

Engagement Report for Clinical Commissioning Policies

Unique Reference Number	1803
Policy Title	Extracorporeal membrane oxygenation (ECMO) for bridge to lung transplant (BTT) (all ages)
Clinical Reference Group	Specialised Respiratory and Cardiac Services CRG
Which stakeholders were contacted to be involved in policy development?	Stakeholders for the specialised respiratory CRG and Cardiac Services CRG. Noting that the primary interest and expertise is within respiratory medicine. NHS Blood and Transplant (NHSBT), the British Thoracic Society, Association of Respiratory Nurse Specialists, Cystic Fibrosis Medical Association Lung Transplant Working Group, British Lung Foundation, Pulmonary Hypertension Association UK, Royal College of Physicians
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	Association of lung transplant physicians, members included in PWG.
Which stakeholders have actually been involved?	There were a number of comments received from CRG members. NHS BT have been involved, particularly providing the data which was shared with stakeholders to set out the experience of the use of ECMO BTT in England between May 2017 – Jan 2019. In addition, it was suggested that the PWG seek input from an ethics perspective on the benefit to the individual vs the benefit to patients on the wider waiting list so both the Rare Diseases Advisory Group Ethics member and the British Transplantation Society Ethics Committee were invited to comment. Their feedback has been added to the report.
Explain reason if there is any difference from previous question	Key stakeholders responded but not all organisations commented on the documents.
Identify any particular stakeholder organisations that may be key to the policy development that	None, all key stakeholders have had the opportunity to comment on the draft policy proposition

<p>you have approached that have yet to be engaged. Indicate why?</p>	
<p>How have stakeholders been involved? What engagement methods have been used?</p>	<p>Policy working group meeting and subsequent contact for policy development. Discussion at NHS BT Advisory Group for Lung transplantation.</p> <p>The draft policy proposition was distributed to stakeholders via email for a period of two weeks of stakeholder testing, in preparation for public consultation.</p> <p>Stakeholders were asked to submit their responses via email, using a standard response and in line with NHS England's standard processes for developing clinical commissioning policies.</p>
<p>What has happened or changed as a result of their input?</p>	<p>Some edits have been made to the policy proposition.</p> <p>The most significant change has been to edit the eligibility criteria to clarify that access to ECMO will only be considered once the patient is already registered on the non-urgent or urgent waiting list for a lung transplant under the care of a cardiothoracic transplant centre. This has been clarified as it is the aim of all organ allocation systems to balance the benefit to the individual with the benefit to the wider population (the waiting list as a whole) hence patients must be already listed. This issue of balance has been considered throughout the policy development process.</p> <p>A number of comments were received from stakeholders relating to capacity in commissioned ECMO centres across England and concern about the impact of a routinely commissioned policy on capacity. ECMO as part of the lung transplant pathway will be provided in lung transplant centres. Transplant units currently provide ECMO as part of the post-transplant pathway to support current activity levels. This policy if agreed will therefore not impact existing Highly Specialised respiratory ECMO services.</p> <p>The impact of effectively prioritising a group of patients over the wider waiting population was raised by many consultees. Non-urgent and urgent cases may wait longer for their organ. Some groups of patients including pulmonary fibrosis and cystic fibrosis patients are more likely to benefit overall from being eligible for the super urgent lung allocation scheme. The survival of patients suitable for ECMO as a bridge to transplant but who are not offered it will be extremely short and markedly shorter than non-urgent listed patients. There is currently inequity in the comparative rates of transplantation for patients with pulmonary fibrosis. Due to the rapid rate of progression of their underlying condition, these patients are less likely to undergo lung transplantation once listed. The impact of the super-urgent scheme on patients not on the list will be monitored and reported on a 6 monthly basis.</p> <p>Stakeholders commented on the low lung utilisation rates in the UK and felt more work was needed to improve the numbers leading to</p>

	<p>overall increases in lung transplant numbers. These comments were noted, and NHS England is working with NHS BT with the aim of increasing lung transplantation. However it should be noted that if the policy were approved for routine commissioning it is not anticipated that it would lead to an increase in organ utilisation or organ availability.</p>
<p>How are stakeholders being kept informed of progress with policy development as a result of their input?</p>	<p>All stakeholders (including CRG members and registered stakeholders) will be notified when the draft policy proposition goes out to public consultation and will be kept informed of the policy's progress through NHS England's consultation portal website.</p>
<p>What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?</p>	<p>The majority view was that the changes could reasonably be expected to be broadly supported by stakeholders and that up to 4-week consultation was required.</p>

Appendix 1 – Stakeholder Engagement Feedback

Organisation Responding	Feedback Received	PWG response	Resulting Action
CRG member	<p>While we can build in lots of metrics for monitoring there is no health economic analysis as far as I can see so it is a bit like opening a blank cheque</p> <p>The problem in reality is insufficient organs so patients wait too long and then become ill and so we are in “salvage” mode using whatever is needed</p> <p>So I cannot really support this proposal. I think we need to</p> <ol style="list-style-type: none"> 1. make more organs available, a major thrust that would reduce deterioration on the list 2. use NIV to support patients and when this occurs that is the trigger for the super urgent list as many will just get worse 3. Use the remaining capacity without expansion for the odd patient who get an overwhelming infection 4 invest the money from the proposed expansion of ecmo into 1 	<p>A financial model and impact assessment will be produced to support the policy going forward. This will be based on the estimated number of patients and expected LoS on ECMO.</p> <p>Out of Scope of the PWG.</p> <p>Use of NIV as a trigger for urgent listing would need to be reviewed by the Lung Allocation Working Group (LAWG) through CTAG. This group is currently looking at ULAS and SULAS and considering progressing to a national organ allocation system but use of NIV as a trigger for the ULAS would still not obviate the need for SULAS and ECMO bridging in the case of further deterioration.</p> <p>The proposal will not impact on capacity in the HSS adult respiratory ECMO service.</p> <p>Out of scope of the PWG</p>	<p>To be picked up in financial modelling</p> <p>No action</p> <p>Comments to be fed into LAWG</p> <p>No action</p> <p>No action</p>
CRG member	<p>My query is about how this will actually work in practice, which tends to the equity of access issue and the availability of ECMO facilities. We have five adult ECMO centres and 5 lung transplant centres, but they are not the same five. Manchester, Harefield and Papworth are on both lists, Birmingham and Newcastle are on the latter only and Leicester and Guys are on the former. Earlier this year there were significant pressures on the ECMO system from flu A patients such that the service</p>	<p>ECMO would be provided in the lung transplant units pre-transplant, these units already offer ECMO peri-operatively for both heart and lung transplant.</p> <p>The proposal will not impact on capacity in the HSS respiratory ECMO service.</p>	<p>No action</p>

	<p>was essentially full. Which would suggest a system that does not have much slack. So how will the system work so that patients at all sites will get equitable access? And how will it cope since I assume in lung transplants, you don't have much time to plan and it's all dictated by when organs become available?</p>		
CRG member	<p>Overall, I support this happening with caveats that key outcomes are measured as noted in statements. It has been a long wait in UK to kick start a super urgent list compared to e.g. USA who had it running for a long time. You would have to be at a transplant centre on your ECMO under transplant teams noses to receive a transplant. As not all transplant teams currently provide ECMO presumably the transplant teams will have to expand to be able to provide it and do the time consuming and unpredictable retrievals of patients from hospitals around their patches. If ECMO access is co-located at all current lung transplant centres access will be similar to that for lung transplant now. ECMO at non-transplant centres will still likely be merited for outbreaks of flu etc as before. This will require quite a lot of change at transplant centres, staffing, upskilling etc an organ retrieval team would still be needed plus an ECMO retrieval team. Would they wait to do this until all centres were ready? Resources would be needed for sure.</p> <p>Re questions on feedback form:</p> <ol style="list-style-type: none"> 1) Equity of access – points above and data must be collected on ECMO retrievals done by distance from transplant centres. 2) Prioritisation over wider waiting population – those most likely to die will be given priority here. Non-urgent cases may thus wait longer for their organ. If they become urgent however they will become the priority. I feel this is the right and reasonable strategy. We are currently constrained by a lack of donors compared to those on waiting lists. Work is ongoing to increase organ donation however with national opt in programmes and use of artificial systems to 're condition' borderline lungs retrieved is ongoing so they can then be used - so work 	<p>Noted</p> <p>All transplant centres provide ECMO peri-operatively. However, although numbers are small capacity would have to be funded in the transplant units to allow for pre-transplant ECMO. Requirements would be quantified in the Integrated Impact Assessment.</p> <p>ECMO used as BTT often involves a retrieval team travelling to the referring centre, stabilising the patient with ECMO prior to transport to the transplant centre. As previously stated access to the SULAS depends on acceptance onto the UK lung transplant waiting list prior to the episode requiring ECMO support. Transplant centres have associated ECMO programs and this process means better integration of those services for the population on the waiting list.</p> <p>Retrieval data is collected by NHS BT</p> <p>Noted. This issue was considered in the work up of the policy and the request for ethics input into decision making.</p>	<p>No action</p> <p>For consideration in financial model</p>

	<p>is progressing to close the donor gap. Any improvements in donor numbers will reduce the impact of prioritisation hopefully over time.</p> <p>3) Potential impact on organ access ECMO super urgents may have on wider waiting lists- see above</p> <p>4) Advantage or disadvantage on older patients on waiting lists of introducing this - looking at the data provided on the additional report provided CF and IPF patients have benefitted most from SULAS. CF a younger group, IPF an older group. It appears patients with COPD appear to be the ones who may wait longer if organ demand continues to outstrip availability. So it 'appears' more 'disease' related than age per se (COPD age and IPF ages were similar) although more younger CF patients got transplanted than IPF. To me the data suggests not an age bias per se but those most likely to die and who had best chances of having a successful procedure were prioritised. Many COPD transplants are more about quality of life than longevity as far as I know –perhaps unless they receive a double lung transplant which is usually only available for those under 50 yrs old with certain features. As donor organs are limited this has always been the way these precious resources were supposed to be allocated. I do not feel a clear age bias is showing here. Lung transplant selection processes do have a 'build in' age bias already - older patients have poorer outcomes generally than younger ones hence why e.g. 72-year olds are not (yet) listed for transplants. Their 'older organs' do not cope well with the massive onslaught of a transplant procedure. This will of course need to be monitored carefully however. If the severity lung scores are reliable need rather than age should prevail.</p> <p>A key feature of this option being introduced for patients will be correct patient selection. Clear advice will be needed about which patients transplant centres feel may benefit from bridging. Those criteria would need wide dissemination to clinicians and expectations of patients and families will need to be carefully managed. Few already get on transplant waiting lists.... Fewer on waiting lists will make it to ECMO..... and less onto a successful transplant.</p>	<p>Noted. This issue was considered in the work up of the policy and the request for ethics input into decision making.</p> <p>Comments noted</p> <p>Bridging with ECMO will be in transplant centres. The SULAS criteria are available, published on the NHS BT website. Clinical teams will need to ensure that the informed consent process includes a clear explanation of risk/benefits.</p>	<p>Audit criteria including age will be collected and reviewed at the Cardiothoracic transplant annual meeting. NHSBT collect geographical information on organ recipients and this will inform part of the review of the impact of the policy.</p>
CRG member	<p>There could be a small disadvantage for those who do not have ECMO. The super-urgent list at present allows the same access for all centres with equal criteria. It would not be equal if a centre did not have ECMO, but not a reason to not go ahead with this.</p>	<p>Bridging with ECMO will be in transplant centres.</p>	

	<p>I am broadly supportive. It will help CF patients more than some other groups so I do have a bit of a COI.</p> <p>ECMO is used as bridge to transplant in some other countries already.</p> <p>It would be important to audit outcomes of patients who are on ECMO, as the document suggests, but also any influence of wait for lungs for those others who are on the list but not on ECMO</p> <p>I am aware that Harefield have been using ECMO already and I think Papworth did at least once. The transplant team at Wythenshawe are also keen to start using it.</p>	<p>The impact of the super-urgent list on patients not on the list will be monitored and reported on a 6monthly basis.</p>	<p>Discussed with NHSBT</p>
<p>Consultant Cardiothoracic and Transplant Surgeon</p>	<p>Thank you for giving us the opportunity to reflect on the use of ECMO prior to lung transplantation.</p> <p>ECMO represents a crucial tool in modern cardiothoracic surgery. Developments in the last decade helped to apply the ECMO circuits to a variety of patients with end stage heart and lung failure.</p> <p>The use of ECMO in patients awaiting lung transplantation has shown to be very effective, with outstanding outcome in the predominantly young patient population. Technical advances of ECMO influenced the concept of EVLP significantly, expanding the donor pool and successful transplantation. In consequence, Harefield has consistently achieved the highest lung utilisation rates in the UK.</p> <p>ECMO technology in clinical use has and will drive investment from manufacturing partners to bring down cost and improve the utility still further, looking toward ambulatory ECMO or even implantable lungs in an process analogous to the development of LVADs and artificial hearts over the last 2 decades.</p> <p>Despite the considerable costs of ECMO treatment prior to lung transplantation, the surgical transplant team in Harefield is convinced that ECMO remains a fundamental treatment concept in lung transplantation, in particular for patients with unforeseen rapid deterioration.</p> <p>We had the opportunity to discuss this topic at the last ISHLT with colleagues from the US and Europe. They all understood the concerns of NHSBT but agree with us that ignoring the individual benefit based only on cost will not serve the need of our patients and in particular the national needs to have one of the most successful and leading lung transplant services in the world.</p>	<p>Comments noted.</p> <p>If the policy were approved for routine commissioning it is not anticipated that it would lead to an increase in organ utilisation or organ availability.</p> <p>ECMO has been in use in the UK for a considerable number of years. The PWG did not agree that the modelling of costs should reflect a possible reduction over time, this did not seem realistic.</p> <p>Noted</p> <p>Noted. No evidence that NHS BT have concerns, the SULAS is based on ECMO becoming an available treatment.</p>	<p>Comments noted no action</p>

<p>British Thoracic Society</p>	<p>2 - up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period</p> <p>The statement and evidence review clearly state that ECMO provides an effective bridge to transplantation; subsequent outcomes are not dissimilar to unbridged lung transplantation.</p> <p>This service will alter which patients are transplanted; it is “instead of” rather than “as well as” and targets specific patient groups. In a public consultation there are a few points that it would be helpful to highlight clearly in the introduction / summary.</p> <p>Commissioning an ECMO service will:</p> <ul style="list-style-type: none"> a) Mitigate some of the inequity in the comparative rates of transplantation for patients with pulmonary fibrosis. Due to the rapid rate of progression of their underlying condition, these patients are less likely to undergo lung transplantation once listed. b) Increase the proportion of younger patients transplanted (cystic fibrosis). c) Probably improve life-years gained once non-transplanted patients are considered. There are a finite number of donor lungs, thus the cost of transplanting one patient is not transplanting another. The survival of patients suitable for ECMO as a bridge to transplant will be exceptionally short if ECMO is not provided and markedly shorter than non-urgent listed patients. d) This is a very expensive intervention suitable for a very small number of patients; a robust health economic assessment should be part of early service provision. e) Older patients with COPD are unlikely to benefit and may be disadvantaged. <p>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?</p> <p>Commissioning an ECMO service will mitigate some of the inequity in the comparative rates of transplantation for patients with pulmonary fibrosis. Due to the rapid rate of progression of their underlying condition, these patients are less likely to undergo lung transplantation once listed.</p>	<p>Noted</p> <p>Agreed that it would be helpful to provide additional background information to support public consultation as for stakeholder consultation.</p> <p>Organ allocation to patients under the NULAS is examined by the LAWG through CTAG and is under rolling review in that committee and will not be affected by the SULAS and ECMO bridging as discussed in CTAG Sept 19.</p> <p>The PWG note the potential for positive impact for PF patients and the positive impact the SULAS should have on access to transplant for this group</p>	
---------------------------------	--	--	--

	<p>Patients with cystic fibrosis currently have a good chance of receiving a transplant, which will be further increased by provision of ECMO as a bridge to transplantation. Of note they are also considerably younger than other diagnostic groups.</p> <p>This will be at the expense of not transplanting some patients on the non-urgent list, and almost certainly will reduce the number of patients with COPD receiving a transplant - they are very unlikely to be considered for ECMO, but some will not be transplanted as a consequence of transplanting ECMO bridged patients.</p> <p>The need for ECMO BTT signifies a failure in the organ allocation system in the UK. There are more organ donors than people waiting for lung transplantation and yet we have a 20-25% mortality rate for people on the lung transplant waiting list. Less than 20% of donors have their lungs used for transplantation and addressing this issue would reduce the likelihood of needing ECMO BTT support.</p> <p>If NHS England are considering the commissioning of ECMO BTT for highly selected patients, NHS England should consider ex-vivo lung perfusion (EVLP) instead of or as well as ECMO BTT. EVLP is a technology to increase the utilisation of donor lungs which are currently deemed unsuitable. The success of the ECMO BTT programme at Harefield has been in part also due to the fact they have EVLP available as well which is funded from non-NHS resources.</p> <p>Increasing access to EVLP would increase the total number of transplants being received and improve the overall mortality rate more than ECMO BTT.</p> <p>Although equity of access is an important principal to protect then it should be interpreted as equal access to ECMO BTT for any eligible patient independent of where they live or which transplant centre they are registered at. It should not mean all patients waiting for lung transplant should have equitable access to ECMO BTT in the event of acute life-threatening deterioration. There should be clear eligibility criteria based on published evidence of highest chance of success.</p>	<p>of patients given the potential for rapid clinical decline.</p> <p>Noted, agree</p> <p>Noted, though out of scope of this policy proposition and consultation.</p> <p>Out of Scope. NHSBT responsible commissioner for organ perfusion.</p> <p>The PWG feel that the policy as written with careful ongoing monitoring and discussion between centres will achieve this aim.</p>	
--	--	---	--

	<p>Some large centres in Europe have dramatically changed their criteria for access to ECMO BTT to maximise the chance of success and this means excluding some patients whose route should be to end of life support rather than ECMO BTT.</p> <p>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?</p> <p>This will probably increase life-years gained once non-transplanted patients are considered. There are a finite number of donor lungs, thus the cost of transplanting one patient is not transplanting another. The survival of patients suitable for ECMO as a bridge to transplant will be exceptionally short if ECMO is not provided and markedly shorter than patients on the non-urgent list (the trade).</p> <p>The prioritisation of patients on ECMO to receive the next available organ is intuitive as their need is greatest but it also means a longer wait for others not on the super-urgent list. There must be care taken to ensure there is not a drift to increased use of ECMO BTT as more and more patients fail to get organs while on non-urgent or urgent waiting lists.</p> <p>It is also essential that strict selection criteria for ECMO BTT are developed which can be objectively audited. There is a chance without this that there is a fall off in post transplant survival after ECMO BTT if inappropriate patients are accessing this and thus donor organs diverted to patients with a significantly worse chance of survival compared to those with a good chance of 5 year survival on the non-urgent waiting list.</p> <p>NHS England could consider the wider provision of ex vivo lung perfusion alongside or instead of ECMO BTT as this is likely to result in a more equitable availability of organs and improve outcomes for lung transplant patients on all lists and at all transplant centres.</p>	<p>Noted</p> <p>This issue is one that guided the discussion of the PWG, how to ensure a consistent approach across the country balanced the needs of patients who would benefit from use of ECMO and the wider waiting list, maintaining a SULAS which ensures average waits don't increase.</p> <p>The PWG discussed this at length and developed criteria set out in the draft policy. Retrospective audit and discussion of cases is planned to take place at CTAG Lungs and the Cardiothoracic transplant service's annual clinical meeting. Audit criteria will also be subject to review to ensure services are collecting the most relevant information.</p> <p>Out of Scope. NHSBT has the commissioning responsibility for perfusion technologies. NHS England to discuss further with NHS BT.</p>	
--	---	--	--

<p>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?</p> <p>Advantages of a commissioned ECMO service include mitigating some of the inequity in access to transplant for patients with pulmonary fibrosis. Patients with cystic fibrosis are younger, are also likely to be considered for ECMO and will also benefit from the service. As noted above, patients with COPD are very unlikely to be considered for ECMO. As the number of donor lungs is finite introducing an ECMO service will come at the expense of the COPD population (fewer will receive a transplant).</p> <p>At present the policy as described does not make it clear that only patients who have previously been formally accessed and accepted onto an active lung transplant waiting list would be eligible for consideration of ECMO BTT.</p> <p>The flow diagram implies this but the description of eligibility does not describe this requirement. This is essential as it would not be appropriate to offer ECMO BTT to a patient with chronic severe lung disease who has an acute life-threatening deterioration but has not previously been referred for lung transplantation, fully assessed, counselled and consented and on an active lung transplant waiting list.</p> <p>Do you have a comment on whether this policy will advantage or disadvantage older patients on the waiting list?</p> <p>Older patients with pulmonary fibrosis will gain an advantage; this mitigates some of the current inequity in transplantation for this group.</p> <p>Older patients with COPD will be disadvantaged (be less likely to receive a transplant).</p> <p>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?</p> <p>The ECMO bridged population would not otherwise survive to transplantation, so their likelihood of receiving a transplant will improve dramatically (from virtually</p>	<p>Only patients who have been formally accessed and accepted onto an active lung transplant waiting list would be eligible for consideration of ECMO BTT. The policy is clear (section 9) that this pathway begins once the patient is on the waiting list for a lung transplant (registered on the non-urgent or urgent scheme) under the care of a cardiothoracic transplant centre.</p> <p>PWG discussed these potential impacts in their development of the policy.</p>	<p>Eligibility section of the policy edited to make this clear</p> <p>No action</p>
--	--	---

<p>zero). To optimise outcomes, including limiting complications (and costs), they must go to the front of the list.</p> <p>Although equity of access is an important principle to protect then it should be interpreted as equal access to ECMO BTT for any eligible patient independent of where they live or which transplant centre they are registered at. It should not mean all patients waiting for lung transplant should have equitable access to ECMO BTT in the event of acute life-threatening deterioration. There should be clear eligibility criteria based on published evidence of highest chance of success. Some large centres in Europe have dramatically changed their criteria for access to ECMO BTT to maximise the chance of success and this means excluding some patients whose route should be to end of life support rather than ECMO BTT.</p> <p>NHS England could consider ex vivo lung perfusion as well or instead of ECMO BTT which is more likely to improve access to organs for all.</p> <p>Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.</p> <p>The following is better regarded as logical deduction, rather than evidence.</p> <p>An ECMO service will probably improve life-years gained once non-transplanted patients are considered. There are a finite number of donor lungs, thus the cost of transplanting one patient is not transplanting another. The survival of patients suitable for ECMO as a bridge to transplantation will be exceptionally short if ECMO is not provided, and markedly shorter than non-urgent listed patients who may not be transplanted as a consequence of establishing an ECMO service. The issue of current donor utilisation rates for lung transplantation should have also been visited as this is intrinsically linked to the need for ECMO BTT. Without doing this – only half the picture is being examined and resources may be more effective if also targeted at increasing organ utilisation rates. The UK has some of the lowest donor lung utilisation rates in the world.</p> <p>Do you have any further comments on the policy proposition document? YES</p>	<p>PWG discussed these potential impacts in their development of the policy. It is unlikely that the financial model will be able to reflect possible comparative costs.</p> <p>Out of Scope. NHSBT has the commissioning responsibility for perfusion technologies. NHS England to discuss further with NHS BT.</p> <p>Out of Scope. Within NHS BT’s remit. NHS England is engaged with NHS BT and other stakeholders in discussion on organ utilisation.</p>	<p>For consideration in financial model</p>
---	--	---

	<p>If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'. At present the policy as described does not make it clear that only patients who have previously been formally assessed and accepted onto an active lung transplant waiting list would be eligible for consideration of ECMO BTT.</p> <p>The flow diagram implies this but the description of eligibility does not describe this requirement. This is essential as it would not be appropriate to offer ECMO BTT to a patient with chronic severe lung disease who has an acute life-threatening deterioration but has not previously been referred for lung transplantation, fully assessed, counselled and consented and on an active lung transplant waiting list.</p>	<p>PWG agree it would be helpful to make this requirement clear in the text of the policy</p>	<p>Section 9 of the policy has been edited to make this clear</p>
<p>Individual</p>	<p>1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 4 week consultation ☑</p> <p>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?</p> <p>Strict Clinical Governance around individual Consultant & MDT decisions needs to be put in place to ensure that the pathway is followed to the letter.</p> <p>With regard to 9. Proposed Patient Pathway the last box in the bottom right hand corner is incomplete. It reads 'Patient is not placed on ECMO and remains on non-urgent or...' ???</p> <p>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?</p>	<p>Retrospective audit and discussion of cases is planned to take place at Cardiothoracic transplant service's annual clinical meeting. Data will be discussed at CTAG Lungs and published in the CTAG papers and in the Cardiothoracic transplant annual report including data on geographic access.</p> <p>Thank you, noted.</p>	<p>Policy reformatted</p>

<p>13. Proposed Audit Requirements (need to correct bullet point 4 and change to Period of Dialysis if required)</p> <p>I feel that in order to audit and review the commissioning guidelines in the future the audit needs to be broken down into age ranges and an additional category added namely Age of Recipient.</p> <p>This would clearly demonstrate whether or not any ageism had occurred pre and post adoption of the ECMO pathway and give reassurance that clinicians' decisions were based on expected 'survivability'.</p> <p>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?</p> <p>If I read the pathway correctly adoption of ECMO will result in the most ill patients receiving priority and whilst I acknowledge that this will save lives strict Clinical Governance Protocols and MDT decisions need to be transparent to ensure that others left on the waiting list are assured that the ECMO recipient have been chosen on the pure grounds of clinical need.</p> <p>This should be overseen by the Medical Director and a Non Executive Director at each participating Trust.</p> <p>Do you have a comment on whether this policy will advantage or disadvantage older patients on the waiting list?</p> <p>As I have stated above I think that the Ages of (anonymised) Recipients need to be recorded as an additional bullet point in Section 12.</p> <p>If it turns out that very few older people receive ECMO that fact needs to be acknowledged and perhaps publicised so that Consultants can have an honest conversation with candidates on the waiting list that their chances of ECMO are slim so that patients can come to terms with that fact. However, relatives of organ donors may question the rationale of organs being donated to younger recipients where the reported failure rate is 30% and the success or failure of ECMO needs to be reported upon.</p>	<p>Thank you noted</p> <p>Agreed that this is an important requirement for audit</p> <p>The intention is to audit at a patient level, small numbers will allow this</p> <p>Oversight will be according to existing trust governance mechanisms and reporting to NHSBT and NHS England</p> <p>PWG agreed that this information will be reported</p> <p>When consenting patients for transplant this option of ECMO would be discussed, however of course it is expected that small numbers of patients will deteriorate on the waiting list to the degree where they would be considered for ECMO. 90% of lung transplants will continue to</p>	<p>Policy edited</p> <p>Policy edited to be clear that age of patient and clinical history will be recorded and reported at CTAG lung and presented to the Cardiothoracic Transplant annual clinical meeting</p>
---	--	--

	<p>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?</p> <p>I assume this question relates to lung transplants. It seems clear from the Proposed Patient Pathway that patients suffering ‘acute deterioration’ will be first in line for ECMO. The NHS needs to ensure that there is a common currency across all sites as to the definition of ‘Acute Deterioration’ and this is not misused or misinterpreted. If there was not a common understanding of this term it could disadvantage certain patients whose clinicians had a different definition of Acute Deterioration.</p> <p>There is a need to ensure that there is no discrimination as to the background, ethnicity or means of the recipients of ECMO.</p> <p>Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.</p> <p>It would have been helpful to have more data from other countries as to the effectiveness, value for money, implications on ITUs, especially paediatric centres, to support the adoption of the policy proposition (or not).</p>	<p>be in patients on the urgent or non-urgent waiting list.</p> <p>This is an important point for consideration and the PWG have described the clinical pathway as far as possible. Access to ECMO and outcomes for patients will need to be monitored closely.</p> <p>Noted, NHS England requires services to comply with its duty with regard to equality regulation and policies are written accordingly.</p> <p>The evidence review was limited only to published evidence from peer reviewed publications in the English language in the past 10 years. The evidence review included data that was available according to these criteria. Opinion pieces / editorials were excluded from the literature review for ECMO BTT by standard review processes. They are the only current reports on providing these services and where available although undoubtedly biased and supportive of a treatment that has good outcomes for patients with a 100% expected mortality. The following outcomes were reviewed: Critical to decision-making:</p>	
--	---	---	--

	<p>Do you have any further comments on the policy proposition document?</p> <p>2. YES: The Governance Section (10) seems to be very 'light' and needs expanding.</p> <p>The highly specialised Lung Transplant providers need to put in place rigorous checks and balances around the recipients and auditing of ECMO.</p> <p>It is not clear whether ECMO takes place on the same grounds in Scotland Wales and Northern Ireland. The repercussions on pressure on English providers needs to be evaluated were patients to move to get the treatment.</p>	<p>Survival to transplant Overall survival at 1 and 5 years Quality of life during the period of bridge to transplant and after transplant</p> <p>Important to decision-making: Adverse events including thrombosis, haemorrhage and infection Duration of ECMO (or ILA) Length of stay post transplant, both in intensive care and overall Cost effectiveness</p> <p>Discussion about bench marking or comparison with other countries was raised at the recent NHSBT lung utilisation meeting and may form part of an approach to improving UK services.</p> <p>Retrospective audit and discussion of cases is planned to take place at Cardiothoracic transplant service's annual clinical meeting. Data will be discussed at CTAG Lungs and published in the CTAG papers and in the Cardiothoracic transplant annual report including data on geographic access. The policy can be reviewed at any point. If significant evidence is published sooner this review can be brought forward in order for this to be considered.</p> <p>There are no lung transplants units in Scotland Wales and Northern Ireland.</p>	
--	--	---	--

	<p>If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial ‘sense check’.</p> <p>The policy was written in plain English, easy to understand and jargon free. It was disappointing that the chart of the pathway was incomplete.</p> <p>Please declare any conflict of interests relating to this document or service area. None.</p>	<p>The decision about access to ECMO as a bridge to lung transplant is for the administrations of these countries to agree. Based on available data this might relate to c4 patients/year across the 5 transplant units so won't impact on capacity to manage, though recognising that these are busy units and the demands placed on CICU beds.</p> <p>The box has been reformatted to stop this happening again when pdf'd.</p>	
<p>Non Profit Professional</p>	<p>1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 4 week consultation</p> <p>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? n/a</p> <p>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? no</p> <p>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? no</p> <p>Do you have a comment on whether this policy will advantage or disadvantage older patients on the waiting list? Disadvantages relating to trauma and other physical complications</p> <p>Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details. n/a</p>	<p>All comments noted by the PWG and assumed supportive of the policy as written</p>	<p>No action</p>

	<p>Do you have any further comments on the policy proposition document?</p> <p>1. NO</p>		
Individual	<p>1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 4 week consultation</p> <p>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?</p> <p>As a result of this policy one aspect of transplanting might be improved certainly. Looking at the organ use associated with lung transplants recorded by CTAG18 within the period 18th May to 17th March, drew attention to transplants requiring more than one organ type. One patient of the urgent and super-urgent groups required a liver as well as a lung and six patients used a heart as well as lungs. Whether within the new scheme or the previous scheme, whenever a multi-organ demand occurs there is the denial of tissue to others. I see that: 'Where patients are considered for multi-organ transplants, they should be accepted for all organs by the appropriate MDT in the hospital. Some patients needing multi-organ transplants may not meet the agreed selection criteria for all organs (for example, a patient who needs a heart transplant and with impaired renal function may need both heart and kidney transplants as the impact of surgery and medication will result in irreversible loss of kidney function). In such situations where the individual organ-specific indications are not met, the listing should be approved through the relevant Appeals/Arbitration panel.' Nevertheless one heart lung block could in theory keep 3 patients of various sizes alive. Perhaps with the improved communications envisaged by the new system there could be enough flexibility by deploying ECMO across all the UK centres because of situations like this where the patient does not have the super-urgency category for all the tissues they are taking.</p> <p>I have seen the distribution policy. i.e. POL230/10 Donor Lung Distribution and Allocation and see that a centre using a heart & lung unit would be rotated to the bottom of both heart & lung rotas. I couldn't access POL 228 for multi-organ or 200.</p>	<p>Access to the SULAS is only for patients needing a single or double lung or a heart/lung transplant.</p> <p>Patients who need a multi-organ transplant are not eligible for super-urgent listing.</p> <p>POL 228 Heart Transplantation: Organ Allocation is on the ODT website: http://odt.nhs.uk/pdf/heart_allocation_policy.pdf</p> <p>POLICY POL200 Introduction To Patient Selection And Organ Allocation Policies</p>	No action

	<p>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?</p> <p>Yes but there are several aspects to this. First off is the idea of maximising survival for as many as possible. To do this we turn to the youngest (e.g. CF) and the medically fittest (this would reduce the CF list) and forget all the old people and people who need more than one organ. Instead we have queuing with queue jumping by worsening condition which is much more civilised but in doing this we must face a shortage of not only donors but adequately trained & experienced staff and equipment.</p> <p>Kourliouros (2018) addressed the question of whether disease type made a difference in the progression towards successful transplantation and it appears that those worse off are Group O, short of stature and suffering from either CF or PF. This should be correctable with attention to Group O and careful review of the respiratory categories under the new system.</p> <p>If the category criteria cannot solve the inequality there are two options: ignore the type of disease as just bad luck or monitor the percentages of occurrence of the different diseases and weight the respiratory categories accordingly. I suspect the latter view would be more ethical because the data itself indicates unfairness; it is not one patient that has been denied but a whole cohort by disease type. It is not the surgeon's fault that a patient has PF instead of COPD but should you lose your life because you are short of stature? Somehow these aspects of the cohort have to be taken into account. Why is it that tall people do better?</p> <p>If some patients are to be prioritised at the possible expense of others on the general waiting list it is important to try to predict how successful their procedures would be.</p> <p>1. The success rate (and quality of life) for patients in the urgent and super-urgent categories.</p>	<p>https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/12777/introduction-to-selection-and-allocation-policies-pol200.pdf</p> <p>The PWG felt that the policy reflected use of a technology in which all centres are experienced in the use of. ECMO is used post operatively. The policy would have to be funded but in itself was unlikely to have a significant impact on staffing and equipment at any one centre.</p> <p>Revisions to the lung allocation scheme and waiting list criteria are agreed by NHS BT and take account of any developments in evidence as well as transplant access and outcomes data.</p>	
--	---	--	--

<p>The evidence for the near equivalent survival of lung transplant in the ECMO-BTT category compared to the non-supported group is fairly convincing, but the additional complications arising after commitment of the tissue prior to, during and after transplantation are relevant.</p> <p>Tipograf's study¹ of this year is relevant although non-UK since it addresses this problem directly. A total of 70/121 (59%) adult patients were successfully bridged to lung transplantation using ECMO BTT.</p> <p>'Simplified Acute Physiology Score II, unplanned endotracheal intubation, renal replacement therapy, and cerebrovascular accident were identified as independent predictors of unsuccessful BTT. Ambulation was the only independent predictor of successful BTT (odds ratio, 7.579; 95% confidence interval, 2.158 to 26.615; p = 0.002). Among the 64 patients (91%) who survived to hospital discharge, survival was 88% at 1 year and 83% at 3 years. Propensity matching between BTT and non-BTT lung transplant recipients did not show a significant difference in survival (log-rank = 0.53) despite significant differences in the lung allocation score (median, 92.2 [interquartile range, 89.0 to 94.2] vs 49.6 [interquartile range, 40.6 to 72.3], p < 0.01).</p> <p>Conclusions ECMO can be used successfully to bridge patients with end-stage lung disease to lung transplantation. When implemented by an experienced team with adherence to stringent protocols and patient selection, outcomes in BTT patients were comparable to patients who did not receive pre-transplant support.'</p> <p>1 Yuliya Tipograf, Michael Salna, Elizaveta Minko, Eric L. Grogan. Outcomes of Extracorporeal Membrane Oxygenation as a Bridge to Lung Transplantation. The Annals of Thoracic Surgery, General Thoracic Surgery, May 2019, Volume 107, Issue 5, Pages 1456–1463.</p> <p>Additionally, it is reasonable to assume that further improvements to procedures associated with lung transplantation may continue and the more procedures that are carried out now will inform that learning process. Any increase in donations would help.</p> <p>2. The rate of supply of donated tissue.</p>	<p>The policy acknowledges these outcomes and includes the criteria that adult patients can only receive ECMO support while conscious and self-ventilating.</p> <p>Although this is a technique not available widely in the NHS, all transplant centres have experience of use of ECMO in the transplant pathway, so no particular requirements to additional expertise have been included in the policy.</p>	
--	---	--

	<p>The opt-out system for donations is expected to come into effect in May 2020 and is likely to increase the amount of all types of tissue available.² Therefore the emphasis could move towards anticipating the need for the establishment of another centre with an option of an additional one in the future. The locations should reflect the population density and the geographical location of existing centres across all of the UK. It has also been recognised that transport specialists work best as experienced well-integrated 'teams' where all the finer procedural details are well known and adhered to so early training to gain experience is important.</p> <p>A middle of the road estimate for additional transplants likely to result from the opt-out system seems to be surprisingly low at 100, unless there is a marked swing in public opinion.</p> <p>Information from Wales where the system has been started would have been interesting as it might account for some of the estimated 21 patients requiring ECMO/yr in the UK.</p> <p>2Is an opt-out system likely to increase organ donation? BMJ 2019;364:l967</p> <p>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?</p> <p>This policy clearly has an enormous impact on those treated on ECMO but it should be cautioned that the outcome of the transplant may not be all that is desired. There are still suicides post transplant. Although the problematic consequences of ECMO are being addressed, particularly by the recognition that awake and as far as possible, ambulatory ECMO, is better than sedated ECMO, the duration of ECMO BTT is also critical. Without the super-urgent and urgent categorisations there is little hope for the patients in this category.</p> <p>Since the donated material is offered specifically to super-urgent and urgent cases, the necessity of both super-urgent and urgent categories could be questioned. Presumably the super-urgent category reflects the many other factors such as time on ECMO, whether there has been a change from venovenous ECMO to venoarterial ECMO for example and the proximity of removal from the list.</p>	<p>Geographic access to transplantation is monitored as is capacity in transplant units. There is no view that additional lung transplant capacity is required in England at this time. The impact of Opt Out is being modelled and will be kept under review.</p> <p>The policy describes the use of ECMO in super urgently listed patients only.</p>	<p>The summary commissioning section of the policy has been</p>
--	---	--	---

	<p>Do you have a comment on whether this policy will advantage or disadvantage older patients on the waiting list?</p> <p>Besides special cases there are 'generally accepted' age-related contraindications and these have been developed in the USA in relation to their emphasis on 'life years' and 'good innings'. In the UK the transplant process is properly orientated towards the survival of the young who have more life to live. This does not make it easier for the elderly of course. My own father died because the only surgeon available chose to save a baby.</p> <p>The procedure will disadvantage the elderly if they must continue to wait their turn while the point where transplantation would be unproductive approaches. Their last days could be spent on longer ECMO while they continue to hope. For such cases it could be productive in advance to review the reasons why donations are declined. If tissue has been declined because of the age of donor or because of some medical manifestation unlikely to be of much consequence to such a patient perhaps it could still be considered. It is important to ensure that the provision of transplants keeps pace with the number of good donations available so the process does not in effect become a cull of the elderly in need of a transplant. There is a view in the Courtwright paper³</p> <p>'8.2 Relative Contraindications</p> <p>The importance of potential contraindications should be discussed openly between all members of the transplant team and interpreted with clinical judgement on a case by case basis:</p> <p>'Patients over 60 years of age will need careful evaluation but age per se is not a contraindication to listing. Age, however, is an independent risk factor for peri-operative morbidity and mortality, and evidence exists that older patients have worse short- and medium-term survival, likely due to comorbidities. The presence of other relative contraindications can combine to increase the risks of transplantation above a safe threshold. Individual cases will be assessed on their merit but patient age will be a factor in candidate selection. The International Society for Heart and Lung Transplantation proposed a guideline of less than 60 years of age for a bilateral lung and heart-lung transplant and less than 65 years for single lung transplant but this does not obviate the need for assessment of each patient and a decision based on that individual.'</p>	<p>NHS England will continue to work with NHSBT and the transplant units to improve lung utilisation in order that more patients can be transplanted.</p> <p>The PWG agree this is important and decision making for each case will be discussed at the cardiothoracic annual clinical meeting and shared with other centres to support consistency and sharing across centres to support consistent decision making. Outcomes are under continuous monitoring by NHSE and NHSBT through CTAG.</p> <p>If agreed this policy will allow for access to ECMO according to the criteria set out in the policy but also in accordance with NHS BT patient allocation criteria and the NHS England service specification for adult lung transplantation.</p> <p>The SULAS criteria are as follows:</p>	<p>edited to clarify this is a proposal to treat patients who need to be urgently listed.</p>
--	--	--	---

<p>3Lung transplantation in elderly patients Andrew Courtwright¹, Edward Cantu² J Thorac Dis 2017;9(9):3346-3351</p> <p>Also in a US study by Sreeja Biswas Roy⁴, Lung transplantation in patients older than 65 years is increasingly common, but questions remain regarding risk vs benefit and procedure choice. We identified short-term and long-term outcomes in older single-lung transplant (SLT) and bilateral-lung transplant (BLT) recipients. We performed a retrospective review of United Network for Organ Sharing data for patients who underwent lung transplantation between May 2005 and December 2012. Patients were grouped by age, and we calculated short-term and long-term survival rates and compared survival distributions. Of the 11,776 patients who received lung transplants, 9,317 (79%) were aged 12 to 64 years, 1,902 (16%) were 65 to 69, 486 (4%) were 70 to 74, and 71 (1%) were 75 to 79. Short-term survival was similar across all age groups and procedure types except those aged 75 to 79, who had lower short-term survival for BLT. Those aged 12 to 64 had higher 5-year survival for SLT and BLT than all other groups ($p < 0.001$), and BLT offered a long-term survival advantage over SLT in this group ($p < 0.0001$). Older age groups trended toward better long-term survival for BLT compared with SLT (65 to 69, $p = 0.059$; 70 to 74, $p = 0.079$). Although data were lacking for 5-year survival for those aged 75 to 79, the 3-year survival for BLT in this group was inferior. Lung transplant can be offered to select older patients up to age 74 with acceptable outcomes. SLT may be preferred for elderly patients, but BLT offers acceptable long-term outcomes without significant short-term risk. Patients older than 75 have acceptable short-term outcomes for SLT, but long-term outcomes for SLT and BLT in this group are poor. Copyright © 2015 The Society of Thoracic Surgeons. Published by Elsevier Inc. All rights reserved.⁴Sreeja Biswas Roy The Annals of thoracic surgery 100(2) · June 2015</p> <p>My view is that although prioritising for the young in transplants is essential the patient's personal characteristics can contribute to choosing between two people. I would consider the slightly older person if they exhibited considerably more determination and fight and their understanding of what was required coloured their outlook sufficiently positively. The mere fight to survive isn't enough but it can make a small difference.</p>	<p>Super-Urgent Lung Allocation Scheme (SULAS): Only patients already known to the local transplant team, having been fully assessed and deemed suitable transplant candidates, already registered on the urgent or non-urgent scheme, and who subsequently suffer acute deterioration requiring extracorporeal support to bridge them to donor organ availability are eligible for SULAS registration. Patients should be removed from the list when the local MDT concludes the patient does not have a reasonable chance of intermediate survival; for example, 50% probability of surviving 3-5 years post-transplant.</p>	
--	--	--

<p>Additionally, If the donations increase more than presently predicted there may be opportunities to provide donated tissue of an age that matches the recipient. I have not noticed any discussion on this point in the information supplied. The question has certainly been asked elsewhere with respect to both kidney and lung.</p> <p>J Am Soc Nephrol. 2004 Apr;15(4):1086-91. Effect of donor recipient age match on survival after first deceased donor renal transplantation. Keith DS1, Demattos A, Golconda M, Prather J, Norman D.</p> <p>Ann Thorac Surg. 2019 Mar;107(3):868-876. doi: 10.1016/j.athoracsur.2018.09.066. Epub 2018 Nov 13. The Impact of Donor and Recipient Age: Older Lung Transplant Recipients Do Not Require Younger Lungs. Hall DJ1, Jeng EI1, Gregg JA2, Pelaez A3, Emtiazjoo AM3, Chandrashekar S3, Pipkin M1, Beaver TM1, Machuca TN4.</p> <p>In the latest data I could find for the new system 31 lungs were declined because of age of donor. Perhaps the reasons for declining lungs could be reviewed to determine whether any would still have been suitable for the elderly who may demand less from them for three years.</p> <p>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?</p> <p>This is a repeated question. If it asks about the impact of elderly patients proceeding through ECMO BTT there will be denial to more patients on the waiting list because the list will be longer. More elderly patients in the future implies more elderly patients on ECMO and perhaps for some, longer on ECMO. This will disadvantage patients suffering from serious conditions that emerge in younger patients (ie. CF).</p> <p>If more donations do not solve this problem and there is shown to be irremediable unfairness in this regard perhaps a further category could be considered. Such a group might include young ARDS patients that remain on ECMO; it would offer a</p>	<p>NHS BT continue to work to improve lung utilisation. A fellow is currently working on defining the ideal lung?</p> <p>Noted. This issue was considered in the work up of the policy and the request for ethics input into decision making.</p>	
--	---	--

	<p>less restricted pathway for them if they had exceptional prospects in terms of life to live.</p> <p>Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.</p> <p>I don't recall much collaboration between English, Welsh and Scottish transplant teams and any experiences they have had with ECMO although it was clear that donations are even obtained from Gibraltar. I would have expected some notable contributions from Wales and Scotland in this area.</p> <p>In the various conditions treatment outcomes can vary greatly between the sexes. I don't recall this being considered.</p> <p>The following document gives an idea of the scale of the financial accommodation required.</p> <p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731915/Organ_donation_impact_assessment.pdf</p>	<p>There are no lung transplants units in Scotland Wales and Northern Ireland.</p> <p>The decision about access to ECMO as a bridge to lung transplant is for the administrations of these countries to agree.</p> <p>PWG noted this comment, data would contribute continuous outcome monitoring</p> <p>This document is the DHSC impact assessment on Opt Out which NHS England contributed to.</p>	<p>PWG have asked NHSBT to review the data available specifically relating to variation between sexes</p>
<p>Association of Respiratory Nurse Specialists</p>	<p>I think there would need the extended period to look at costs/provision sites and anticipated numbers and criteria</p>	<p>Noted. The stakeholder consultation provides an opportunity for suggestions to be made to strengthen the criteria. Further comments can be made including during public consultation. Impact work is underway in parallel considering costs and patient numbers. This information will be included in the public consultation information for comment.</p>	<p>No action</p>

<p>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? There would have to be very strict criteria. There would be significant costs-where would the treatment be cased? equity of access to organs: for a long time patients awaiting transplant don't ever stand much of a chance unless on the urgent list.....by creating a super urgent list those patients will now stand less of a chance.</p> <p>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? If patients on ECMO get priority then someone who is waiting longer may be jeopardised-inequality as to get on the list means they are very unwell and if they then deteriorate would end up on ECMO</p> <p>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?</p> <p>The main issue is lack of suitable donors-this will not improve so non ECMO patients would face longer waits.</p> <p>ECMO is expensive and carries a higher mortality rate in those that have transplants than those who do not go on to ECMO first. Do we need to consider a window of opportunity here? The longer someone is on ECMO the less successful transplant and therefore is it reasonable to use organs with a smaller chance of success? Especially when someone on the urgent list would have an 80% chance of survival.</p> <p>Could you end up with many patients on ECMO all over the country when projected number of organs would never meet the ECMO demand – they'll end up dying anyway, probably in hospital (maybe in an ITU – assume this is where ECMO would be used) – is this how people would choose to die?</p>	<p>The PWG note this as a consequence of a higher urgency list.</p> <p>Noted</p> <p>Noted</p> <p>The evidence review reported data on 1, 3- and 5-year survival. The rate of survival reported is no worse in critically ill patients requiring ECMO compared with less ill patients who survive to transplant without ECMO bridging support.</p> <p>The intention behind the criteria is that this limits use of ECMO to a small high-risk well-defined cohort of patients. The intention is not to offer ECMO to so many patients that this then results in the likelihood of a transplant being educed and the waiting time increasing to the point when a transplant would prove futile. This has been a</p>	
--	--	--

	<p>Do you have a comment on whether this policy will advantage or disadvantage older patients on the waiting list?</p> <p>If ECMO is mainly aimed at younger patients then yes it will disadvantage older patients. Each patient must be looked at individually but if the decision is to not give ECMO over a certain age this would be reducing their chance of getting a transplant.</p> <p>As older patients are unlikely to get ECMO and therefore potentially will be on the list longer, unlikely to get an organ this would disadvantage them. If age is a cut off for transplant as outcomes are not as good and the projected life years gained would be less but the attached document seems to imply that the older person is already being declined ECMO – Will this be based on outcomes and not age!</p> <p>Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.</p> <p>Would there be more hospitals able to do ECMO-assuming patients on ECMO would need to be hospitalised-is there the capacity for this-do they need ITU/HDU care.</p> <p>What training would be needed?</p> <p>If ECMO patients have 20% less chance of transplant being successful is this appropriate use of organs</p> <p>How do we increase the number of donors so more available</p> <p>Do we prioritise genetic conditions-CFibrosis?</p> <p>Do you have any further comments on the policy proposition document?</p> <p>1. NO</p> <p>If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial ‘sense check’.</p> <p>The expense would seem to be an issue – there also be added expense as additional resources would be needed for the other non-transplant patients who’d have ECMO if these units become tied. Have we got enough critical care beds for these extra patients (again assuming it’s delivered here) or would the knock on</p>	<p>significant issue for consideration in drafting the policy.</p> <p>The criteria are not age related. The service specification for the adult lung transplantation service describes that all patients must be biologically fit, regardless of age. In practice, most recipients are less than 65 years of age as there is an increase in co-morbidity with the ageing process.</p> <p>The adult transplant centres would be required to offer capacity to manage patients on ECMO pre-transplant according to the estimate of numbers in the policy proposition.</p> <p>The evidence review reported data on 1, 3- and 5-year survival. The rate of survival reported is no worse in critically ill patients requiring ECMO compared with less ill patients who survive to transplant without ECMO bridging support.</p> <p>Respiratory ECMO is provided and funded as a separate service. Access to beds in transplant units is of course an issue for consideration, the PWG has developed the criteria to ensure ECMO</p>	
--	--	---	--

	effect be tying up existing beds resulting in other patients not getting their surgery?	is used on only a small number of patients for a short time. Retrospective audit and discussion of cases will help understanding of the impact of implementing this policy.	
Cystic Fibrosis Medical Association Lung Transplant Working	<p>Cystic Fibrosis Medical Association Lung Transplant Working Group is that we support the routine commissioning of ECMO as a bridge to lung transplantation to save the lives of individuals who need support to help then when there has been an unexpected 'dramatic' turn for the worse. However, although individuals with CF may benefit from this approach, we are concerned that there is a risk that, with injudicious use, ECMO may become the default option as a stepping stone to lung transplantation, which may result in worse overall outcomes and worse patient experiences. Thus we support its commissioning with the following provisos:</p> <ol style="list-style-type: none"> 1. that the same rules apply to all PWCF in England 2. that lung transplant centres seek to work with the devolved regions to ensure equity of access for all PWCF in all parts of the UK 3. that ECMO as BTLT is only for PWCF who are already on a lung transplant waiting list 4. that ECMO as BTLT is only for PWCF who experience a rapid, unexpected and sustained deterioration, and is not for cases of expected predictable disease progression 5. that steps are taken to ensure that data is collected and published on frequency of use of ECMO as BTLT, and on subsequent outcomes, as well as any taking any other necessary steps to ensure that proviso (4) does not come to pass. <p>We would also request that NHSE and NHSBT take steps to address the organ utilisation gap that exists between UK and some other European countries. By doing so, the need for ECMO could be reduced or even eliminated. Such a step may result in a far preferable situation where ECMO as BTLT was not required in the first place. We would be happy to work with NHSE and NHSBT to achieve this goal.</p>	<p>Noted</p> <p>The policy aims to ensure a consistent approach across all transplant services so access based on need and potential to benefit from treatment. Access for patients from Wales, Scotland and NI would have to be agreed This is included in the criteria</p> <p>Agreed it is important this information is made available, discussed and published.</p> <p>Out of Scope. Within NHS BT's remit. NHS England is engaged with NHS BT and other stakeholders in discussion on organ utilisation.</p>	The policy has been edited to make this clearer

1. Organ transplantation is transformative and lifesaving.
2. ECMO is a technology that already exists and is in use in some centres; it allows the sickest of potential lung transplant recipients to be kept alive, thereby opening access to lifesaving transplantation for this group of patients. As such, the use of ECMO permits the allocation of donor lungs to recipients who might otherwise not have survived.
3. The provision of ECMO in order to permit 'super-urgent' lung transplantation should therefore be seen as part of the lung allocation system as a whole.
4. All organ allocation systems involve a balance between utility and equity. Allocation systems that value utility prioritise the allocation of organs to those recipients who might be expected to derive the greatest benefit, or in whom graft survival might be expected to be the longest. In contrast, giving primacy to equity leads to allocation systems designed such that no individual group of patients is systematically disadvantaged in their access to organ transplants, even at the cost of inferior graft outcomes. As such, balancing the benefit to the individual with the benefit to the wider population (the waiting list as a whole) is an inherent feature of all organ allocation systems.
5. The impact on equity of a lung allocation system that incorporates the use of ECMO to enable a super-urgent allocation tier will ultimately depend on the numbers involved. If the numbers of patients who might need ECMO is relatively small, its impact on the wider waiting list may not be great: the effect of diverting a small number of donor lungs to a super-urgent category (facilitated by the use of ECMO) on waiting times and waiting list mortality for patients with diagnoses such as COPD may be anticipated to be relatively slight. This can, of course, be modelled based on anticipated patient numbers. It is worth also noting that the availability of ECMO as a bridge to transplantation in some, but not all, centres raises an important concern regarding equity of access.
6. Assessment of the impact of the use of ECMO on utility depends on a number of considerations:
 - If graft and patient survival were found to be significantly inferior in recipients who had been treated with ECMO prior to transplantation, a utility argument may be made against the use of donor lungs in this way. The panel has examined the available evidence in this regard.
 - However, as recipients requiring ECMO are likely to be younger, there is the potential for greater benefit from transplantation enabled through the use of ECMO.
 - The panel has considered whether the use of ECMO as a bridge to transplantation may be considered as an instance of 'the rescue rule' in healthcare resource allocation. As the demand for organs continues to outstrip supply, it is an unfortunate reality that patients die while waiting for a transplant; the prioritisation of patients most likely to die on the waiting list is an accepted feature of allocation systems for lungs, hearts and livers.
7. Any secondary consequences of widening access to ECMO as a bridge to lung transplantation also need to be considered. A concern may be raised that centres might be incentivised to lower the threshold for initiation of ECMO in order to facilitate

transplantation for certain individuals. This risk may be mitigated by the adoption of agreed criteria for ECMO initiation. In addition, there is evidence that introduction of the super-urgent allocation category has been associated with an increase in donor lung utilisation [1].

8. It is certain that organ support technologies such as ECMO will continue to develop. Any decisions regarding the role of organ support in transplant allocation systems need to be as 'futureproof' as possible.

9. As noted above, the fundamental problem in organ transplantation is the shortage of donor organs: it is this shortage that necessitates the balancing of competing priorities in allocating organs and in the care of potential recipients. It is important to note the efforts of the transplant community and the NHS as a whole to address this underlying problem.

Dr Refik Gökmen MA PhD FRCP
refik.gokmen@gstt.nhs.uk
On behalf of the BTS Ethics Committee

[1] The PWG would like to respond to one point raised here which is that use of ECMO has not been proven to have an overall effect on organ utilisation and is an advance in technology which is life saving for individuals untenable to not utilise in a modern health care setting.

Framing Comment	
This note is based on a short reading of NHS policy documents on the subject of transplantation; it is not a reflection of the authors opinion or of any lobby. It could possibly form the basis for further discussion but should not be read as recommendation for action. More interdisciplinary expert inputs would be needed on the points raised.	
1 Introduction	
1.1	It has been concluded that ECMO BTT is “reasonable” for the individual patient.
1.2	Concerns remain whether prioritising patients acutely ill for a lung transplant deprives others who may have an equal place in access to lung transplant.
1.3	Ethical Question <ul style="list-style-type: none"> • Is the fact of being acutely ill an appropriate access/prioritization factor?
1.4	Initial Finding <ul style="list-style-type: none"> • The findings of an initial review is no: fact of being acutely ill is not a priori an appropriate access/prioritization factor.
2 Central Principles That Guide Organ Allocation	
	Looking at various NHS policy documents, the central principles that guide organ allocation include the following:
	<ul style="list-style-type: none"> -Equity of access: all patients with similar characteristics should have the same chance of being registered on the UK National Transplant List and of receiving an organ - Patient Benefit: donated organs should be distributed in a way that provides greatest good to the cohort of patients on the UK National Transplant List for that organ - Benefit should be estimated from the point of registration rather than transplantation. - Age Legislation precludes disadvantaging any group on the grounds of age. However, in some instances, there are objective clinical reasons why one age group should be prioritised over another for receipt of an organ. (Eg the fact that transplantation can offer a chance to correct growth retardation can be a proportionate and justification for prioritizing individuals who are still growing) - Selection should be based both on the patient’s clinical need and on their capacity to benefit. -The scarcity of donor organs makes it necessary also to consider the population of potential heart transplant candidates, not only the situation of a particular individual.
3 Focus on Principle/Criteria: Capacity to Benefit	
3.1	Organ scarcity requires that the principle/criteria of ‘capacity to benefit’ be estimated for an individual so that it can be compared with other candidates.

3.2	<p>An initial reading of the evidence leaves an impression that the conclusion reached that there is “enough evidence to consider making the treatment available” must be difficult and complex matter, i.e. when considering the following quotes from the documents:</p> <p>“there is a high degree of uncertainty as to the exact rate of mortality to expect in patients on ECMO BTT while awaiting transplant as varying rates have been reported in the studies.”</p> <p>“several post-operative complications were more likely in ECMO BTT patients”</p> <p>“overall, there is evidence that ECMO BTT is associated with some increased post-operative complications.”</p> <p>“ECMO BTT is associated with higher rates of some serious complications such as bleeding, delirium, myopathy and vascular and thrombotic events, although the exact magnitude of these risks is difficult to determine due to heterogeneity in the post-transplant outcomes and indicators used in different studies. ECMO BTT is associated with a risk of mortality in patients on this treatment, based on five studies around 20% - 30% of patients die on ECMO before transplantation.”</p> <p>“Hence it is assumed that ECMO improves overall survival against comparable patients</p> <p>“The evidence from NHS-BT is that there is a different case mix in this patient group. As the superurgent list is recent (2 years) there is not an evidence base that they have better outcome than the wider cohort waiting transplant.”</p>
3.3	<p>This complexity suggests that the work of needing to apply selection/ prioritization criteria such as capacity to benefit is very demanding; it is surely problematic to judge fairly and equitably the following factors for an individual:</p> <p>(a) the potential survival benefit from transplantation</p> <p>(b) a potential significant improvement in their quality of life for an individual</p> <p>(c) projected post-operative survival time.</p>
3.4	<p>The fact of being “acutely ill” is important is as much as it will impact on selection/ prioritization criteria such as those named above.</p> <p>It is not in itself a basis for decision.</p>
4	Conclusion
	<p>The fact that an individual is acutely ill is tragic, particularly when a child involved.</p> <p>There will often surely be a considerable emotional pull to prioritize such patients.</p> <p>However a wider set of basic principles as outlined in point 2 and as explicated in 3.3 above (agreed in a reasonable democratic way, it is supposed) should ethically prevail in order to be fair, equitable and transparent in prioritizing access.</p>