RINTAG
7th May 2019
Annual Review of National Research Organ Allocation Scheme and Ranking System

Status – Public

Executive Summary

The current ranking system has now been in place for over 2 years and is subject to annual review. Comments from researchers and queries from the ODT Research team over how best to score studies have resulted in a number of points for RINTAG to discuss and agree:

- Should a study's acceptance criteria be factored into their feasibility?
- Should the number of organs offered and matching a study's acceptance criteria, but not accepted/called in about, affect their score?
- Is there a better way to assess how soon a study can increase the number of organs available for transplantation?
- Does RINTAG agree with the proposed definition of 'novel technologies'?
- Does RINTAG agree that split/reduced livers should be offered out to all liver studies if there is consent/authorisation for research?

Background

The allocation scheme for research organs – that have been removed for the purposes of transplantation, assessed, and then been deemed to be untransplantable – went live on the 20th February 2017. The scheme ranks studies in order of priority. Prior to this, research organs were offered to studies on a geographical basis.

The scheme was devised by a sub-group of RINTAG in 2016 led by Dr Nick Watkins, Assistant Director for Research & Development. As noted in POL263 – Allocation of Research Organs, the allocation policy and associated ranking system should be reviewed by RINTAG annually.

There are four main criteria for scoring studies: whether they can transplant the organs they receive, their feasibility, how soon they will increase the number of organs available for transplantation and the level of peer review. Additional binary categories measuring collaboration, alignment to the NHSBT ODT strategy and use of novel technologies help to distinguish between studies that receive the same numerical score.

Feasibility Category

Currently scored as:

Feasibility - number of research organs required per year	Mark	Score
<25 % of available organs	A	4
26 - 50 % of available organs	B	3
51 - 75 % of available organs	C	2
76 - 100 % of available organs	D	1

However, feasibility can be calculated two ways, simplistically as:

Method 1.

$$\frac{Total\ Number\ of\ Organs\ Requested\ by\ a\ Study}{Study\ duration\ (years)} = Organs\ required\ per\ year$$

$$\frac{Organs\ required\ per\ year}{Average\ no.of\ organs\ offered\ through\ national\ scheme\ per\ year} = Feasibility\ Score$$

Or, for studies that are already up and running, the number of organs they have already received can be incorporated to result in a more dynamic score.

Method 2.

$$Total\ Number\ of\ Organs\ Requested\ by\ a\ Study - Number\ of\ Organs\ Already\ Received^{*} = Number\ of\ Organs\ Remaining$$

$$\frac{Number\ of\ Organs\ Remaining}{Years\ Remaining\ When\ Progress\ Report\ Received} = Organs\ required\ per\ year$$

$$\frac{Organs\ required\ per\ year}{Average\ no.of\ organs\ offered\ through\ national\ scheme\ per\ year} = Feasibility\ Score$$

**taken from progress report*

An unintended consequence of using the number of organs already received by a study is that it disadvantages studies that have fallen behind on their recruitment targets (for example, due to having more narrow acceptance criteria).

In order to reach their total requested in their original timeframe, these studies require more organs in a shorter space of time, resulting in a low score for feasibility and a lower rank, making it even harder to reach that total.

It is worth noting that if every currently-active study accepted the full number of organs they were supposed to in a year (in order to meet both their target end date and number of organs), the pool would more often than not be completely used up (table available in the Appendix).

Discussion points for RINTAG:

- Should a study's acceptance criteria be factored into their feasibility?
- Should the number of organs offered and matching a study's acceptance criteria, but not accepted/called in for, affect their overall score?
    - If so, would this take into account periods of annual leave; unavailability of reagents (such as non-clinical issue blood); the study not having enough money to pick up an organ from its location; for example?

- Vice versa, should the number of organs called in for but not received (due to a higher-ranking study also calling in) be incorporated?
  In other words, should good researcher availability/a high response rate be rewarded?
- Are there any other improvements that could be made to this category?

How Quickly Will This Study Increase the Number of Organs Available for Transplantation? Category

Currently scored as:

Time-scale from start of study to increase number of organs available for transplantation	Mark	Score
Within 18 months	A	4
19 - 36 months	B	3
> 37 months	C	2
Not applicable	D	1

This is now a question on the new-style application form, but unless a study can transplant the organs it receives or is totally unrelated to transplantation, it is difficult to judge objectively.

To make this as objective as possible, this score has been previously calculated using a study's end date. This favours studies with end dates in the near future (such as PhD students who have to finish their work quickly), assuming that they will receive all of the organs they need and then close, rather than 'drip-feeding' organs to all studies on the list.

Studies that extend their end dates (due to falling behind on recruitment targets) are disadvantaged here as with (and sometimes also as a knock-on consequence of) the feasibility category.

<u>Discussion points for RINTAG:</u>

- Is there a better way to assess how soon a study can increase the number of organs available for transplantation?
  - Potential proxies: number of papers published in a year/posters presented at conferences, amount of funding received; number of Google searches for that research group/topic/study
- Or could something simple like the following be used instead?

Time-scale from start of study to increase number of organs available for transplantation	Mark	Score
Can transplant the organs it receives	A	4
Related to transplantation	B	3
Unrelated to transplantation	C	2

Use of Novel Technologies (Binary Category)

Defined as perfusion, scaffolding technologies, persufflation and cellular therapies.

Discussion point for RINTAG:

- Does RINTAG agree with this definition?

Split Liver Allocation

From the most recent round of progress reports, we became aware that one liver study was keeping split/reduced livers locally for their research, with some of them not being offered by the Hub.

Split/reduced livers are occasionally offered through the national scheme and are often accepted by other liver studies, showing that there is demand for this tissue.

Discussion point for RINTAG:

- Is it right that split/reduced livers can be kept locally?

Hannah Tolley
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Appendix:

If all active studies accepted their full quota of research organs (in order to meet their target end date and organs required), what percentage of the organs (offered for research in one year) would they take up?

These should be viewed as estimates due to missing progress reports from some researchers.

Organ Type	Proportion of the pool of research organs required by all live studies in order to meet their target end date and number of organs	
	By Calculation 1	By Calculation 2 (includes organs already received)
Hearts	833%	1154%
Lungs	92%	110%
Kidneys	50%	84%
Pancreases	39%	107%
Livers	84%	101%