NHS Blood and Transplant

NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION AND TRANSPLANTATION DIRECTORATE
CTAG LUNG ALLOCATION SUB-GROUP
ON FRIDAY 12 JANUARY 2024
MINUTES

Present:

Jasvir Parmar	Chair CTAG Lungs; Royal Papworth Hospital
Christopher Blake	Patient Representative (RPH)
Rossa Brugha	Great Ormond Street Hospital (GOSH)
Martin Carby	Royal Brompton and Harefield Hospital (Voting member)
Havi Carel	Patient Representative (Harefield)
Andrew Fisher	Freeman Hospital, Newcastle (Voting member)
Iain Harrison	Product Owner (IT) – OTDT, NHSBT
Rachel Hogg	Statistics and Clinical Research, NHSBT
Sam Kennedy	Freeman Hospital, Newcastle
Lisa Mumford	Statistics and Clinical Research, NHSBT
Sally Rushton	Statistics and Clinical Research, NHSBT
Karthik Santhanakrishnan	Wythenshawe Hospital, Manchester (Voting member)
Debra Thomas	Royal Papworth Hospital (Voting member)
Richard Thompson	Queen Elizabeth Hospital, Birmingham (Voting member)

Attending:

Caroline Robinson	Advisory Group Support, OTDT, NHSBT (Minutes)

			ACTION
1.	**Declarations relevant to the agenda**		
	There were no declarations made at the meeting.		
1.1	**Welcome**		
	- J Parmar welcomed all to the meeting and particularly the two patient representatives (C Blake and H Carel) who are both on the lung transplant waiting list and who are attending this group for the first time. - I Harrison, Product Owner who will be responsible for helping with any IT changes needed in the allocation scheme was also welcomed. - Apologies were noted from V Gerovasili, H Spencer.		
1.2	**Minutes and Action Points from meeting of 11 May 2023**		
	The Minutes and Action Points from the last meeting on 11 May 2023 were circulated but not discussed.		
2.	**Overview of issues in allocation**		
	Background: - Historically, allocation has been centre based. Individual centres have been in a zone and centres decided who would receive a transplant. - In 2017, CTAG changed the allocation scheme to a 3-tiered system (super urgent (SU), urgent (U) and routine). The SU and U tiers became part of a national scheme to allow more opportunity for patients in these categories. - The proposal from CTAG lung to examine the urgent criteria as part of the agreed iterative process.		

<table>
<tr><td></td><td>

- The SU criteria were considered to be robust, but it was agreed to re-examine the urgent criteria in light of the changes in the waiting list and the development of new therapies.
- The model used by the liver transplant community was examined for routine lung patients based on transplant benefit alongside AI or other decision-making tools like analytical hierarchy.
- Other countries allocate differently and within the UK, different organ groups have contrasting allocation schemes. The purpose of this meeting is to consider what is the best scheme for lung patients needing transplant while ensuring equity of access, appropriate organ utilisation and effective treatment.
- Ethical principles to consider include *patient autonomy* (the patient's right to choose/refuse an organ), *beneficence* (the patient's best interest), *non-maleficence* (obligation not to intentionally inflict harm) and *justice* (using scarce resources appropriately).

Possible Models of Allocation:
- *Needs based* – allocate to patient with highest predicted waiting list mortality. These are likely to be the sickest patients whose post-transplant survival is likely to be affected.
- *Utility* – allocate to patient with longest predicted post-transplant survival.
- *Transplant benefit* – allocate to patient with most to gain from transplant (ie difference between survival with or without transplant.
- *Hybrid of data driven and expert opinion* – combination of all above models. There is now better data collection and information. However, the data set to be used in future is still to be decided.
- *Status quo* – ie centre choice following SU/U turn down.

It is accepted that there is a tension between rescue therapy (and a possible short-term gain for the patient) and post-transplant survival. Each allocation policy has compromises.
</td><td></td></tr>
</table>

3.	**Lesson Learned from other allocation schemes**	
	L Mumford gave a presentation of lessons learned from the past: • A working group is needed including patient representation. • Objectives for the new scheme need agreement. • Evidence needs review (data driven where appropriate) • All relevant factors need identification. • Results need comparison and simulation. • IT implications need consideration. • Following wider consultation, the optimal scheme is agreed. To develop a scheme for the future: • Complex mathematics and statistics can be instrumental in developing a new organ offering algorithm. • Clinical input is essential from all interested parties. • Simulations are needed to fine tune a scheme to ensure it meets the objectives. • A simple design is key to successful implementation as testing uses a lot of resource to ensure the scheme is safe to deliver. An added complexity with lung transplantation that differs from other organs is the availability of 2 organs and therefore 1 or 2 potential recipients. can be built into any points allocated.	

4.	**Update on Newcastle study**	
	S Kennedy presented an update on the work he has been doing on analytical hierarchy as a tool for allocation: Why Research Allocation: • For non-urgent patients, geographic boundaries play a role in allocation resulting in inequitable access to transplant. • There are some numeric boundaries (Category 21) when listing for urgent and non-urgent allocation. • Subjective decision making about appropriate candidates for transplant by clinicians is based on experience and judgement. The data set of UK lung transplant patients went into a simulation engine developed by S Kennedy to simulate different policies. What has been done: • How different allocation priorities affect the patient to reduce waiting list mortality, increase post-transplant survival and prioritise net benefit were modelled. • A survey has been undertaken to establish which priorities patients and clinicians believe are most important. There are compromises in the analytical hierarchy approach. Prioritising waiting list mortality may mean post-transplant survival reduces. Similarly, concentrating on post-transplant survival may mean SU and U patients do not get a transplant. Net benefit may be a compromise between the two options. Potential next steps: • Develop predictive models for waiting list and post-transplant survival. • Use survival models to develop an allocation score with higher scores to patients likely to benefit most from transplant. • Deploy an invisible protocol allocation system. • Log all patient matching runs to compare existing and proposed patient rankings. • Record survival outcomes and evaluate the predictive ability of the allocation score to ensure organs are allocated to those who will benefit most. Single lung prediction • The left lung has a higher risk. This is reflected in literature where single or left, right and bilateral transplantation are compared. This was taken into account in the simulations with patients with a higher risk lung generating lower survival times in the simulation while calculating overall net benefit. Paediatric patients • These have not been included in the simulation due to low numbers. Only adult transplantation is considered currently. Comments • The definition of output of a lung allocation scheme needs to be clearly defined before introducing it. **ACTION: J Parmar, L Mumford, J Whitney, A Fisher, S Kennedy to discuss nest steps offline.**	**J Parmar / L Mumford / J Whitney / A Fisher / S Kennedy**
5.	**Change in urgency status**	
	Current urgency criteria have been operational since 2017. However, low levels of lung transplant and the pandemic have made it challenging to examine data and determine their success. Key points for consideration in a new allocation scheme:	

		• Heart and lung transplant teams are co-located. This sets up a competition between heart and lung allocation. • The urgency criteria determine which organs are offered first. The number of urgent patients on the heart transplant waiting list is large, whereas it is small numerically for lungs. • Double the number of heart transplants are performed compared to lungs (eg in the last year hearts = 210, lungs = 90). • The waiting list mortality for lung transplantation is substantially higher than for heart. A large proportion of lung patients will never get the opportunity to have a transplant. • As patients become sicker in both SU and U tiers, there is increased early mortality. Being able to transplant before a patient reaches this stage and ensuring the allocation scheme can deliver this is the best option.	
5.1		Recommendations from PH Physicians - Four diagnostic categories for which there is data are conglomerated (fibrotic lung disease, obstructive lung disease, pulmonary hypertension, cystic fibrosis/bronchiectasis). The following recommendations were suggested: • Persistence in ERS high category (>3 high risk criteria on the ERS PAH risk calculator) despite optimal pulmonary vasodilator therapy • Hospitalisation for decompensated heart failure despite maximum tolerated medical therapy including IV prostaglandin therapy, diuretics + / - inotropes. • Recent RHC RAP >20mm Hg (15mm Hg) and CI <2.0L/min/m² despite optimisation of therapy. RHC data within 3 months of request to add to urgent list. • 1 life threatening admission after listing as a criterion for higher priority escalation criteria. Comments: • Having 3 criteria by amalgamating 2 and 4 above and bringing down right atrial pressure to 15 is suggested as an option. However, it is suggested measuring right atrial pressure is as much to do with fluid balances and level of hydration or dehydration as anything else. • Admission to hospital could be for any reason and move someone up the waiting list. • 3 months is perhaps too long before being added to the urgent list. If patients cannot be included in option 2, they could go through the adjudication panel to give them a greater chance of transplantation before they are too sick. **ACTION: Based on the comments above, J Parmar will re-word the options to be discussed and agreed at CTAG Lungs in May.**	**J Parmar**
5.2		Criteria for ILD Urgency (updated July 2023) – The aim is to develop criteria for these patients who are the largest constituents of the waiting list. The experts consulted have expressed most concern for those who have exacerbations within 3 months as shown below: • Persisting hypoxia (PO₂ <8kPa) despite continuous O₂ at 10L/min • Refractory right heart failure despite all pharmacological interventions to support the right ventricle. Recommendations from ILD Physicians: • Acute exacerbations are defined as progressive symptoms, worsening hypoxaemia and new ground infiltrates on CXR or CT	**J Parmar**

	chest scan within 30 days. This includes those affected by infection and those without identified infection. <u>Proposed new criteria for urgent listing:</u> • Hospitalisation for infection and/or acute exacerbation of pulmonary fibrosis within the preceding 3 months. No evidence of persisting or active infection. • This criteria was felt to be too vague by 2 out of the 5 centres • Evidence of rapid disease progression despite optimal standard of care therapy as defined by FVC ≥ 10% in less than 6 months. • This criteria was felt to be too vague by 2 out of the 5 centres • • Increasing oxygen requirements at rest with persisting hypoxia (PO_2 <8kPa) despite continuous oxygen >5L/min or unable to maintain SpO_2 ≥88% on a walk test despite supplemental oxygen. • It was agreed that this was reasonable • Refractory right heart failure despite all pharmacological interventions to support the right ventricle. Generally, there is a feeling that right heart failure can be re-modelled and reversed post-transplant. • Rmove this criteria • Progressive pulmonary fibrosis (with increase in reticular change or honeycombing or pneumomediastinum) on CT chest over 6 months despite standard of care therapy. • This criteria was felt to be too vague by 2 out of the 5 centres <u>Comments:</u> • Any change will require an impact analysis if possible, prior to implementation in a new allocation scheme. The data is currently not held centrally and so will require centres to provide data • The wording is currently too vague and needs more clarification. Any criteria need more objectively verifiable data to be transparent. • It is unlikely patients with an active infection would be included and more likely they would be suspended from the list until recovery. However, published data from USA suggests that the outcome is good for patients with an acute exacerbation than not doing anything. The criteria need to be clear what will happen after 3 months of an acute exacerbation. **ACTION: J Parmar to return to experts to better define.** • Unclear how many if any patients have been listed due to refractory right heart failure therefore its value as an urgent criterion is not confirmed. It is suggested this is removed. • Criteria for progressive pulmonary fibrosis is hard to quantify. **ACTION: J Parmar to remove this criterion.**	
5.3	<u>CCF guidance - Suggestions from UK CR Physicians:</u> • Worsening hypercapnic respiratory failure (PaO_2 <7.5kPa and $PaCO_2$ >6,5kPa) despite appropriate oxygen and maximal non-invasive ventilatory support • Refractory right heart failure despite all pharmacological interventions to support the right ventricle.	**J Parmar**

	• Ongoing episodes of life-threatening massive haemoptysis despite bronchial artery embolization. Comments: • Refractory right heart criterion to be removed. **ACTION: J Parmar to make all changes and to circulate the document and slides to the group for further comment and discussion at CTAG Lungs**	
6.	**Any Other Business**	
	NAD	
7.	**Date of next meeting:** TBA prior to CTAG Lungs (16 May)	