RINTAG and ODT Research Annual Report – May 2019

Introduction

At the end of the financial year, it is quite befitting to pause and reflect on the RINTAG activities over the last twelve months. Five new studies have gone live with several more waiting in the wings, continued support to two key service evaluations (DCD heart and NRP) and an on-going development of logistic support and infrastructure for research.

RINTAG is a unique setting that places the UK at the forefront of innovation and developments in organ donation and transplantation research. Several studies have transgressed the research setting turning discarded organs into successful transplants by using novel technologies in perfusion and preservation. It is also worth noting that three of the papers (including the winning one) in this year's BTS Medawar session have been facilitated and supported by RINTAG's activity.

There are a number of projects in development. These include the delivery of the INOAR initiative - increasing the number of organs available for research. We will also continue to work with the Clinical Trials Unit to support the design, development and delivery of studies across the theme of donation and transplantation.

The ODT research team have had a busy year progressing your research applications through the approvals process and are continuously supporting all these service development projects. I would like to thank Hannah, Maggie, Maria and Liz for their dedication and hard work in making all of this happen.

Gabi Oniscu
Chair of RINTAG

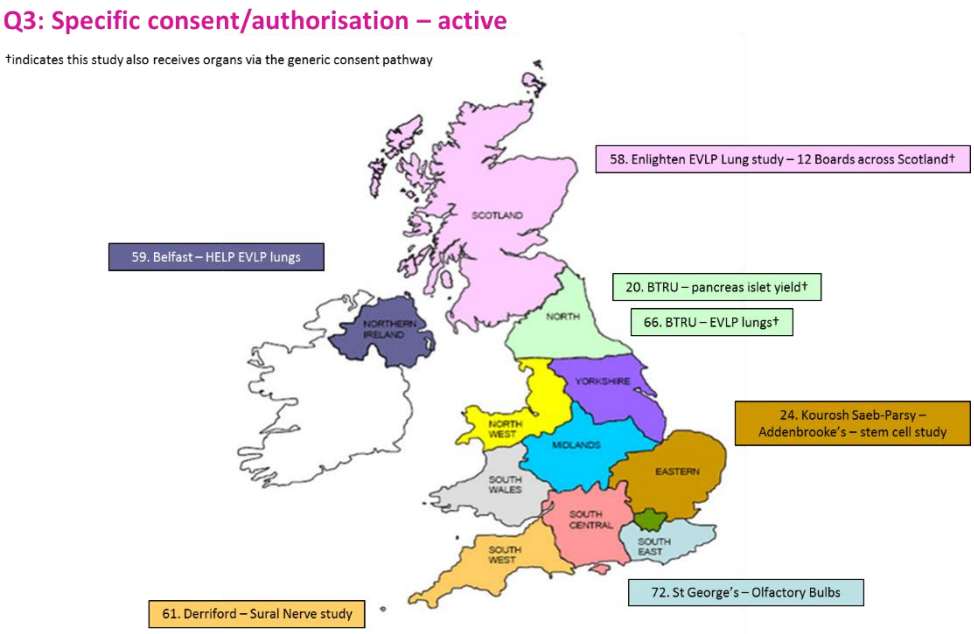
Studies

Generic Consent Studies

With 28 studies currently receiving organs under generic consent (organs that have been removed, assessed and found to be untransplantable), we have a further 11 waiting on approvals outside of NHSBT's remit, but otherwise ready to go live.

With an average of 3 new enquiries a month, there's a steady stream of research on the way.

Specific Consent Studies



A great success story in the last 12 months has been the pilot of the olfactory bulbs study in Tooting. The team were given RINTAG approval to retrieve olfactory bulbs from three deceased organ donors and assess their viability for use in spinal cord injury research.

A few of our specific consent studies are on pause at the moment due to maternity leave and ethical approval renewal, but we look forward to being back at full specific consent study capacity. Feedback from the researchers is positive and they are full of gratitude for the SNODs who make their studies possible.

There are several specific consent studies in the pipeline. Two new heart perfusion studies in Newcastle and Cambridge will go live in the next couple of months and we wait to hear if other studies will be successful in receiving the grant funding they need to get up and running.

Service Evaluations

PITHIA: the Pre-Implantation Trial of Histopathology In renal Allografts

PITHIA

The PITHIA trial officially started on the 1st October 2018 with four months of data collection and monitoring. The trial's unique 'stepped wedge cluster' design involves all 22 UK kidney transplant centres, and a random four or five centres gain access to the urgent biopsy service every four months.

The first four centres that went live on the 1st February 2019 were Portsmouth, Belfast, Coventry and Glasgow, and the next centres to join them on the 1st June are Manchester, Birmingham, Guy's, Nottingham and Liverpool.

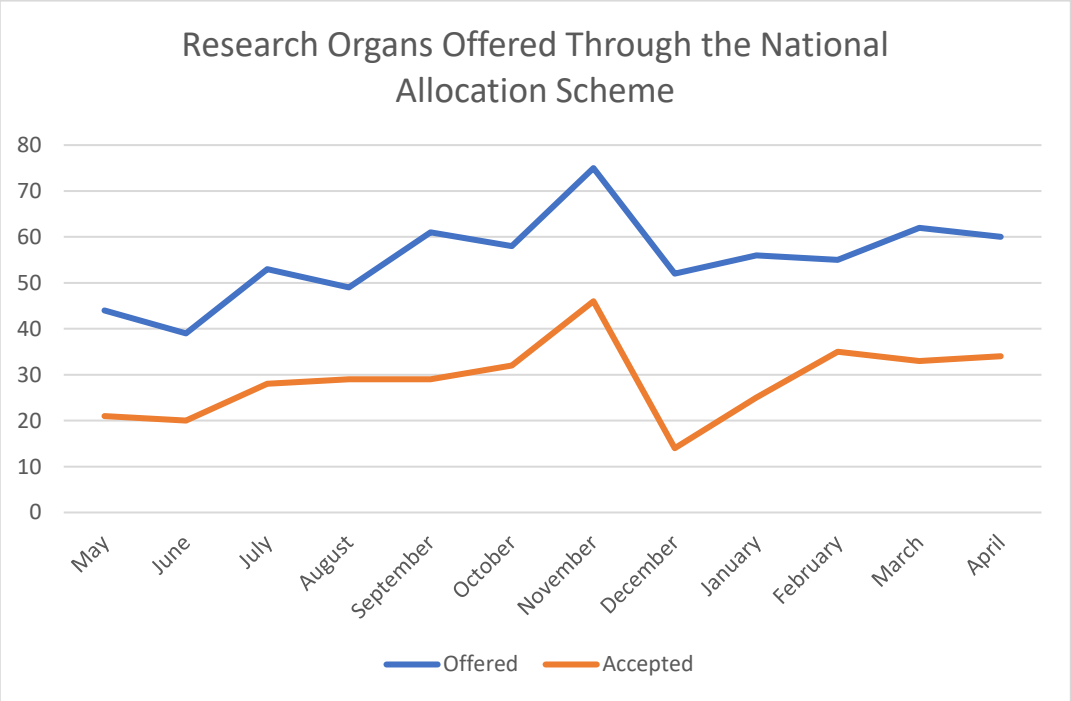
Go-live with PITHIA involved a huge amount of work from a large range of people, including Maggie and Tanya Partridge in Hub Operations.

QUOD Bronchoalveolar Lavage (BAL) Samples and Cardiac Biopsies

In the past year the Quality in Organ Donation (QUOD) biobank has reached 4000 donors which is a massive achievement. Collection of BAL samples and cardiac biopsies from untransplantable hearts went live alongside PITHIA on the 1st February 2019 and are a fantastic resource to cardiothoracic researchers.

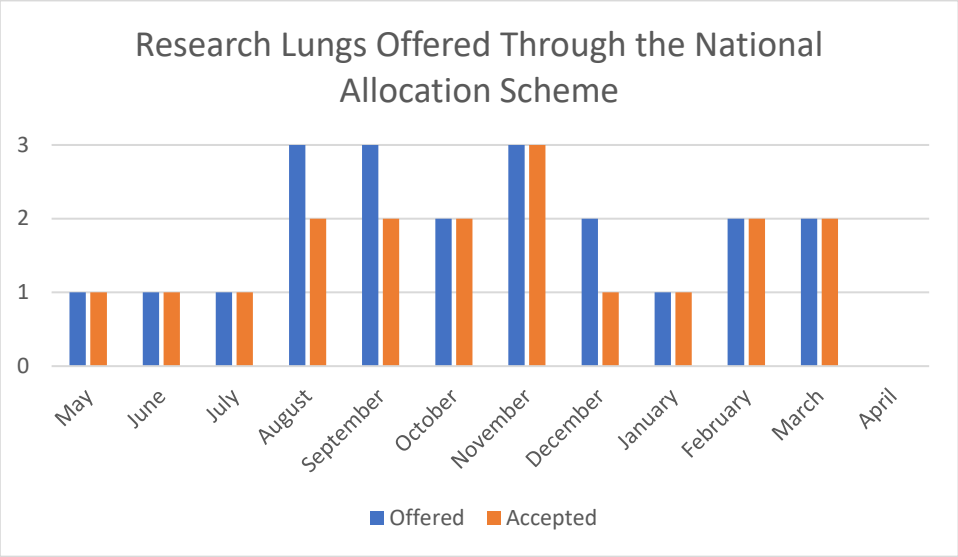
Organs offered through the National Research Allocation Scheme

The Research team now have 12 months of data on organs offered for research through the national allocation scheme. These organs have been retrieved from donors for the purposes of transplantation, assessed on the back bench of the operating theatre, deemed untransplantable and then offered to RINTAG-approved studies and tissue banks if the donor's family have consented/authorised for this.



There have been 664 organs offered for research in the past 12 months. 346 of these were accepted (by ranked studies and tissue banks), meaning that 318 were disposed of. Like donation, research offering typically takes place outside of core working hours and 73% of offers were made over weekends, bank holidays and 6pm – 8am Monday to Friday.

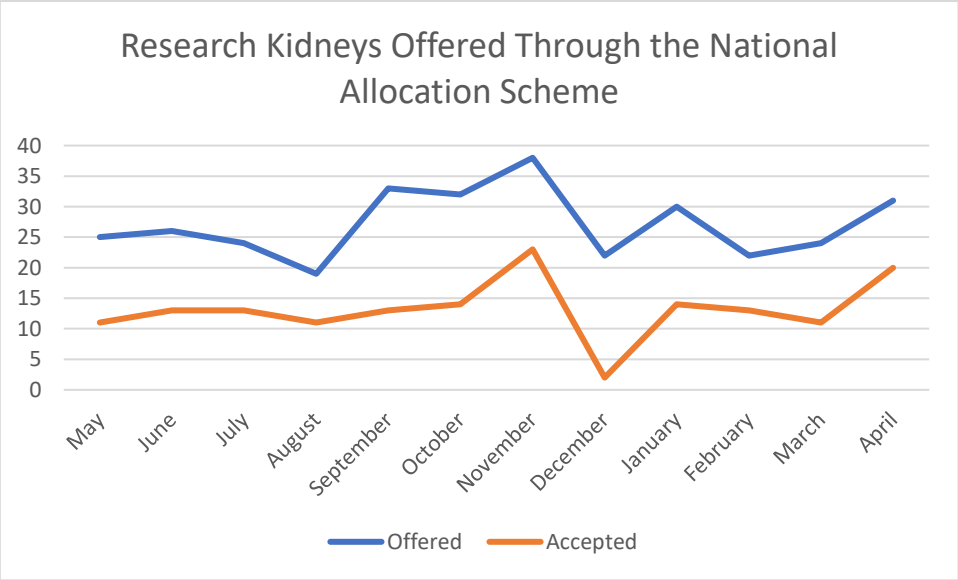
Cardiothoracic Organs



Over the past 12 months we have seen 21 lungs (both pairs and singles) offered through the national allocation scheme. It's only on rare occasions that research lungs are not accepted. The average acceptance rate is 86%.

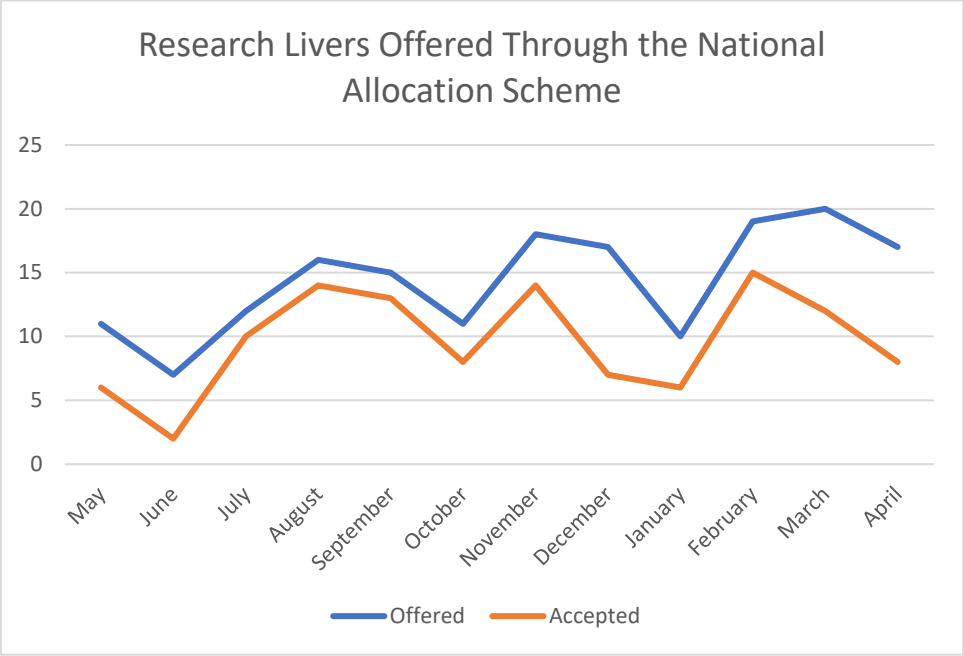
There has only been one heart available through the scheme in the past year, which was accepted.

Kidneys



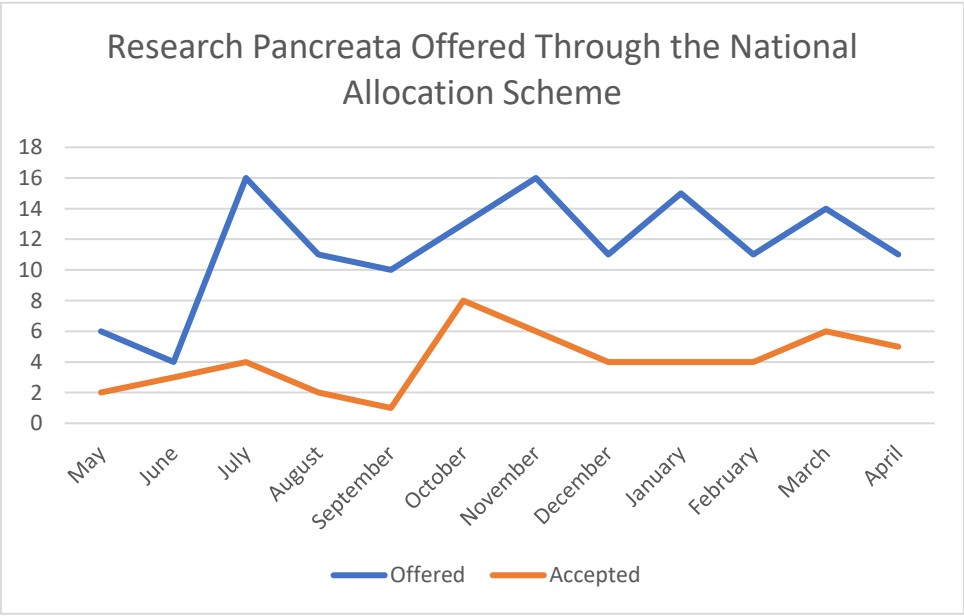
Kidneys are the research organ we see the most of, with an average of 27 offered each month. There have been 326 kidneys offered for research over the past 12 months. Acceptance rates have remained fairly steady at an average of 48%, although acceptance in December was very low at just 9% (2 out of 22 accepted).

Livers



Livers are the best accepted abdominal research organ, whether that's due to the smaller numbers offered (an average of 14 per month) or shorter ischaemic times than research kidneys. Acceptance has been 66% over the past 12 months.

Pancreata



The average acceptance rate for pancreases has been 36%. Several of our pancreatic studies are islet labs, with strict cut-offs for cold ischaemic time and 9-5pm working hours.

Five already-isolated pancreatic islets have been offered and all of these accepted.

Service Development

INOAR

This is a complex piece of work that will impact on the entire donation to transplantation pathway and facilitate access to an increased number of organs donated. We are confident that the appointment of a project manager - Kam Rai - will enable us to deliver Phase 1 in the Summer as planned. Phase 1 includes the opportunity for donor families to consent to the removal of Heart, Lungs and the Diabetic Pancreas for research.

Cell lines

Work has now begun to design a consent process for the creation of immortalised cell lines from donated tissue.

Uterine Transplantation

The Team have been working with Imperial and Oxford to set up a deceased donor uterine transplantation programme. This piece of work has recently been handed over to Angie Scales (Lead Nurse – Paediatric donation) and Dr Dan Harvey (Research and Innovation Clinical Lead in Organ Donation [CLOD]).

Website Redesign

The RINTAG and ODT Research pages have been given a redesign and a refresh with the addition of animated videos made by Hannah. The pages are still a work in progress so please let Hannah know if you have any feedback.

Specialist Nurse in Organ Donation Training

Part of the ODT Research team's remit is to teach trainee SNODs so that they feel confident discussing research with donor families and understand the implications of it. We estimate that we have taught 75 trainees in the past 12 months.

Every Organ Donation Services team (ODST) has its own Research Lead. The Leads have become an invaluable network for cascading training and catch up with Maggie once a month over the phone and once a year in person.

Hannah Tolley
ODT Research Manager