

## Consultation Report

### Topic details

<b>Title of policy or policy statement:</b>	Extracorporeal membrane oxygenation (ECMO) as a bridge to lung transplant (all ages)
<b>Programme of Care:</b>	Internal Medicine
<b>Clinical Reference Group:</b>	Specialised Respiratory
<b>URN:</b>	1803

## 1. Summary

This report summarises the outcome of a public consultation undertaken to test the policy proposition for use of ECMO in deteriorating patients with terminal respiratory failure waiting for a lung transplant as a bridge to transplantation.

## 2. Background

Lung transplantation is routinely performed for selected patients with respiratory failure in whom there are no other options for treatment. Due to the scarcity of organs, patients are put on a waiting list until suitable lungs for transplantation become available. Approximately 25% of patients on the waiting list die from respiratory failure. Some of these patients could be given respiratory support to keep them alive until a transplant becomes available. This is known as Bridge to Transplant (BTT). There are currently no treatments available for rapidly deteriorating patients with terminal respiratory failure. Such patients are removed from the lung transplant waiting list and given end-of life care.

The urgent lung allocation schemes (ULAS) and super-urgent lung allocation schemes (SULAS) were introduced in May 2017 with the aim of balancing the needs of reducing waiting list mortality with improving outcomes for all listed patients. There was a concern that the previous allocation scheme created a difference between patient's clinical risk and their chances of receiving a lung transplant. Under that earlier scheme patients with cystic fibrosis (CF) and pulmonary fibrosis (PF) had the highest mortality rates whilst on the waiting list, while patients with chronic obstructive pulmonary disease (COPD) had the greatest chance of receiving a lung transplant.

To be eligible for SULAS patients must be already registered on the ULAS or non-urgent waiting list (NULAS) and have an acute deterioration which they are highly unlikely to survive without extracorporeal support. These patients could receive veno-venous (VV) ECMO as a bridge to transplant. These patients should have good rehabilitation potential which usually

means they have had a short duration of severe illness. Patients whose clinical condition has deteriorated on the SULAS (e.g. major sepsis, extrapulmonary organ failure) are de-listed.

This policy proposition sets out a proposal for routine commissioning of ECMO as a bridge to lung transplantation in the five adult lung transplantation units and two paediatric lung transplantation units in England.

The Clinical Panel in considering the proposition had agreed the intervention reasonable for the individual patient but were concerned whether prioritising patients acutely ill for a lung transplant deprives others, who may have an equal place in access to lung transplant. The Clinical Panel asked therefore that the consultation included questions on individual access versus population equity for lung transplant.

### **3. Publication of consultation**

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days which closed on the 27<sup>th</sup> August 2020. Consultation comments have been shared with the Policy Working Group (PWG) to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following targeted consultation questions agreed by the National Programme of Care:

1. Do you have a comment on any potential impact on the equity of access to organs that may arise as a result of this policy?
2. Do you have a comment on the prioritisation of individual patients over the wider waiting list population that may arise as a result of this policy?
3. Do you have a comment on any potential impact this policy will have on access to organs for those treated on ECMO compared to the rest of patients on the waiting list?
4. Do you have a comment on whether this policy will advantage or disadvantage any particular groups on the waiting list?
5. Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.

### **4. Results of consultation**

There were sixteen responses submitted to the public consultation from the following:

Clinician	4
Patient group	1
Professional body	4
Provider	3
Member of public	3
Non-profit professional	1

Two clinicians at Trusts sent in comments directly through commissioning links. The Royal College of Physicians has endorsed the response submitted by the British Thoracic Society.

4.1 Do you have a comment on any potential impact on the equity of access to organs that may arise as a result of this policy?

Nine responses were received on this question. Key issues/ themes raised:

- NHS Blood and Transplant provides clinical oversight and leadership for organ donation (allocation). They supported the proposition and commented that prioritisation in the allocation of organs is always done on some basis, that the proposal is no different to other allocation systems, noting that ECMO is included in the allocation algorithm in most of Europe, the US and Canada. That VV ECMO and super-urgent listing will make organs available to a small number of patients who are critically ill but have the capacity to be bridged to a successful lung transplant.
- It was noted that there is inequitable access to ECMO as BTT in England currently due to non-commissioned access via one Trust.
- One response suggested that ECMO should be used at an earlier stage to improve outcomes.
- The issue of access to transplant for patients on ECMO in non-transplant centres was raised by several respondents. The policy proposition is for listed patients in cardiothoracic transplant centres. There may be future opportunities to link into other ECMO centres and this issue can be explored by the highly specialised commissioning team working with both ECMO and transplant clinicians.

4.2 Do you have a comment on the prioritisation of individual patients over the wider waiting list population that may arise as a result of this policy?

Eight detailed responses were received to this question. Key issues/ themes raised:

- NHS BT commented that the introduction of VV ECMO and super-urgent lung listing introduces another method of prioritisation. They did not consider this as a departure from current practice of allocating organs according to clinical need providing the patient retains the capacity to benefit.
- Some responses recognised that ECMO would offer lifesaving treatment for a cohort of patients whose outlook is otherwise poor. It was noted that across the NHS priority is given to those patients at greatest risk of serious harm or death.
- Monitoring of the impact of the proposal if agreed, was raised several times. This included monitoring beyond the clinical indication, overall use and impact on the wider waiting list and overall survival. These will be part of the metrics.

4.3 Do you have a comment on any potential impact this policy will have on access to organs for those treated on ECMO compared to the rest of patients on the waiting list?

Ten responses were received to this question. Key issues/ themes raised:

- Concern about the impact of the policy on the existing paediatric ECMO centres and their activity levels. If agreed ECMO for lung transplant will be provided and funded as a

separate service to the paediatric respiratory ECMO services. Expected numbers of paediatric patients each year who would need to be bridged to transplant is very small.

- It was noted in some responses that this policy will mean that without an increase in the number of organs available that more severely ill patients will be transplanted but that most of these patients would die without ECMO and super-urgent listing.
- A national charity suggested that centres will be more willing to accept organs they otherwise wouldn't have done, in the knowledge that an individual is on ECMO as a BTT and desperately needs an organ.
- Patients treated for acute lung failure on ECMO (with no previous lung condition) who could potentially benefit from a new lung will continue to be excluded in favour of those with an acute deterioration on the background of chronic lung failure. The vast majority of patients have underlying lung pathology and would be listed. The management of these patients can be considered by the Highly Specialised Commissioning Team working with both ECMO and transplant clinicians.

4.4 Do you have a comment on whether this policy will advantage or disadvantage any particular groups on the waiting list?

Eight responses were received to this question. Key issues/ themes raised:

- That the policy would disadvantage less sick patients and elderly patients, particularly those with COPD due to the evidence showing they would more likely suffer from complications and poorer outcomes if they were considered for ECMO as a BTT. There would be a need to inform patients about potential treatment options.
- That the policy would advantage younger patients, possibly those with Cystic Fibrosis and Pulmonary Fibrosis noting that these patients under the previous Waiting List system had the highest waiting list mortality.
- That there should be agreed national clinical criteria for respiratory ECMO and for ordering the transplant waiting list based on multiple factors including stability, disease severity, survival without ECMO, survival and waiting time possible on ECMO, age, disease natural history. National clinical standards for respiratory ECMO are in place and published. The policy for organ allocation is regularly reviewed and data reported to the NHS BT Cardiothoracic Advisory Group.

4.5 Has all the relevant evidence been taken into account? Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.

Fifteen respondents answered yes to this question, two said no.

- It was requested that the impact on the paediatric population was clarified. Currently there is insufficient data to fully quantify the potential impact. The number of lung transplants in children each year is very low and the impact of the policy has been assessed as very low. This will be monitored if the policy is implemented.

- There was a point made whether local tariffs are the same for paediatric and adult ECMO. The tariffs are different, this has been taken account of in the financial impact model.
- Additional evidence was presented, this has been considered in the Public Health additional Evidence Report. The new evidence presented was published after the original review was conducted and is consistent with the overall policy proposition. As requested, the reference to the “ILA” device has been removed from the policy as superseded by other technology.

4.6 Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.

There were 14 responses to this question. Key issues raised:

- Respondents asked that we ensure critical care and ECMO capacity in the NHS be considered when planning this service. This service would be separate to the nationally commissioned respiratory ECMO service and would be provided in existing lung transplant units.
- A number of respondents raised the importance of improving organ utilisation rates to increase the number of organs available to transplant.
- ECMO BTT should not be seen as negating the need for timely referral for lung transplantation.
- The importance of careful patient selection by an expert team able to take all aspects of the patient and their disease process into account in order to ensure those most in need benefit and that therapy is cost effective.
- Another comment made was that where ECMO BTT is provided now there hasn't been escalating demand. This is an important issue as significant increase in use of ECMO BTT would likely extend waiting times and reduce patient outcomes.
- The need for national protocols for the use of ECMO BTT was raised to ensure nationally equivalent services.
- The issue of transporting the patients in need of ECMO BTT is unclear, as it is unclear if some patients might need to be moved between centres after being placed on ECMO. This policy currently applies to patients in cardiothoracic transplant centres.
- The impact on the paediatric transplant population needed to be carefully considered and kept under review. Initial discussions with paediatric transplant services suggest that use would be very limited, organ availability for use in children is very limited currently.

## 5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the PWG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document

- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

Many of the issues raised in the consultation fell into Level 2 category and already considered by the PWG. In addition, comments about ongoing monitoring and impact on different patient groups and overall impact on the lung transplantation programme will be considered if the policy is agreed. Specific consideration will be given to the impact on the paediatric lung transplant programme. Some comments were out of scope and related to the management of patients in the national respiratory ECMO service who experience deterioration and would not currently be eligible for listing for lung transplant.

## **6. Has anything been changed in the policy as a result of the consultation?**

The reference to specific branded technology has been removed from the draft policy. Also, specific mention has been made of the need to appropriately consent patients with consideration given to the potential for end of life care for patients awake on ECMO but who do not subsequently receive an offer of suitable organs.

## **7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?**

No.