years is as high as 36 percent, excluding patients receiving ECMO as part of a transplant. Fourteen percent died within a week of admission/transfer to Auckland for treatment
- patient morbidity and outcomes patients are highly complex, with a prolonged length of stay, and requiring specialised care from a multi-disciplinary team
- patient and family experience patients are often acutely ill and transferred rapidly from their local DHB to Auckland. This may be an overwhelming experience for patient and family
- cardiothoracic Surgery service impact providing ECMO treatment impacts on delivery of cardiothoracic surgery, and creates pressures for ICU capacity within Auckland DHB, resulting in cancelled elective surgery, and occasionally in unplanned outsourcing of this work to continue to meet targets
- retrieval service impact there are retrieval costs where the team is despatched for patients found not to be appropriate, and expectations for repatriation of ECMO patients are not well defined. This can prolong the length of stay, exacerbating CVICU bed availability
- impact on staff the retrieval team is part of the core CVICU service, provided through on call arrangements. ECMO retrievals impact on the availability of staff, and on hours of work.

Due to the high impact of providing ECMO treatment, and the patient mortality rates, a nationally-agreed pathway should be developed to enhance efficiency.

It is important that referral pathways allow appropriate and timely referral to ensure the best possible outcomes are achieved.

#### **Guiding principles**

As with all health services, the service model for ECMO will align with the principles underpinning the New Zealand Health Strategy.

- Acknowledging the special relationship between Māori and the Crown under the Treaty of Waitangi.
- The best health and wellbeing possible for all New Zealanders throughout their lives.
- An improvement in health status of those currently disadvantaged.
- Collaborative health promotion, rehabilitation and disease and injury prevention by all sectors.
- Timely and equitable access for all New Zealanders to a comprehensive range of health and disability services, regardless of ability to pay.
- A high-performing system in which people have confidence.
- Active partnership with people and communities at all levels.
- Thinking beyond narrow definitions of health and collaborating with others to achieve wellbeing.

The service model will also incorporate the five themes of the Health Strategy to provide a focus for change.

Figure 2: The New Zealand Health Strategy



#### Scope

This service model applies to VV ECMO for adults (aged 16 and above). Under the service model there will be a single provider of adult VV ECMO services in New Zealand – Auckland DHB.

VA ECMO may be required for patients undergoing cardiac surgery to enable them to come off by-pass. In this situation, the best outcome for patients is to remain with their local clinical team, who may seek advice from the Auckland ECMO service.

Where elective patients are known to be high-risk cardiac surgical patients consideration should be given to referring to the Auckland Cardiac Surgery Service so that if ECMO is required, this can be managed by the Auckland ECMO service.

VA ECMO may also be required urgently for other acute cardiac conditions. In these cases it is recommended that the treating clinicians discuss commencement of ECMO with the Auckland ECMO service, so that a management plan may be developed, and a retrieval timeframe agreed.

The Auckland DHB provider of VV ECMO services will provide advice and support to other DHBs with patients on VA.

Where patients are receiving VA ECMO in a regional cardiac centre, the provider will be required to collect data and report on the same quality indicators as the Auckland ECMO Service.

The recommended referral pathway for VA ECMO is in Appendix 1.

#### Methodology

A Technical Advisory Group (TAG) was convened to:

- provide broad perspectives into the recommended service model for adult ECMO through application of specialist knowledge and expertise
- review, revise and endorse a service model for adult ECMO, patient pathways and referral documentation
- provide advice on stakeholders for communication/consultation
- provide input into an implementation action plan.

The TAG members were nominated by DHB chief operating officers, and attended a one day workshop in November 2016. Consumer and Maori health perspectives were also included in the TAG to ensure consideration was given to service-user priorities. At the workshop the TAG was asked to confirm the service model objectives, and to consider an initial draft service model.

Changes were made to the draft model following the workshop which were confirmed by the group. The updated draft model was endorsed in March 2017.

The updated draft service model for ECMO was then endorsed by the National Services Governance Group, which includes Ministry and DHB representation. This was followed by a period of targeted sector consultation (see Appendix 5).

Changes were made as a result of feedback received, and a final draft service model was presented to the National Services Governance Group for endorsing.

#### **Service model Objectives**

There are six key objectives of the service model.

- 1. To have a clearly defined patient pathway to ensure patients who are clinically eligible for ECMO have, as far as clinically possible, equity of access to the service
- 2. To provide referrers and patients requiring ECMO within the CVICU at Auckland DHB with:
  - a. expert advice on the diagnosis and management of potentially reversible severe respiratory and/or cardiac failure, including collaboration with other tertiary providers where appropriate
  - b. a retrieval service for those patients that meet the criteria and are accepted for ECMO, including safe mobile ECMO
- 3. To support safe repatriation of patients to an appropriate hospital close to their home following ECMO
- 4. To improve patient outcomes through timely and appropriate referral to the ECMO service, as reported within the local clinical outcomes database and through submission of data to ELSO and communicated nationally
- 5. Safe and high quality clinical care for all patients referred for ECMO
- 6. To provide cultural, as well as family and whānau support.



# PART 2: Service model for ECMO

#### The service model

The service model for ECMO services is centred around a single provider (Auckland DHB) for the timely provision of VV ECMO for adult patients with severe, potentially reversible respiratory failure.

The key elements of the service model of patient and family/whānau centred care are:

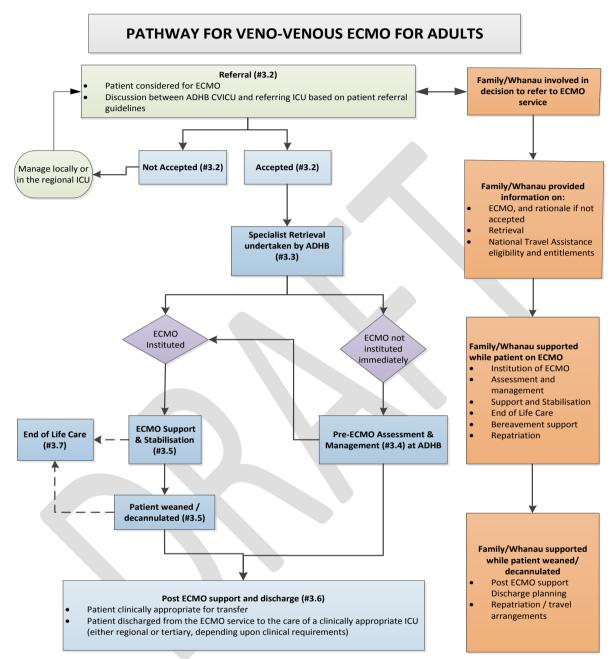
- referral, advice and acceptance of patients who fulfil eligibility criteria for service
- specialist retrieval
- assessment
- treatment by provision of extracorporeal life support using a standard protocoled pathway of care
- post treatment support (post decannulation)
- return to suitable regional / local ICU
- · end of life care
- patient information and family/ whānau support.

Patients discharged from the specialist ECMO service following the period of post ECMO support should be transferred back to the referring ICU or a regional tertiary ICU depending on clinical appropriateness in accordance with existing national transfer and transport arrangements.

#### The patient pathway

The patient pathway is for referrals for adults for VV ECMO is described below.

Figure 3: Patient pathway processes



#### **Equity of access to services**

Access to ECMO services should be available to all DHB populations. The aim is to establish processes that support equitable access irrespective of the referring hospital, including:

- finalising and implementing the service model with all ICUs
- ensuring the referral pathway and model are easily accessible to potential referrers
- · audit of referrals and acceptance rates by ICU, with feedback to the referring units
- regular review of the referral process and acceptance criteria based on audit findings.

#### Patient referral

Referrals to the service should only be made for patients who are critically ill and already receiving conventional intensive care therapies after discussion between local intensivists and the Service. Auckland DHB will consider accepting patients referred to the service with:

- absence of serious pre-morbid illnesses that significantly impact quality of life or are likely to significantly shorten life
- potentially reversible severe respiratory and/or cardiac failure
- failed optimal conventional intensive care management early in the course of their illness.

Referral will be made using the prescribed referral form (Appendix 2). Referrals will be reviewed by at least two CVICU specialists prior to acceptance in conjunction with the referring centre.

Patients who are not accepted for ECMO will be managed in the local secondary or tertiary ICU. Patients who are accepted for ECMO may have cannulation for ECMO undertaken locally either prior to retrieval by the ECMO service (when there is an accredited cannulation and management service and when clinical urgency dictates), or as part of specialist retrieval.

The Health Policy Advisory Committee on Technology (HealthPACT) has cited some indications and contraindications for ECMO (Kulkarni, Sharma, & Diaz-Gusman, 2016)v, which are identified in Appendix 3.

#### Specialist retrieval

As the national provider with the appropriate skills and expertise Auckland DHB will retrieve patients where a referral has been accepted for ECMO support.

Depending on the distance travelled, transportation will be by road ambulance, helicopter or fixed wing aircraft. Where fixed wing aircraft is used, road ambulance is required for transfer between the hospital and the airfield.

The ECMO service will liaise with ambulance providers to ensure appropriate transportation protocols are in place for the transfer of patients between the referring DHB and Auckland City Hospital.

As with other inter-hospital transfers the retrieval is funded by the DHB of patient domicile.

#### **Assessment and management**

Some patients who are accepted for ECMO will not require ECMO prior to transfer to Auckland DHB. Patients not transported on ECMO will undergo continuous clinical assessment and management. This will involve maximising conventional care through advanced circulatory and ventilatory support techniques until either ECMO is instituted or the patient is able to be repatriated to their local or regional ICU.

#### ECMO support - stabilisation

A patient is weaned from ECMO support once they demonstrate clinical improvement in respiratory parameters including measures of lung compliance, radiological changes, improvement in blood gas exchange and the ability of the heart and circulation to maintain homeostasis without mechanical support.

#### Post ECMO support and discharge

Post-ECMO support will be provided at Auckland DHB until the patient is clinically appropriate for transfer.

Once a patient has been weaned from ECMO support, decannulated, and is clinically appropriate for transfer they will be discharged from the ECMO service. Arrangements will be made to transfer the patient to the care of the most clinically appropriate ICU, after discussion between the family/whānau and the intended receiving ICU.

In some cases the most clinically appropriate ICU will not be at the patient's DHB of domicile, but will be at a regional tertiary DHB ICU. To ensure patients are well supported, there may also be situations where the most clinically appropriate ICU will be where the family/whānau DHB reside. This should not be a barrier to a patient and family/whānau centered repatriation. Under section 7.6 of the OPF a providing DHB "must accept acute or arranged patients whether by referral or presentation at a health care facility".

As with retrieval, transport to repatriate patients back to their referring hospital is covered under the inter-hospital transport rules and processes, and the NTA policy.

#### End of life care

There are some patients who will fail to improve despite ECMO support and on these occasions it may not be clinically appropriate to continue ECMO. In such cases the multi-disciplinary team should meet to discuss options with the family/whānau, including end of life care.

End of life care is included within the scope of the service and it is expected that Auckland DHB will follow best practice, as described in the ANZICS *Statement on Care and Decision-Making at the End of Life for the Critically Ill*<sup>vi</sup> (Australian and New Zealand Intensive Care Society, 2014). This document describes ethical and legal frameworks for making end of life decisions, communication and documentation, managing conflict and caring for dying patients and their families. Principles, recommendations and case examples are included to guide and assist staff in working with patients and their families/whānau. The 10 principles of end of life care in intensive care are identified in Appendix 4.

#### Patient information and family/whānau support

The ECMO service will ensure that information is available for patients (where relevant) and family/whānau at all stages of the care pathway. Information will be in the following areas.

- Referral and Retrieval: Family/whānau should be informed about the referral and
  retrieval process and of ECMO with particular reference to the associated risks. The ADHB
  Confirmation of Authority to Treat form (CRO114) should be used
- National Travel Assistance (NTA): NTA for family/whānau is funded through the patient's DHB of domicile. Family/whānau should be advised of the entitlements and the application process for NTA support
  - Referrals to NTA will be made by a specialist within the ECMO service. In general, eligibility will be determined by entitlement to publicly funded care in New Zealand, distance travelled criteria, frequency of visits criteria, or client long stay near hospital criteria (section 2)
  - The NTA provides for a support person, and in some circumstances a second support person (section 7.1)

- NTA eligible supporters who live in another location from the client are entitled to travel assistance based on the client's eligibility
- Supporters of long term inpatient adults (stay of 16 days or more) may receive additional travel assistance (section 7.3.1)
- NTA support for inter hospital transfers/repatriation depends upon the clients' NTA eligibility (section 6.7 and section 8)
- Travel and accommodation assistance provided under the NTA is identified in section 10
- Refer to the NTA for detail on entitlements and application process or contact the Ministry's NTA payment team on free phone 0800 281 222 or email to travel@moh.govt.nz
- **Assessment, treatment and post-ECMO:** Regular contact will be maintained with the referring hospital and with families, including discharge and repatriation arrangements and processes especially where the patient may require post ECMO care at a regional ICU
- **End of life care**: Bereavement and counselling services are available and will be offered to all families.

#### Follow up care

Patients are routinely followed up at their local DHB. However, a patient may be seen by, or advice sought from, Auckland DHB for ECMO-related issues. This may be at the request of the general practitioner or referring hospital. All reasonable requests will be accommodated.

#### Interdependencies with other services

While there are no formalised national/regional ICU networks in place, the service model may provide an opportunity to develop a framework for management of national capacity, referral patterns and processes around ICU beds.

#### **Quality assurance**

Auckland DHB CVICU is a member of, and contributes data to ELSO which provides international benchmarked data comparisons. Data will also be available from the ANZCIS registry.

#### Applicable service standards

Relevant service specifications according to the National Service Framework Library (NSFL) ICU standards.

Table 4: Proposed quality performance indicators

	Quality performance	Threshold	Method of	Report
	indicator		measurement	due
QPI 1	Survival rate to	Comparable with ELSO	ELSO reporting/	Annually
	decannulation	registry outcomes	local reporting	
QPI 2	Survival rate to hospital	Comparable with ELSO	ELSO reporting/	Annually
	discharge	registry outcomes	local reporting	
QPI 3	Cannulation and ECMO	Comparable with ELSO	ELSO reporting/	Annually
	circuit-related	registry outcomes	local reporting,	
	complications		critical incident	
			reporting	

	Quality performance indicator	Threshold	Method of measurement	Report due
QPI 4	Patient and family/whānau experience of:  communication partnership coordination physical and emotional needs	8.3 8.5 8.3 8.6	Modified HQSC Patient Experience Survey	TBD
QPI 5	Referrer experience	TBD	TBD	TBD

As part of implementing the service model for ECMO, further work to define appropriate quality indicators will be required. These should cover the areas of patient/family/whānau experience, service delivery and clinical effectiveness.

The proposed QPI 4 is derived from the HQSC patient experience questionnairevii which uses 20 items to assess inpatient experience in the four domains of:

- communication
- partnership
- coordination
- physical and emotional needs.

The survey is administered quarterly to randomly selected patients. It is recommended that this survey be adapted for completion by ECMO patients and their families/whānau.

Further work to understand referrer experience is also recommended.

# PART 3: Implementation Action Plan

#### Establishing the project group

The initial step to implement the service model, following endorsement, is to establish a project group. The project group will be include Ministry of Health and ECMO service team members, including a clinical leader.

The project group will be accountable to the National Services Governance Group, and to the Auckland DHB executive for delivery of the Action Plan and implementation of the ECMO service model.

#### **The Action Plan**

The following actions have been identified to implement the ECMO service model which link to the six objectives for the service model.

Obje	ctives
1	Clearly defined pathways
2	Referrers/patients are supported
3	Safe Repatriation
4	Improved patient outcomes
5	Safe and high quality clinical care
6	Patients and family/whānau are supported

Action	Description	Lead	Timeframe
1	A project group, clinical leadership and governance framework is established for the ECMO service, providing ongoing oversight of the service model implementation.	МоН	July 17
2	DHB accountability documents are updated to identify Auckland DHB as the provider of veno-venous ECMO for adults in New Zealand with compromised respiratory status.	МоН	Oct 17
3	The ECMO service model is published on the NSFL.	MoH	July 17
4	The ECMO service model is disseminated to ICU directors through a range of media, including mailing lists, newsletters, local and national committees or meetings.	Project group	Dec 17
5	The referral form is reviewed and updated, providing clarity of referral outcome.	Project group	Aug 17
6	The quality and effectiveness of the ECMO service model is monitored through agreed quality indicators that assess clinical effectiveness and responsiveness for patients, family/whānau and referrers.	Project group	Baseline – July 17 Annually

Action	Description	Lead	Timeframe
	Three indicators of clinical effectiveness are measured annually:	ECMO service	July 18
	a. survival rate to decannualation		
	b. survival rate to hospital discharge		
	c. cannulation and ECMO circuit related complications.		
7	Patient and family/whānau experience is assessed - the HQSC patient experience questionnaire is adapted for use.	Project group	Sept 17
8	Referrer experience is assessed – a questionnaire is developed to assess referrer experience of referring to and interface with the ECMO Service.	Project group	Sept 17
9	Ambulance providers develop and implement a protocol for patient retrieval that ensures appropriate transportation for patients on ECMO.	CD Air Ambulance St John	Sept 17
10	Existing patient and family/whānau information is reviewed to ensure any written material in use covers information priorities, noting that written information will be used as an adjunct to other methods of communication.	Project group	Sept 17
11	Referral pathways for elective cardiac patients considered high-risk are reviewed, in conjunction with the Cardiac Surgery Service at Auckland DHB.	Project group	Sept 17
12	Cardiac centres providing VA ECMO collect and report on the same measures of clinical effectiveness and patient and family/whānau experience as the ECMO Service.	Cardiac providers/ ECMO Service	Feb 18
13	<ul> <li>Equity of access to the ECMO Service is assessed through:</li> <li>annual audit of referrals and acceptance rates, by ICU</li> <li>review of the referral process and acceptance criteria.</li> </ul>	ECMO Service	Annually July 18
14	Protocols for managing ECMO patients are regularly reviewed and updated as clinical practice evolves, and made available to other users through the Auckland DHB website.	ECMO Service	Annually
15	A staff development programme is established to develop and/or maintain the clinical expertise of the CVICU team in managing patients on ECMO.	ECMO Service	July 18
16	Opportunities are explored to develop or promote collaborative relationships between stakeholders of the ECMO Service	ECMO Service	July 18

## **Abbreviations**

ANZICS - Australian and New Zealand Intensive Care Society

CD - Clinical Director

CVICU - Cardio Vascular Intensive Care Unit

DHB - district health board

DRG - Diagnostic Related Group

ECMO - Extra Corporeal Membrane Oxygenation

ELSO – Extracorporeal Life Support Organisation

HealthPACT – Health Policy Advisory Committee on Technology

**HQSC** – Health Quality Safety Commission

ICD - International Classification of Diseases

ICU - Intensive Care Unit

**IDF** - Inter District Flow

MoH – Ministry of Health

NMDS - National Minimum Data Set

NSFL - National Service Framework Library

NTA – National Travel Assistance

**OPF** - Operational Policy Framework

PICU - Paediatric Intensive Care Unit

TAG - Technical Advisory Group

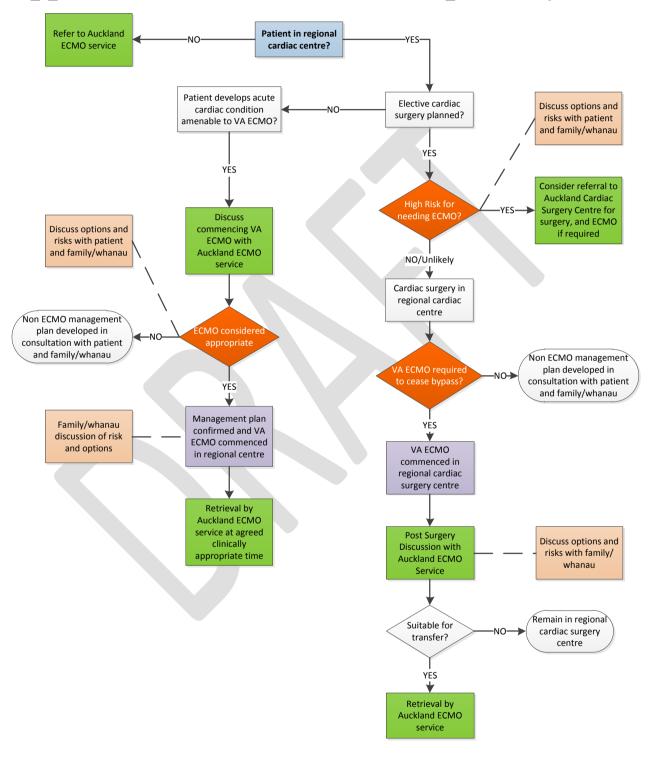
TBD - To be determined

VA - veno-arterial ECMO

VV – veno-venous ECMO

## **Appendices**

### **Appendix 1: Recommended VA pathway**



## **Appendix 2: ECMO Referral Form**



#### **Cardiothoracic and Vascular ICU**

Auckland City Hospital

#### 0800 ADULT ECMO

	CV.	ICU ECMO Referral F	orm	
REFERRING HOSPITA	AL DETAILS			
Date		Time		
Referring Doctor		Cellph	none	
Referring Hospital				
PATIENT DETAILS				
First Name		Surname		
NHI	DOB DD/MM/YY		ender M / F Weig	ht
Blood Transfusion Lim	nitations (eg religion, anti	bodies etc) YES / NO	Heigh	it
CLINICAL DETAILS				
Working Diagnosis			Allergies	
Preg Test	Smoking		Alcohol	
Clinical Summary				
Research Studies Enro	olled in/screened for			
Research Studies Enro				
		Time		
RESPIRATORY DETAI		Time PEEP	PIP	PLAT
RESPIRATORY DETAI	LS	-	PIP FiO2	PLATSats
RESPIRATORY DETAI	ILS Mode	PEEP		
RESPIRATORY DETAI  Intubation Date  Ventilation	Mode RR	PEEP TV	FiO2	
RESPIRATORY DETAI  Intubation Date  Ventilation	Mode RR	PEEP TV	FiO2	
RESPIRATORY DETAI  Intubation Date  Ventilation  Adjuncts	Mode RR Steroids	PEEP TV Proned	FiO2 iNO	
RESPIRATORY DETAI  Intubation Date  Ventilation  Adjuncts	Mode RR Steroids PH	PEEP TV Proned pCO2	FiO2 iNO pO2	
RESPIRATORY DETAI  Intubation Date  Ventilation  Adjuncts	Mode RR Steroids PH BE	PEEP TV Proned pCO2	FiO2 iNO pO2	
RESPIRATORY DETAI  Intubation Date  Ventilation  Adjuncts  Current ABG	Mode RR Steroids PH BE	PEEP TV Proned pCO2	FiO2 iNO pO2	
RESPIRATORY DETAI  Intubation Date  Ventilation  Adjuncts  Current ABG  Duration FiO2 > 80%	Mode RR Steroids PH BE days	PEEP TV Proned pCO2	FiO2 iNO pO2	
RESPIRATORY DETAI  Intubation Date Ventilation  Adjuncts  Current ABG  Duration FiO2 > 80%  CXR/CT Findings	Mode RR Steroids PH BE days	PEEP TV Proned pCO2	FiO2 iNO pO2	

CARDIOVASCULA	D DETAILS											
Vitals	HR			MAP			CVP			СО		7
Inotropes	Adr			Norad						Othe		╣
				Norau			Dopamine Feeding		NJ / TP			╡
Fluid balance daily/Cumulative Urine Output				RRT			Ischaem		_	IN	mls/hr	╡
Echo findings				KKI			Ischaem	ia/IIIOC	uiiig			╣
Cardiac Arrest			ROSC			CNS fur	ction post	arrect				$\exists$
L	ritec					CNS ful	iction post	arrese				$\exists$
vasculai access/s	Vascular access/sites											
NEUROLOGY DET	TAILS											
Neurology status	pre-sedation	Pupil size & reactivity								7		
Current sedation	/Paralysis								Ī			
INFECTION DETA	AILS											
Confirmed Infect												7
Current Antibiotic	L											╡
Anitviral												
												J
BLOOD RESULTS												
Haematology		Hb			WCC			Plts				
		INR			APTT			Fib				
Biochemistry		Na			K			Creat			Urea	
		Bili			ALT/AS	г		Albumin				
REFERRAL OUTC	OME											
Accepted		Mode	of Trans	port			Team D	epartur	e Time			
Additional Notes												

Please Fax to (09) 307-4906

## **Appendix 3: Patient selection for ECMO in adults**

Source: (Kulkarni, Sharma, & Diaz-Gusman, 2016)

Clinical indications for ECMO	Contraindications for ECMO
Hypoxic respiratory failure	Absolute contraindications
Acute respiratory distress	Uncontrolled active haemorrhage
Bridge-to-lung transplant	Terminal illness
Primary graft failure of lung transplant	Irreversible or end-stage heart or lung failure in patients who are not candidates for transplant
Hypercapneic respiratory failure	
Exacerbation of COPD	
Status asthmaticus	
Cardiac failure	Relative contraindications
Myocardial infarction-associated cardiogenic shock	>7 days on mechanical ventilation with high FiO <sub>2</sub> or high-pressure ventilation
Fulminant myocarditis	Non-pulmonary organ dysfunction, especially renal failure
Sepsis-associated myocardial depression	Turna and the control is among anothers
Extracorporeal cardiopulmonary resuscitation	Irreversible central nervous system dysfunction
Post-cardiotomy or post-heart transplant cardiogenic shock	Conditions precluding use of anticoagulants
	Advanced age
Primary graft failure after heart transplant	Weight >125kg
Bridge to VAD implantation or heart transplant	

## Appendix 4: ANZICS principles for end of life care in ICU

Source: (Australian and New Zealand Intensive Care Society, 2014)

- 1. The goals of intensive care are to return patients to a quality of survival that is acceptable to them and to reduce disability and, if these are not possible, to compassionately support the dying process. At all times the aim is to minimise suffering.
- 2. Intensive care treatment is often lifesaving for patients with reversible critical illness. As predicting survival of an individual critically ill patient is imprecise, however, all patients should receive simultaneous attention to both therapeutic (and potentially burdensome) medical interventions and to ensuring their comfort and controlling distressing symptoms. 4 The balance of attention may shift between these objectives during the patient's critical illness, including the possibility that the only objective may be patient comfort and symptom control.
- 3. When a decision has been made that active treatment is to be withheld or withdrawn, a palliative care plan should be implemented, in consultation with the patient and/or family and the ICU nurse, with a focus on dignity and comfort, considering physical, psychosocial and spiritual needs. The use of medication for patient symptom control in this setting is ethically and legally appropriate, even though this may shorten life.
- 4. There is no ethical or legal obligation to provide treatments where considered medical opinion is that the burdens to the patient outweigh any potential benefits. The patient and the substitute decision-maker do not have the right to demand treatment (except in Queensland5). Medical consensus should be achieved between the intensive care and other medical teams before changing the goals of treatment.
- 5. The adult patient who has the capacity to decide is entitled to refuse or withdraw consent for any treatment at any time, even if this may shorten his or her life.
- 6. Medical staff and their patients should aim to make a shared decision about treatment options. The process of shared decision-making involves a consensus among the patient (if the patient has the capacity to make decisions), a substitute decision-maker or family (if the patient does not have the capacity to decide), the intensive care team and other medical teams involved.

Under shared decision-making, the responsibilities of the parties involved are as follows.

It is the responsibility of the intensivist to:

- determine what treatment options are clinically indicated
- determine the existence of an Advance Care Plan or Advance Care Directive if present
- inform the patient (or substitute decision-maker in the case of a patient who lacks capacity) of the nature (including potential burdens and benefits) of these options and to provide professional recommendations about these options.

It is the responsibility of the patient with capacity to:

• inform the intensivist of what further information they require about the treatment options available in order to be involved in the decision-making.

It is the responsibility of the substitute decision-maker of the patient who lacks capacity to:

• inform the intensivist of the patient's (and their own) goals, values and preferences that will inform decision-making.

It is a shared responsibility of the intensivist, patient or substitute decision-maker to:

• use their shared understanding of the patient's goals, values and preferences, as well as the potential burdens and benefits of the clinically indicated treatment options, to make

a decision about what treatments should take place. The goal is to reach a shared decision that reflects the best understanding of the patient's prognosis and of the patient's wishes in the current clinical circumstances.

- 7. In cases when there is disagreement that cannot be resolved with discussion and time, consideration may be given to involving additional medical opinion, non-medical professional opinion (elders, clerics or spiritual advisers), clinical ethics consultation or legal processes.
- 8. All decisions regarding the withdrawing or withholding of treatment should be documented in the clinical record. The documentation should include the basis for the decision, identify those with whom it has been agreed and specify the treatments to be withheld or withdrawn.
- 9. The principles set out above apply equally whether withholding or withdrawing treatment is being considered.
- 10. Every intensive care unit (ICU) and its hospital should develop and implement guidelines in accordance with these principles. This should include the evaluation of care at the end of life as a quality measure.



#### **Appendix 5: Consultation**

The Service model was endorsed to proceed to targeted sector consultation by the National Services Governance Group, who commissioned the work. The National Network of General Managers, Planning & Funding also endorsed the Model.

The stakeholders that received a copy of the Service model as part of the Consultation have been identified below. Consultation was through an email invitation to comment through an on line survey, or through a written submission.

Table 5: Stakeholders included in consultation

Group/organisation	Key contact		
Cardiovascular Intensive Care Unit staff, Auckland DHB	Mark Edwards		
ICU and associated clinicians in regional DHBs	Directors of ICU		
DHB Funders	Carolyn Gullery – lead GM		
DHB Chief Medical Officers	Ken Clark – lead CMO		
DHB Chief Operating Officers	Dale Olliff – lead COO		
Respiratory physicians	CMOs		
Cardiac Surgery Clinical Network	Harsh Singh		
Cardiac Network	Gerry Devlin		
Heart and Lung Transplant Service, Auckland DHB	Mark Edwards		
National Travel Assistance administrators	Mark O'Hara, Akenese Sione		
National Ambulance Sector Office	Sarah Hoyle		
Directors of Nursing	Jane O'Malley		
Maori Leadership	Alison Thom		
Australian and New Zealand College of Perfusion	John Van den Berg		
Directors of Allied Health			
Ambulance New Zealand	David Water, CE		

Stakeholders were asked to consider the appropriateness of the Service model for Adult ECMO within a New Zealand context, including opportunities to improve the Model the following, or challenges for implementing the Model.

### Question 1: Do you agree that the described Service model for ECMO is appropriate within a New Zealand context?

#### Please indicate the level of your agreement

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

Question 2: What are the strengths of this service model?

Question 3: Do you have any suggestions for improvements?

Question 4: Can you see any potential challenges?

Question 5: Do you have any additional comments?

### References

<sup>i</sup> Operational Policy Framework: http://nsfl.health.govt.nz/accountability/operational-policy-framework-0/operational-policy-framework-201617

<sup>ii</sup> National Travel Assistance Policy, 2005, http://www.health.govt.nz/our-work/hospitals-and-specialist-care/national-travel-assistance-scheme

<sup>iii</sup> D16/S(HSS)/a 2013/14 NHS Standard Contract for Extracorporeal Membrane Oxygenation Service for Adults with Respiratory Failure

<sup>iv</sup> Barbaro RP, Odetola FO, Kidwell KM, Paden ML, Bartlett RH, Davis MM, Annich GM. Association of hospital-level volume of extracorporeal membrane oxygenation cases and mortality. Analysis of the extracorporeal life support organization registry. Am J Respir Crit Care Med. 2015 Apr 15;191(8):894-901

<sup>v</sup> Kulkarni, T., Sharma, N. S., & Diaz-Gusman, E. (2016). Extracorporeal membrane oxygenation in adults: a practical guide for internists. *Cleveland Clinical Journal of Medicine*, 373-378.

vi Australian and New Zealand Intensive Care Society. ANZICS Statement on Care and Decision-Making at the end of Life for the Critically Ill (Edition 1.0). Melbourne, ANZICS, 2014.

vii Health Quality Safety Commission, Adult Inpatient Experience – Patient Survey - https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/health-quality-and-safety-indicators/patient-experience/adult-inpatient-experience/ - the recommended thresholds are the NZ weighted average as reported by HQSC