NHS BLOOD AND TRANSPLANT

CARDIOTHORACIC ADVISORY GROUP

URGENT LUNG ALLOCATION SCHEME

1. Members of CTAG have proposed that NHSBT should revise the national lung allocation scheme: lungs from deceased donors should be allocated first nationally to those on the urgent lung list and lungs that have not been accepted should be offered to centres on a zonal basis. Criteria for entry to the urgent lung list have been developed by a subgroup of CTAG who have also agreed the national and zonal allocation rules. These developments have been supported by the clinicians, patient support group and some MPs.

2. The rationale for the change is the belief that moving to a national allocation scheme would reduce the mortality of patients waiting for a lung transplant without significantly affecting overall benefit and utility. It is suggested that moving to such a system would save up to 30 lives a year and that offering lungs to a named individual would increase the probability of organs being accepted.

3. The current rules based engine for supporting a computer-based offering system is inadequate to deliver these proposals. NHSBT is currently preparing a business case for the development and implementation of a new system that would be safer for the patient and allow adjustment but the complete delivery of such a system may take up to 5 years.

4. Therefore, ODT SMT has been asked to consider the benefits of introducing the national urgent lung allocation scheme against the operational and patients risks associated with using a manual process.

5. If ODT SMT agrees to the proposals, then the new system will be introduced for six months with close audit of benefits (overall lives saved), utility, safety and operational issues (such as impact on offering times, acceptance rates). The revised policy will be reviewed and, depending on the findings, extended, modified or abandoned.

6. ODT is very grateful to the clinicians and others who have worked hard to develop these proposals.

7. Slides specifically relating to the results of a statistical modelling exercise which are to be included in the presentation by James Neuberger to ODT SMT on 23 September 2014 are included below.

James Neuberger **September 2014**

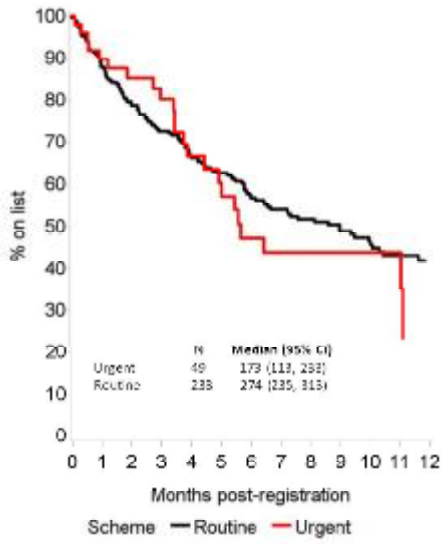
Modelling

- Transplant centres asked to classify each listed patients to one of the three tiers (Super-Urgent, Urgent or Routine) based **at the time of registration**.
- Cohort;
  - Adults (>=16 years) registered on to the lung waiting list **1 January 2013 - 31 December 2013**.
  - First-graft and lung-only registrations only

Scheme	Category	N
Super-Urgent	Super-Urgent	7
Urgent	COPD	2
	CF	7
	IPF	24
	PAH	2
	Adjudication Panel (Total)	14 (49)
Routine	Routine	233
Total		**289**

Modelling

Time to transplant by urgency status



- There is *some* evidence of a difference in time to transplant between the urgent and routine groups (non-overlapping confidence intervals for median waiting time but risk-adjusted p value =0.67757)
- Urgent patients appear to be transplanted sooner.
- This will be an underestimate as some of the routine patients will later be moved to the urgent category post-registration

Note: Kaplan-Meier plot and median waiting time are unadjusted for other risk factors

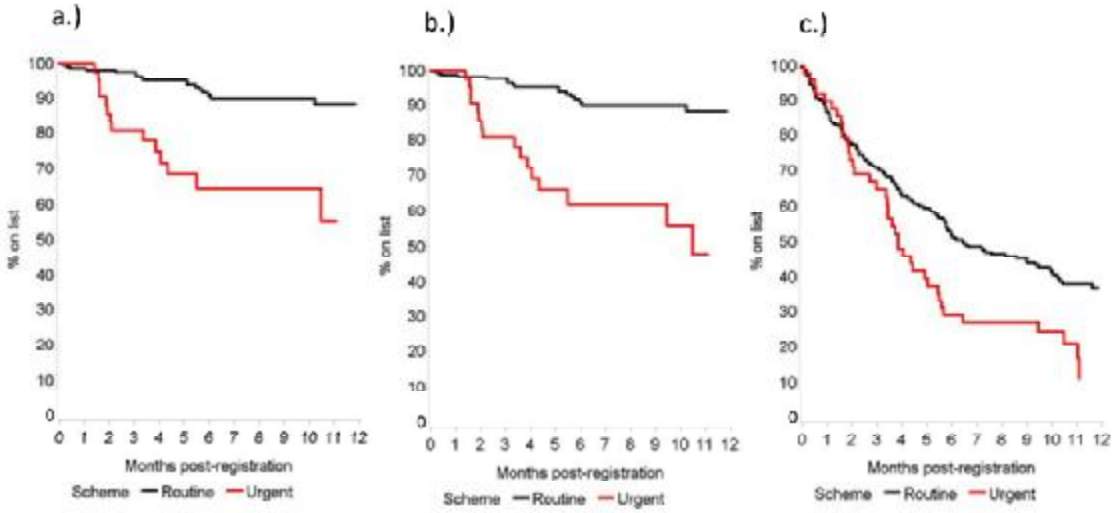
Modelling

Time to:

a) death

b) death or remove due to deterioration

c) death or removal due to deterioration or transplantation



Note: Kaplan-Meier plots are unadjusted for other risk factors

Modelling

Time to:

a) death

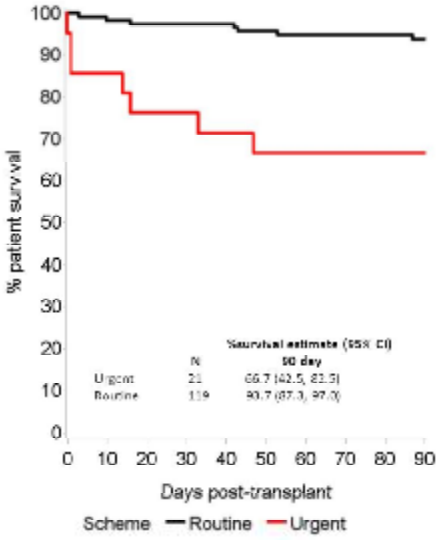
b) death or remove due to deterioration

c) death or removal due to deterioration or transplantation

- There were 31 deaths on the list (and 6 removals) as at 10 June 2014 for these 289 patients
- There was a statistically significant difference in time to death on the list between the two groups.
- There was also some evidence that this was the case when assuming that the patient would have died at time of transplant if they had not received their transplant (case c.))
- The same conclusion was reached when risk-adjusting for other factors (a.) p= 0. 001, b.) p=0. 0002 , c.) 0.069)
- This will be an underestimate as some of the routine patients will later be moved to the urgent category post-registration

Modelling

90-day patient survival post-lung transplant



- There is a strong statistically significant difference in 90-day post-transplant survival between the urgent and routine groups (risk-adjusted p value =0.008)
- 90-day patient survival appears to be lower for the urgent patients
- This will be an overestimate however as some of the urgent patients would have deteriorated too far while waiting. Under the proposed urgent lung scheme they would have been prioritised.

Note: Kaplan-Meier plot and survival estimates are unadjusted for other risk factors

Modelling

- It is not possible to conclude from the data that the scheme will save lives.
- A more accurate method to evaluate the benefits of the scheme would be to run an intensive simulation study as is currently being run for the Liver Advisory Group.
- Such a study would take 1 – 2 years.