

**Retrieval Advisory Group
(RAG)**

29th September, 2020

Transplant and Research Development Delivery Team Update

1. Status – Public

2. Executive Summary

The COVID – 19 pandemic paused a number of projects contributing to continuous improvement within Transplant and Research Development.

Working with colleagues across OTDT, the team are recovering and restoring these projects. In addition, the team are developing and delivering new ideas and initiatives that will support the achievement of our new Strategy.

3. Action Requested

Note the progress made by the Transplant and Research Development Delivery Team.

4. Background

Studies paused due to COVID - 19

As of the 25th March 2020 the following studies were paused due to the COVID – 19 pandemic:

- Study 20 - Process development for islet isolation targeted at enhancing islet yield and viability (Pancreas and Islet)
- Study 48 - Establishing ex-vivo normothermic and hypothermic perfusion of livers for transplantation (Liver)
- Study 59 – Human ex-vivo lung perfusion research consortium UK (HELP RCUK) (Lung)
- Study 66 - Further Evaluation of Ex Vivo Lung Perfusion to Improve Transplantation Outcomes (Lung)
- Study 67- Structural and functional analysis of intact myocardium and isolated cells from explanted hearts (Heart)
- Study 83 – Evaluation of Hypothermic Oxygenated Perfusion (HOP) Ex-Vivo Heart Perfusion to Expand the Donor Pool and Improve Transplant Outcomes (Heart)
- Study 76 – ES-NMP (Heart)
- Study 19 - Establishment of cultured human glomerular cells for study of glomerular function in vitro (Kidney)
- QUOD
- PITHIA

Projects paused due to COVID - 19

The Uterine Transplant programme was paused.

INOAR phase 1, due to go live 18th March was paused.

Organs offered for research – generic route

Organs removed for the purposes of transplantation, subsequently deemed unsuitable for transplant continued to be offered via the generic route. The number of organs offered via the generic route decreased in Q1 2020/21, this was due to a reduction in organs being offered for transplant due to changes to donor criteria, closure of transplant units and the suspension of some generic studies.

Table 1. Organs offered for research/ accepted for research

April	Offered for Research	Accepted for Research
Kidney	3	2
Liver	9	0
Pancreas	0	0
May		
Kidney	4	2
Liver	5	0
Heart	1	0
June		
Kidney	7	7
Liver	5	0
Pancreas	4	0
July		
Kidney	28	23
Liver	13	1
Pancreas	4	3

5. Update

The OTDT Recovery Programme Board (RPB) was commenced in June, 2020. 8/10 studies paused have now been restored.

QUOD

QUOD sampling was restored on 28th July 2020. 2 process deviations are in place against the Standard Operating Procedure:

- Due to the risk of infection from COVID-19, restrictions have been placed on BAL sampling:

DBD - lungs accepted for transplant – YES proceed with BAL sampling	DCD – lungs accepted for transplant – NO stop BAL sampling
DBD – lungs not accepted for transplant – NO stop BAL sampling	DCD – lungs not accepted for transplant – NO stop BAL sampling

- In Scotland and Northern Ireland QUOD sampling has recommenced in DBD donors only.
- DCD sampling in Scotland is suspended until a favourable opinion is received from the Scotland A REC regarding the revised process for DCD donors. This application is going to the Scotland A REC meeting on 29th Oct 2020.
- Further advice is being sought from the Manchester REC regarding DCD sampling in Northern Ireland.

PITHIA and Study 76 – ES-NMP

The 2 remaining studies yet to be restored are PITHIA and Study 76 – ES-NMP (Heart). Study – 76 have advised that adaptations are currently being made to their 'Morgan Machine' in readiness for a future Paediatric – ES- NMP study.

Uterine Transplant programme

The Uterine Transplant programme remains suspended and will remain so until we are advised by Oxford University Hospitals and Imperial College Hospitals that they have the necessary approvals to restore their programme.

INOAR phase 1.

INOAR phase 1. 'go live' is being scheduled for January 2021. SNODs will undertake 8-week refresher training via the Quality Leads. 'Go live' has been agreed in conjunction with the operational teams via the strategic workload planning group.

Histopathology

In April 2020, SMT agreed the establishment of a working group to explore options and identify strategies to ensure that there is out-of-hours access to a sustainable and cost-effective donor histopathology service to support organ donation and transplantation.

A donor histopathology steering group was established and met in July 2020 to begin to identify options for consideration, noting that NHSBT does not commission donor histopathology services.

Following a review of donor histopathology audit data October 2019 – March 2020 and a high level SWOT analysis of a range of options to ensure a sustainable and cost-effective donor histopathology service, 4 options will be worked up in detail for consideration by NHS Commissioners.

Liz Armstrong – Head of Transplant Development on behalf of the Transplant and Research Development Delivery Team.