NHS BLOOD AND TRANSPLANT

MINUTES OF THE RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP HELD AT 10.30 A.M. ON TUESDAY 7 MAY 2019 THE PRINCIPAL YORK HOTEL, STATION ROAD, YORK YO24 1AA

PRESENT:

Mr Gabriel Oniscu	GO	Chair
Ms Ayesha Ali	AA	NHS England, NHS Improvement (by telephone)
Mrs Liz Armstrong	LA	Head of Transplant Development
Dr Richard Baker	RB	Clinical Governance Lead
Mr John Casey	JC	Chair, Pancreas Advisory Group
Mr Ian Currie	IC	Chair, National Retrieval Group
Ms Alison Deary	AD	Head of Clinical Operations, NHSBT
Prof Andrew Fisher	AF	NIHR BTRU Representative
Prof John Forsythe	JF	Associate Medical Director, ODT, NHSBT
Dr Victoria Gauden	VG	National Quality Manager, ODT, NHSBT (by telephone)
Mr Dan Harvey	DH	National Innovation and Research Clinical Lead, Organ Donation
Dr Florence Hogg	FH	St George's Hospital (by telephone for point 7)
Ms Lisa Mumford	LM	Head of ODT Studies, NHSBT
Dr Jayan Parameshwar	JP	Chair, Cardiothoracic Advisory Group
Prof Rutger Ploeg	RP	Director of QUOD
Ms Karen Quinn	KQ	Assistant Director, UK Commissioning, NHSBT
Ms Maggie Stevens	MaS	Specialist Nurse, Research & Service Delivery
Mr Michael Stokes	MiS	Head of Hub Operations
Ms Hannah Tolley	HT	ODT Research Project Manager
Dr Nick Watkins	NW	Assistant Director, Research & Development, NHSBT
Prof Chris Watson	ChW	Chair, Kidney Advisory Group
Mrs Fiona Wellington	FW	Interim Assistant Director, Organ Donation & Nursing (by telephone)
Mr Colin Wilson	CoW	Consultant Hepatobiliary Surgeon, Newcastle University

APOLOGIES:

Ms Hazel Bentall	HB	Lay Member
Mr Marius Berman	MB	National Clinical Lead, Retrieval
Ms Rebecca Cardigan	RC	Head of Component Development Laboratory, NHSBT
Prof Peter Friend	PF	Chair, Multi-Visceral & Composite Tissue Advisory Group
Prof Derek Manas	DM	Clinical Governance Lead
Ms Gail Miflin	GM	Medical & Research Director, NHSBT
Prof Elizabeth Murphy	EM	Lay Member
Dr Douglas Thorburn	DT	Chair, Liver Advisory Group
Ms Michelle Willicombe	MW	BTS Representative
Mrs Claire Williment	CW	Head of Legislation Implementation Programme
Dr Mike Winter	MW	NHS National Services Scotland (Observer)

IN ATTENDANCE:

Heather Crocombe	HC	Clinical & Support Services, NHSBT

ACTION

1 Welcome & Apologies

GO welcomed everyone to the meeting and gave details of apologies received as shown above.

ACTION

2 Declarations of interest in relation to the agenda

There were no declarations of interest in relation to the agenda

3 Minutes of the Research, Innovation and Novel Technologies Advisory Group Meeting held on Tuesday 2 October 2018

Accuracy of Minutes

The Minutes of the last meeting were deemed to be a true and accurate reflection of that meeting – no changes required.

Action Points from the Meeting

Research Matrix

Paper and update to follow during today's meeting

Kidney Research UK/Fibrosis Network

RP advised that discussions have taken place with the Fibrosis Network and it has been agreed that their fibrosis studies will be incorporated within those of Kidney Research UK. There will be no separate biobank.

DCD Hearts

Amendment of DCD Heart, TA-NRP Protocol is ongoing

4 Research Activity – Statistics & Clinical Studies

Consent RINTAG(19)01

Lisa Mumford

LM presented this paper which summarised how research consent/authorisation rates have changed over the last ten years in the UK. Research consent/authorisation rates were analysed for actual organ donors where at least one organ was retrieved for the purposes of transplantation in the UK from 01.01.2009 to 31.12.2018. When considering organ specific consent/authorisation rates, donors with contraindications for specific organs were excluded:

{Intestinal: donors aged >56 or weighing >80kg excluded
Pancreas and islets: donors aged >60 excluded
Heart: donors aged >65 or who died of myocardial infarction excluded
Lung: donors aged >65 excluded}

Conclusion

The overall UK consent/authorisation rate for research was 83% in 2009 and has risen to 91% in 2018. England and Wales have had the highest consent rates for research over the past 4 years ranging from 91% to 95%.

Allocation Review RINTAG(19)02

Lisa Mumford

This paper reflected the results of the third two-month review to determine the effectiveness of the research organ allocation scheme. Data collected by NHSBT does not capture offering of research organs, so Hub Operations (HO) had completed a spreadsheet for this review, listing occasions where an organ was retrieved and not transplanted for the period 01.10.2018 to 30.11.2018.

Summary

- 156 organs (94%) potentially available for research, 70 (45%) were not used. 134 organs (86%) were offered through the research allocation scheme, 57% of which were used.
- Organs accepted within closer geographical proximity to study

ACTION

- Higher number of organs offered between 12pm and 12am
- Median number of responses per offer was 1

Collating these data is incredibly time-consuming for HO. It was suggested that HT and MS take over collation (using the research offer messages that they are copied into) rather than HO, although there is the possibility some data may be missed, for example if no research offer message is sent out and a centre keeps a research organ locally. GO asked if there is enough manpower in Research to collate data. LA and ODT Research Team to have a conversation offline with LM as to what information the ODT Research Team will be able to collect, without Stats input. GO then to be advised what information will not be able to be captured by the ODT Research Team before a decision is made to cease this stats report. **LA/GO**

RINTAG agreed that it would be useful to understand the number of organs retrieved for research, deemed unsuitable for transplantation that are offered for research, accepted and subsequently transplanted. Researchers are asked to provide this information in progress reports. Discussion that the ODT research team should be able to collect this information retrospectively on a monthly basis as currently there are only 2 research studies accepting organs for research with a view to transplant following assessment.

Availability of Organs for Research RINTAG(19)03
Lisa Mumford
This paper investigated the pathway of organs that had been retrieved and not transplanted, to assess the availability of organs for research as well as identifying the number of organs received by research studies in the last calendar year.
Conclusion

- Total number of organs retrieved and not transplanted has steadily increased. Proportion of these organs with consent/authorisation for research has increased to 93% in 2018 **LM**
- Proportion of discarded organs available with research consent/authorisation higher than previous years – 40% in 2017 and 46% in 2018. Mostly abdominal organs discarded.
- Utilised research organs were distributed across many studies, meaning that lower ranked studies were still able to obtain research organs (however three pancreas and kidney studies received no organs for research in 2018)

Research Team KPIs/Performance Report RINTAG(19)04
Hannah Tolley
Paper for information
The Objectives for this report were to (1) Measure the research team's activity, (2) To ensure that researchers are returning completed progress reports within 2 weeks, (3) To increase the proportion of organs accepted for research and (4) To increase the proportion of organs accepted for research regardless of day or time. Please see paper for details. GO thanked HT for collating all the information contained in this paper, which would be very useful for people to digest

5 Annual Report May RINTAG(19)05
Hannah Tolley
This was the first Annual Report to be produced. Key points:

Generic Consent Studies

- 28 studies currently receiving organs under generic consent, a further 11 to go live pending approvals outside of NHSBT's remit
- Average of 3 new enquiries a month – steady stream of research on its way

Specific Consent Studies

- Great success story in the last 12 months is the olfactory bulbs pilot study in Tooting – see Item 7
- Some specific consent studies currently on hold
- Several specific consent studies in the pipeline, two new heart perfusion studies in Newcastle and Cambridge in the next couple of months, other studies poised but awaiting grant funding

PITHIA *(Pre-Implantation Trial of Histopathology in Renal Allografts*)

- PITHIA trial commenced 01.10.2018, involving all 22 UK kidney transplant centres
- 4 centres went live on 01.02.2019 (Portsmouth, Belfast, Coventry and Glasgow), going live on 01.06.2019 will be Manchester, Birmingham, Guy's, Nottingham and Liverpool

QUOD Bronchoalveolar Lavage (BAL) Samples and Cardiac Biopsies

QUOD Biobank has reached 4000 donors in the last year. Collection of BAL samples and cardiac biopsies from untransplantable hearts went live alongside PITHIA on 01.02.2019

Organs offered through National Research Allocation Scheme

- 664 organs offered for research in past 12 months
- 346 were accepted (by ranked studies and tissue banks)
- 318 disposed of

Cardiothoracic Organs

- 21 lungs (pairs and singles) offered through NAS
- Average acceptance rate of 86%
- 1 heart in the last year, which was accepted

Kidneys

- 326 offered for research in last 12 months
- 48% acceptance rate

Livers

- Average of 14 per month offered
- Acceptance stands at 66% over past 12 months

Pancreata

- 5 already-isolated pancreatic islets offered and all accepted

Service Development

- INOAR
- Cell Lines
- Uterine Transplantation
- Website Redesign
- SNOD Training

This has been a very successful year. GO and RP thanked HT, MS and LA for all their hard work in getting the studies going. HT wanted to recognise the huge amount of work done by MS and The Hub.

It would also be useful to have information in the paper around which centres are developing novel technologies.

ACTION

There was some discussion about whether the allocation scheme was working, in that the number of organs available for research has increased but acceptance has decreased. It was recognised that research studies can be more selective when there are more organs offered. There was a suggestion that research studies should keep a log of all of the organs offered to them and the reason why they were suitable or not, equivalent to a clinical trial's screening log. CoW noted that his study does not have the funding to staff a 24/7 rota for accepting research organs.

CW queried where offering to Category 2 transplant recipients ends and research offering begins – something to be discussed at solid organ advisory groups if appropriate.

Points made in discussion:

- Default system needs to be in place eg. a fall-back automatic response to offer organs to QUOD
- Some studies seem to never respond. Some studies never take organs. Many then complain that they are not receiving organs. Suggestion to have a record of number of organs offered (fulfilling study criteria) and number of replies from each study.

Research kidneys declined in November 2018 RINTAG(19)06
Hannah Tolley

Following discussions at RINTAG in October 2018, the ODT Research Team conducted an exercise with kidney researchers during the month of November 2018. The aim was to understand why researchers do not respond to organ offers made by The Hub. Full Methodology available in the paper.

Conclusions

- One month's worth of data may not paint a totally representative picture
- Analysing the parameters from the offer message didn't provide as much illumination as hoped
- Some important insights have been identified

Ask of RINTAG: To note paper and then to ask Statistics & Clinical Studies team to carry out a logistic regression analysis on a larger dataset.

The consensus was that this has been a really useful piece of work. If we continue to collect this data, could potential reasons be reduced to eg. half a dozen, and collection be more in real time/by email? HT: will contact researchers to find out their thoughts on the best way to collate data. **HT**

6 Annual Review of National Research Organ Allocation Scheme and Ranking System RINTAG(19)07
Hannah Tolley

The current ranking system has been in place for over 2 years and is subject to annual review.

The group discussed whether acceptance criteria should be factored into a study's feasibility and agreed that it should. The first step would be to understand the acceptance criteria of each study. HT to collate this information using the next progress report. Once this is better understood, the team will be able to check if studies are responding to the offers that meet their criteria, with a view to potentially penalizing **HT**

ACTION

studies that do not respond. One of the alternative possible changes to the feasibility category would be to reward researchers who call in, even if that doesn't always result in them receiving a research organ.

RINTAG agreed that the number of organs already received by a study should be used to calculate their feasibility score (Method 2 in the paper). For new studies, Method 1 must be used as they have not received any research organs yet.

The "timescale from start of study to increase number of organs available for research" category is difficult to judge objectively. A study's end date has been used to calculate this category in the past in order to make it as objective as possible. NW noted that the aim of this category when the scheme was designed was to prioritise studies whose work was the closest to clinical implementation. RINTAG agreed that a simpler system should be used for this category instead, such as whether the study:

- Can Transplant The Organs It Receives
- Is Related to Transplantation (translational vs. basic science)
- Is Unrelated to Transplantation

It was noted that there will need to be further work on the definitions before the studies are re-scored appropriately. HT to work on alternatives for RINTAG review and agreement. **HT**

Comments during discussion:
If a study has a well set-up logistical system, and is responding properly, and doing its best to receive organs according to their remit, this should be rewarded and counted as a positive.
The definition of "use of novel technologies" needs to be refined and perhaps this criterion should be superseded by an alternative option.

Lung Research Allocation Resource Sharing – Newcastle & Edinburgh RINTAG(19)08 Andrew Fisher
Newcastle and Edinburgh, the only two centres with active RINTAG projects for lungs, have been working together to ensure that a robust on-call arrangement is in place to limit the likelihood that an available organ is missed – as a result, the percentage of offered organs accepted for research approaches 100%. With two centres competing for use of these organs a different approach is suggested – both teams to maintain full time on-call arrangements but with open dialogue between centres, available organs will be allocated equitably by:

- Alternating top ranked centre monthly
- Use a shared WhatsApp group for offers for all on-call parties on both sites
- 45 mins to accept an offer, as currently
- If only one team messages the group and there is no response from the other team within 20 mins, the team who is aware of the offer should proceed to accept
- From ODT Hub perspective lungs would be offered on a first come basis as the secondary team for that month should only call to accept if it has been discussed and agreed with the month's primary centre in advance or if the primary centre fails to respond

Some concerns were raised about the use of Whatsapp and the group suggested that the proposal is simplified and the Hub is provided with a rota stating which lung centre

ACTION

is first on which month. If the centre ranked first does not reply, the offer goes automatically to the other centre.

7 Olfactory Bulbs Team
Prof. Marios Papadopolous
Review of pilot study and plans for the future.

Dr Florence Hogg, Neurosurgical SPR and Research Fellow at St George's dialled into the meeting as Prof Papadopolous was unable to attend. Key points from Dr Hogg:

- Trial opened in March 2018 in a pilot phase and has so far recruited 3 patients. Excellent relationships with local SNODs and so far, consent process has gone very well.
- So far 22 DBDs screened for the study. Details on reasons patients were not suitable conveyed. Only one donor family when approached declined Olfactory Bulb (OB) donation. On some occasions pre-consent discussions were such that SNOD did not approach re OBs as families wishes were clear about research or donation from the head. On 4 occasions research team declined prior to family approach either due to conflict of interest, team away, clinical reasons to indicate OBs would not be viable). On 2 occasions early on in study research team declined after family approached and had given consent – now all SNODs discuss whether we would recruit patient prior to family discussion.
- 3 patients recruited. In all cases research team attended NORs handover to ensure transplant team were aware of what they were doing. In all patients craniotomy only started once transplant team confirmed they were closing and, in all patients, excellent cosmesis achieved (incision behind the hairline, no headshave, transparent sutures).
- Patient 1 was confirmed brain dead after a posterior fossa haemorrhage and had kidney and liver donation. OBs were successfully retrieved and procedure took 33 mins from start to closure. OECs were cultured.
- Patient 2 was confirmed brain dead following a sub-arachnoid haemorrhage and had pancreas, liver and kidney donation (aborted heart and lung). OBs were not identified as brain swollen and necrotic.
- Patient 3 was confirmed brain dead following sub-arachnoid haemorrhage and had heart, pancreas and kidney donation. Again, brain swollen and necrotic and unable to identify OBs
- Likely that better candidates for successful OB retrieval will be those where there is brain stem haemorrhage/pathology with relative preservation of frontal lobes. The wish is to continue screening all DBDs and make decisions on who to proceed with based on clinical history and imaging.
- Conveyed thanks for the amazing support and relationship with local SNODs and ongoing support from RINTAG (particularly MaS and HT). Also, thanks to the transplant surgeons who have been very supportive and accommodating
- The only change to be considered is starting the craniotomy once the transplant team confirm that the solid organs are retrieved and when they start to inspect the body cavity which will cut down the ischemic time for OB retrieval. This has been discussed with transplant teams during the retrievals St George's has been part of and they thought this was reasonable

Comments:
This has been a fantastic case of working collaboratively

ACTION

Currently, the Olfactory Bulbs team can only begin the craniotomy once the chest and abdomen are being closed and all organs have been retrieved for transplant. This status quo was to continue but GO asked FH and MaS to liaise with Ian Currie (Clinical Lead for Organ Retrieval) regarding potential changes to this. **MS/IC**

8 INOAR – *Increasing the number of organs available for research*
RINTAG(19)09
Liz Armstrong

Update on the progress of the INOAR sub-group since its inception in 2017. INOAR proposals to increase the number of organs available for research were agreed in principle by RINTAG, ODT SMT and QA SMT in 2017. Main proposal of INOAR was to extend the existing Liverpool Research HTA Licence (12068) to permit the removal of whole organs for research purposes. This licence currently used for QUOD covers 41 hospitals.

- INOAR project has encountered software/electronic/operational challenges, initial go live date of Nov 2018 was not achieved
- Work streams identified
- Project management support in place since March 2019
- Project team telecons commenced Apr 2019
- Next steps, risks and issues discussed in ODT CPB monthly

Next steps

- Continue to report progress of INOAR Project via ODT CPB
- Ensure effective stakeholder communications internally and externally regarding INOAR project development and delivery

Comments

- IC would like to see a process map of the end to end INOAR to visualise the process and responsibilities. IC advised further engagement required with NORS teams re roles and expectations in the INOAR process prior to go live. IC suggested a face to face meeting with the retrieval community as a way of ensuring commitment and buy in to the project. Comment noted by LA and IC was aware following previous comments made at NRG that this has been raised as a risk with the INOAR project manager and will be included on the INOAR project plan, Communications representation has also been obtained for the project.
- Challenges in delivering INOAR at the current time noted to be related to complex electronic/ IT changes and the operational team's capacity to develop and deliver the change.
- JF advised he was aware of ongoing challenges to the project and his commitment to resolve these. MiS confirmed that the HUB operations team were fully commitment to the development and delivery of the INOAR project. **JF**
- It was noted that alternative solutions have been put in place for the studies that are supposed to launch INOAR.

9 Studies for Approval and Information RINTAG(19)10(a-f)
Hannah Tolley

Study 45: *Oxford Islet Lab*

Existing study, aiming to identify ways to improve islet isolation outcomes and hence transplantation success rates, and encompasses functional and genomic studies. GO

had asked that this study's long-term storage of RNA be discussed. RINTAG agreed that the storage of any samples should be by QUOD and the study should not be allowed to store the samples for 10 years independently (QUOD consent needs to be checked for storage).

Study 89: T*he Emotional Impact of Deceased Organ Donation upon Specialist Healthcare Professionals*
Studying 15-20 SNOD and NORS team members. Awaiting approval from HRA. The group gave approval but commented that this number of participants doesn't seem very substantial, although this is often the norm for qualitative studies.

Studies 90 and 91: *QUOD Organ Atlas (Hearts and Pancreases)*
Attendees agreed that the studies should be approved, but with a review of their acceptance rates every month for the first few months. Organs can be offered now but if they are turned down because of capacity then that will be an issue long term. RINTAG suggested clear "Go/No Go" and Milestones.

Study 92: *SIRT1 and its role in lipid metabolism (sub-study to Study 68)*
No comments and no objections.

11 **Cell Line Consent Process Update**
Maggie Stevens
MaS was asked to look at a two-step consent process following comments made at the last RINTAG meeting.
Feedback

- Process has been mapped out by MaS and DH from a QA and regulatory point of view
- This is a complex process which will result in a lot of changes needed to consent forms
- Researchers don't know donor families, don't have a connection with them and don't have access to donor notes to even know if the family wanted to be contacted post-donation. Sharing a family's contact details with external researchers raises GDPR concerns.
- Most researchers would feel uncomfortable calling a recently bereaved family. Consenting is an HTA-regulated activity, so the researchers would have to be trained to take consent and training records kept.
- The most sensible answer would be to take a group of SNODs and train them on taking consent for immortalised cell lines
- Need to speak to research community and find out what they need
- Find out how many studies need cell lines – lot of changes/work if e.g. only two studies need cell lines
- VG needs to go back to the HTA

The group noted the sensitivities around immortalised cell line (ICL) creation, particularly in light of the origin of HeLa cells (the first ICL). It was suggested that researchers should be creating ICLs from the living rather than the deceased or buying them if they are really necessary. If this process (of ICL consent) is not carried out correctly, it poses a risk to NHSBT (and organ donation and transplantation more generally's) reputation.

ACTION

GO noted that organoid creation could pose a similar issue in future, therefore a scoping exercise should be carried out and discussed at the next RINTAG meeting.
It was agreed that studies involving ICL creation from the deceased should be stopped in light of the above but in parallel Dan Harvey should look into ways to address this challenges and future proof the approach (see comment about organoids).. **DH**

12 **Clinical Governance Update RINTAG(19)11**
Overview of key trends
There have been an increasing number of reports that relate to novel technologies and their impact on the retrieval process. Whilst the general principle is that novel technologies should not impact on the "standard" retrieval in any way, it is being reported via Incidents that they can cause delays and conflict during the retrieval process and potentially impact on other organs accepted for transplant. Novel technologies clearly bring benefits to transplantation; however, this needs to be done alongside minimising significant impact to the retrieval and not least the length of the pathway. Due to the complex multi-faceted aspects that feed into this area, various groups are exploring ways to ensure novel technologies can work cohesively within the "standard" retrieval process.

13 **Extracorporeal Liver Perfusion**
Colin Wilson
Articles referred to: see footnote[1]
CoW explained that he would like access to untransplantable livers to treat patients with fulminant liver failure. The livers would be attached to the patients extracorporeally (using a bypass machine) for approximately 12 hours, either as a rescue therapy or bridge to transplantation. A multi-disciplinary team (including DH) would then make a decision about the patient's care. CoW noted that many of the patients suitable for this treatment are on the transplant pathway but fall off it because they become too unstable.

Period covered: 2017 – End 2018
22 patients were identified (9 males and 13 females) that would have been suitable for this therapy. The average age was 42.5 (18-73), and the average length of their total admission was 13.4 days (0-49). 20 of these patients had evidence of multiple organ failure upon admission, commonly renal dysfunction. Only 3 of these patients managed to receive a super-urgent liver transplant. 10 died during the admission and 12 survived. Of the transplanted patients, one passed away due to primary transplant failure of unknown cause. The commonest cause of ALF was overdose (12 paracetamol, and 6 mixed). There was 1 acute on chronic alcoholic liver disease patient, 1 leflunomide toxicity and 2 seronegative hepatitides. The patients who died had a far worse biochemical picture. Their liver enzymes were more deranged, and they had a higher ammonia, lactate, and lower platelets.

New Intervention Governance
The Clinical Ethics Advisory Group, NuTH Critical Care Director, the Blood and Transplant Research Unit's PPI Panel, NIPC, NHSBT's LAG and HTA Regulatory Authority

[1] *"Extracorporeal liver perfusion as hepatic assist in acute liver failure: a review of world experience", Xenotransplantation 2002*
"Extracorporeal liver perfusion using human and pig livers for acute liver failure", Transplantation, 2000

have all given consent to this. The HTA noted that this would come under 'Human Applications' rather than transplantation.

CoW advised that this is a supportive therapy and people are ideally treated for at least 12 hours in order to see the benefit. Theoretically it is possible to leave people on a lot longer than this. Therapy allows patients to benefit from livers not thought suitable for transplantation. CoW advised that he will be aiming for between 8 and 10 livers per annum.

RINTAG deliberated and agreed that they were happy to support the project. The group suggested that CoW get LAG's approval that this project is allocated livers above Category 2 recipients. If this is not agreed, CoW can be allocated untransplantable livers through the national allocation scheme.

14 **QUOD Report – RINTAG(19)13**

Paper shows

- QUOD Bioresource Key Figures
- QUOD Donors in Total and Per Region
- QUOD Samples in Total and Per Type
- QUOD Biopsy and Incident Metrics
- Consent for QUOD Research and Actual QUOD Donors
- QUOD Samples issued to Applications:
  Biobank items issued to applications: 12,146
  Total number of research project applications: 50
  New applications (currently at preliminary stage): 15, including 1 being reviewed
  Among the approved applications, 16 were completed by QUOD and 19 are in progress

RP noted that there has been an increase in the number of Serious Adverse Reactions (SARs) mostly due to the change in biopsy technique that accommodated the PITHIA clinical trial. The SARs are being closely monitored. RP and the QUOD team have agreed that a smaller punch biopsy can be taken and the whole sample given to PITHIA if a PITHIA biopsy is requested – rather than a larger biopsy being taken and it being split between PITHIA and QUOD.

GO congratulated RP on the amount of work that he has done surrounding QUOD.

15 **DCD Heart Activity RINTAG(19)14**

Lisa Mumford

<u>Key Results</u>

- In the time period (01.02.2015 – 31.03.2019), 153 DCD heart retrieval attendances took place, 101 proceeded to retrieval, 90 hearts successfully transplanted
- Retrieved but untransplanted DCD heart rate was 11%
- Survival information available for 84 out of 90 transplants
- 14 recorded deaths post DCD heart transplantation
- 1-year post-transplant survival rate of 82.5%, which is comparable with DBD heart survival rate

ACTION

- 33% of DCD heart recipients required mechanical circulatory support within first 30 days, one patient required re-transplantation within 30 days
- Hub Ops advised that between 01.04.2017 and 31.03.2019, 265 DCD hearts had been offered from 11 of 12 SNOD regions, highest from Eastern region but also North-West and London. Of the 265 hearts offered, 186 were from potential DCDs aged 16-50 years

The paper shouldn't refer to NRP, but in every instance, TA-NRP. LM will take this information back to Statistics & Clinical Studies

DCD Heart Working Group Update RINTAG(19)15

Minutes were attached from DCD Heart Working Group Meeting held in Oct 2018. These notes have now been overtaken by events. The next working group meeting is on May 22, 2019. **LM**

Uterine Transplant Update

Dan Harvey

DH and Angie Scales (Lead Nurse – Paediatric Donation) have taken the project over from MaS and HT. The team are aiming for a go-live in the autumn, with just the London ODST participating. A decision was made at the recent NRG meeting that the Oxford NORS team will be ringfenced for a uterine donor for the 1st case and then a report submitted to NRG and other stakeholders.

JC asked for sight of the protocol from a PAG point of view, as the original uterine donation protocol retrieved iliac vessels, which are also required for pancreas donation. DH noted that the protocol had changed so that iliac vessels are no longer required and will send this to JC. **DH** Uterine Transplant is shown on the Clinical Trials website (despite not being a trial in the usual sense). GO noted that all service developments should be added to that website.

NRP - Current status in the UK

Gabriel Oniscu

Progressing well. Had a meeting with Kings who have agreed to take part in both training to establish a service and accepting NRP livers. Birmingham is nearly up and running.

Status of the Business Plan

Karen Quinn

Business Plan has been presented to the four UK Health Departments. Scotland has approved, Wales, England and Northern Ireland in process of approval. KQ to take to next SMT. **KQ**

16 **NHSBT Clinical Trials Unit**

Alison Deary

Grant Funding and Excess Treatment Costs (ETCs) for trials in organ donation and SSCs (Service Support Costs) RINTAG(19)18

One of the types of cost in a clinical trial is a treatment cost. This cost covers the following scenario: if the trial's intervention became standard practice, the device/product/intervention/change in practice would be an ongoing treatment cost to the NHS. If that cost is more than the cost of standard practice, it becomes an excess treatment cost (ETC).

ACTION

ETCs are paid by Commissioners. The NHS England commissioner that the CTU have been working with on other trials suggested that in an organ donation trial, NHSBT would be liable to pay the ETCs. KQ noted that NHSBT commissions only organ retrieval, not donation or transplantation. Trials in donation would be covered by the donating hospital.

Other points from paper:

- Organ donation and transplantation not currently represented in list of specialisms for service support costs and clinical research network support. Plan is to approach clinical research network coordinating centre which manages local clinical research networks to clarify how best to obtain service support for trials
- System for applying for ETCs has been changed from 01.04.2019 - now to be calculated at grant application stage and agreed by a trial cost attribution expert from the CRN. If grant is awarded, the HRA will authorise the CRN to pay the ETCs to the hospitals where the trial treatment is being undertaken. In view of uncertainty as to which body is responsible for organ donation ETCs, the plan is to talk to HRA about them to ensure no difficulties going forward.
- CTU to build on PITHIA model. CTU aware that an additional burden might be placed on already busy people, so wish to minimise additional burden whilst still conducting efficient trials
- CTU happy to advise potential collaborators about funding streams, service support and ETCs for proposed trials: ClinicalTrialsUnit@nhsbt.nhs.uk

17 **Declined Offers due to logistical reasons**
John Forsythe **HC**
N/A for RINTAG – remove from agenda

18 **Any Other Business**
None

Date of next meeting: 9 October 2019, The Montague on the Gardens, 15 Montague Street, London WC1B 5BJ