To be ratified
NRG(M)(16)2(Am) **LAG(16)44**

NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE FIFTEENTH MEETING OF THE NATIONAL RETRIEVAL GROUP (NRG) WEDNESDAY 6th JULY 2016 FROM 10:30 UNTIL 15:30

ASSOCIATION OF ANAESTHETISTS, PORTLAND PLACE, LONDON

MINUTES

Present:

Rutger Ploeg	National Clinical Lead for Organ Retrieval **(Chair)**
Karen Quinn	Assistant Director – UK Commissioning, ODT **(Co-Chair)**
Liz Armstrong	Head of Service Development, ODT
John Asher	Clinical Lead, Medical Informatics, ODT
Emma Billingham	Senior Commissioning Manager, ODT
Roberto Cacciola	Associate National Clinical Lead for Organ Retrieval, ODT
Chris Callaghan	National Clinical Lead for Abdominal Organ Utilisation, ODT
John Casey	Pancreas Advisory Group Representative
Akila Chandrasekar	Consultant Haematologist, Tissue Services
Ian Currie	Lead Clinician, Royal Infirmary of Edinburgh
John Dark	National Clinical Lead for Governance, ODT
John Forsythe	Associate Medical Director, ODT, NHSBT
Victoria Gauden	National Quality Manager, ODT, NHSBT
Clare Jones	QA Manager, ODT, NHSBT
Richard Lomas	Senior Clinical Development Scientist, Tissue Services
Derek Manas	Liver Advisory Group Representative
Jennifer Mehew	Statistics and Clinical Studies, NHSBT
Gabriel Oniscu	Research, Innovation & Novel Technologies Advisory Group Representative
Gavin Pettigrew	NORS Retrieval Teams Representative
Angie Scales	National Paediatric & Neonatal Specialist Nurse, ODT, NHSBT
Anne Sheldon	Head of Referral & Offering, ODT, NHSBT
Mick Stokes	Duty Office Services Manager, ODT, NHSBT
Steven Tsui	Cardiothoracic Advisory Group Representative
Chris Watson	Kidney Advisory Group Representative
Fiona Wellington	Head of Operations for Organ Donation (SN-OD Representative)
Julie Whitney	SN-OD Representative
Claire Williment	Head of Transplant Development, ODT, NHSBT

In Attendance:

Benjamin Jones	Clinical Research Fellow, Imperial College
Richard Smith	Consultant Gynaecology Oncologist, Imperial College
Amanda McEvoy	Clinical & Support Services ODT, NHSBT
Rajamiyer Venkateswaran	Manchester CT Transplant Centre Representative

Item **Action**

Apologies – Dave Collett, Peter Friend, Ben Hume, Rachel Johnson, Sally Johnson, David Metcalf, Paul Murphy, Triona Norman, Sally Rushton, Andre Simon, Anthony Snape, John Stirling, Helen Tincknell, Belinda Wright

1 Declarations of interest in relation to the agenda

Please note that it is the policy of NHSBT to publish all papers on the website unless the papers include patient identifiable information, preliminary or unconfirmed data, confidential and commercial information or will preclude publication in a peer-reviewed professional journal. Authors of such papers should indicate whether their paper falls into these categories.

There were no declarations of interest in relation to the agenda.

2 Minutes of the National Retrieval Group meeting held on Wednesday 9th March 2016

2.1 Accuracy Item 11 point 4 - take out CTAG - Completed

2.2 Action points – any queries – Section 17 b revise names against actions - Completed

2.3 Matters arising, not separately identified - there were no matters arising, not separately identified

Advisory Group priorities

- Bowel

  There were no major concerns and P Friend was not present to give a report

- Cardiothoracic

  -**Paediatric Cardiac Donor Size – Should we go up to 40 kg?**

- Concerns had been raised about small donors
- After some discussion, it was decided at CTAG to use height as a measure rather than weight – now agreed at 145cm
- This equated to about 43 kg and the revised description would be "small cardiothoracic donors "
- This means that the new limit would be 145cm and no less than 40kg

  -**CT Perfusion Protocol**

- Discussion about DCD donors about to go on NRP
- The issue of whether to retrieve the lungs immediately or whether to wait for abdominal NRP to complete
- There have been instances where bleeding has led to loss of organs
- Before the cardio team leave, they need to check that the abdominal team is happy with haemostasis
- Trying to mitigate bleeding issues but no appetite for alternative proposal
- Leaving the lungs in situ for 2 hours – concern that they will become ischemic in a warm cadaver
- There will be a session at the Masterclass to include this
- S Tsui stated that a small working group should be established to develop a strategy **S Tsui**
- R Ploeg stated that the cardio team should only leave if there was haemostasis and this could be integrated as a workshop at the Masterclass
- Feedback from E Billingham about ceasing the use of T3 – she will check that this has been communicated out **E Billingham**
- Discussion about Harefield starting a trial on OCS
- Suggestion that bank blood could be used – SNODS could order in advance
- G Oniscu will circulate a spreadsheet including new technologies and specialty requirements for all abdominal groups **G Oniscu**
- R Ploeg will call A Simon to find out about the Harefield trial **R Ploeg**

  - **Kidney**

- No significant retrieval issues to report

- **Liver**

- D Manas spoke about the ongoing issue of utilisation and the disparity in documentation between units
- LAG is keen to explore the decline of organs. I Currie is working on this but it is complex

- LAG Chair needs to reactivate the working group on liver splitting in order to address concerns on who undertakes splitting and where. Current guidance is that the liver is allocated to the paediatric patient first **D Manas**
- G Oniscu will finalise the forms to reflect the use of novel technologies to make them easier to use **G Oniscu**
- Also looking at small adult females who do not get access to paediatric livers

- Pancreas

- J Casey spoke about the introduction of clear packaging to eliminate risk of any mix-up
- C Wilson was putting a document together regarding fluid contamination at the time of retrieval – which will come to NRG
- Discussion took place about priorities regarding the liver and pancreas – communication between surgeons, damage of the pancreas and dividing or keeping the pancreas intact. The agreement between LAG and PAG to divide the accessory right hepatic artery allowing the use of both organs has never been included in the NORS Standards. The default in the NORS Standards is that the liver takes priority which has to be changed. D Manas and J Casey to write a clear paragraph for inclusion in the NORS standards re division of the accessory right hepatic artery by liver and pancreas surgeons **D Manas/ J Casey**
- G Oniscu asked if the incidents should be recorded **R Ploeg**
- NORS Standards to be updated with the above change when agreed
- J Casey stated that there is a need to emphasise in NORS Standards that the Pancreas should be retrieved with the same care whether for solid organ or islet transplantation.

4 NHSBT Update

4.1 <u>General Update & New appointments</u>

- There were no new appointments to report
- J Forsythe spoke about improved communications being forged between the British Transplantation Society and the Director of Transplantation
- The way that a case involving a potential donor with the Zika virus was handled had informed updated advice on the Website.
- Donor characterisation project run by H & I and Microbiology – S Fuggle is the Chair - looking at standardisation of laboratory data
- O McGowan is running a project to identify delays in the DCD donation process

4.2 Update on RINTAG - Where are we now (NRP/EVLP)?

- G Oniscu spoke about a review of the services - NRP and EVLP There are 50 NRP donors in the country. EVLP occurs in 2 centres and 7 lungs have been perfused this way so far
- G Oniscu recorded his gratitude to V Gauden for her help
- An NRP service evaluation is active in 5 centres
- The logistics of uterine and face transplantations are being examined
- There are 20 active research studies across all organs
- The contracts were signed for the service development of NRP in July 2015 with a target of 60 - 100 donors.

4.3 Paediatric & Multi-visceral Retrieval .

K Quinn advised that funding had been secured for paediatric cardiothoracic retrieval for this year and would be made substantive. This resulted from the fact that NORS was set up as an adult retrieval service; an update on abdominal paediatric and multi-visceral showed that these services were covered by NORS but governance needs to be clarified. Update to come to next NRG.

4.4 Data on Coroner's Refusals

- J Mehew explained that it was agreed at Spring NRG meeting that Statistics and Clinical Studies would present a summary of Coroner (or Procurator Fiscal) refusal data at each NRG meeting
- The report showed the number of Coroner refusals (either restricted or full) as a percentage of cases where permission was requested from the Coroner
- This number was presented by quarter from 1st April 2013 to 31st March 2016 and it had been found that Coroner involvement differed regionally
- In some areas, Organ Donation Services Teams contacted the Coroner for consent/authorisation for all potential donors. In other areas, the Coroner was only approached for permission under certain circumstances
- On average 17 - 20% of all cases taken to the coroner were refused
- R Ploeg asked that J Mehew and her team add the actual numbers, not just percentages **J Mehew**
- NHSBT is liaising with Coroners to raise awareness. Although small numbers it is enough to require action
- We need to know how many donors we are losing
- Different criteria for England and Wales regarding when to contact the Coroner
- J Neuberger met with the Chief Coroner and there was ongoing training around this
- J Forsythe raised the fact that this will come up in the BMJ soon and may attract significant interest

4.5 ODT Hub Update

- A Sheldon explained that there was a need to invest in IT in order to improve the transplantation pathway. The old manual processes were being replaced to eliminate the risks. The vision was to have "a simpler, safer, responsive service that supports clinicians in matching world class performance in organ donation and transplantation, with a clinically led 24/7 support centre at its core and renewed technology as its foundation". This would start with the cardiothoracic pathway later in the year
- The IT infrastructure was being built to support all organs going forward
- The next step was to make sure that transplant surgeons were included in the ongoing workshops to develop the new systems, following which Advisory Group involvement is required **A Sheldon**

4.6 Responsibilities and Operation re Dispatch Function NHSBT for NORS Teams

- M Stokes spoke about the centralisation of NORS teams and the importance of keeping the rota current and up to date
- A NORS allocation lead will be on each shift
- J Forsythe suggested a 'Flag' system to flag the urgency and risk of the donor to improve prioritisation – M Stokes to look at this suggestion **M Stokes**
- Better forward planning to eliminate delays
- Algorithms are being refined to estimate travel time for each NORS team to any donor hospital and prevent unnecessary travel from far north to far south and vice versa
- There will be a "Rapid Improvement" event in August to look at case studies and identify where improvements could be made – this information will inform the changes
- Support is needed from clinicians
- Duty Office will investigate first then pass to nominated clinicians (J Asher to look at who could help out) for their feedback **J Asher**

5 Digital Pathology Workforce

5.1 Progress towards service and research

- R Cacciola explained that the project was complete and he thanked G Pettigrew for his assistance
- The workforce has met and engaged with their pathologist colleagues
- There is the possibility of funding through NIHR and the deadlines were coming up – 27th July
- Hoped to return to NRG in November with a success story
- This was about changing the way of working and improving the safety and number of transplants
- Evaluating the histopathology

- The next phase would be to make the service available to transplant surgeons
- There would be 4/5 digital scanners to identify malignancy before any transplant commenced
- Would finance eventually come from NHS England or NHSBT?
  K Quinn stated that evidence of better utilisation and improvements was required before a business case would be led by NHSBT

6 Clinical Governance

6.1 NORS Standards Review

- R Ploeg stated that he wanted to have a more formal review and he needed the assistance of the other NRG members
- Advisory Group members were also needed for each organ AG Chairs to nominate a representative for the review — **AG Chairs/ D Manas**
- R Ploeg will approach individuals by email then he will organise a final sign-off meeting in October/November — **R Ploeg**

6.2 Electronic Quality Form Pilot – working group results

- Clinicians are updating data fields for each organ
- Will be approaching Advisory Groups
- There have been complaints about filling in forms
- Possibility of using 'Y' or 'N' instead of 'Yes' or 'No' as easier
- A pilot will take place - taking out donor specific details
- Timeline – completing technicalities and finalisation of data – Pilot by end of year to record data — **J Asher/ C Williment**

6.3 Priming of NMP devices with RBC (donor/recipient centre)

- Issues with NRP discussed earlier
- Question of bank blood versus donor blood and whether the donor hospital should supply the blood
- Principle is that for any perfusion initiated in the donor centre the NORS team is arranging and ex-vivo perfusion initiated in the transplant centre then recipient team is responsible
- The question of what blood to use has to be tailored to donor organ
- G Oniscu will add use and traceability of blood to his spreadsheet — **G Oniscu**

6.4 Risk for SAE (a Liver case Leeds/Southampton)/ Governance Report

There were 32 incidents out of 320 retrievals reported to the governance team between 1st April and 30th June 2016

- There were four organ losses due to damage and four heart valves deemed not suitable
- There were nine organs damaged at retrieval but otherwise transplanted successfully
- 19 organisational (not strictly surgical) events
- Mainly issues with packing of organs (5); delays (5); communications (4)

Points for discussion

- Incident involving candida contamination in transport fluid - final considerations and actions
- Delays - impact on quality of organs and NORS Teams activity
- Packing - NORS Teams should ensure an adequate level of consumables
- Communications
- NRP incident - potentially preventable event?

Conclusion

- Organ damage leading to organ loss represented 2.5% of all retrieval performed
- The CRM round will include review of performance of each NORS Team
- Organ damage seems to be associated with a number of varying organisational events
- A retrospective review of 12 - 24 months would give valuable information
- After the candida incident, Advisory Groups stated that routine culture of perfusion fluid would be advised
- J Casey – no objection to routine testing from PAG
- Damage reporting is not consistent
- Packaging – E Billingham demonstrated the new packaging – much improved

6.5 Pancreas Discard Assessment Project

- G Oniscu and R Ploeg – this is a working initiative to try to identify clear indications for turning down or accepting a pancreas. This will start this month and carry on for three months then there will be analysis of the data
- The flow sheet has been completed and the Duty Office is ready

7 DCD Human Heart

7.1 Manchester OCS Experience

- R Venkateswaran described the pilot at Manchester with an OCS machine initially using DBD hearts
- Manchester had received generous funding from the New Start Charity to start the pilot after dialogue with NRG, NHSBT & CTAG
- Two day training in Boston and also presented to Leeds NORS
- 2 OCS retrievals carried out at Harefield – then a final rehearsal before going live in Manchester
- Three DBD donors – all recipients doing well
- There had been no issues with using the OCS machine and no graft dysfunction
- Manchester team wanted to continue to use the OCS machine and they wanted support to continue
- R Ploeg and S Tsui recorded their congratulations for a well run pilot with meticulous training and preparation
- S Tsui stated that the first DCD heart retrieval with the OCS machine was 28th Feb 2015 and to date 24 DCD hearts had been retrieved and

transplanted from the machine
- 23 of those 24 were alive at 30 days
- Department of Health specified that a business case was required
- D McGuckin was now preparing a business case for NHSBT and no other centres are to be added until a decision on the DCD heart programme for sustainable DCD retrieval
- K Quinn stated that there was only agreement for Harefield and Papworth, who received support with transport costs as well as the actual transplant
- A gap analysis had been done in Manchester that concluded that funding was required for around 5 extra hearts on the OCS machine per year

- Manchester has already gone through the process that the DCD Steering Group assigned
- NODC, NRG and CTAG need to decide on the approach
- R Ploeg will discuss with P Murphy, S Tsui and J Forsythe **R Ploeg**

8 Training and Certification

8.1 Perioperative training progress

- Final meeting in May but further work in certification, curriculum, E Learning etc
- Not able to train workforce
- NHSBT gave extension to the end of the financial year
- A further group with J Stirling for clinical lead
- Curriculum – competency based
- Train the trainers approach with training pack
- On the job training, masterclass, sign-off by NORS leaders by the end of financial year
- Simulation training (end of June/beg July) needs reviewing
- Phased approach focusing on DBD
- Scouts – external peer review of the Scout Project
- Meeting in September to review, then a business case will be submitted in November

8.2 Organ Retrieval Masterclass 2016

- This year, the Masterclass will take place in Bristol on Monday 12th and Tuesday 13th December at Tortworth Court Four Pillars Hotel and Vesalius Clinical Training Centre, University of Bristol
- Good facilities and cheaper than previous venues
- Option to stay on 11th December for those who have far to travel
- Letters currently going out

9 Retrieval of Tissues

9.1 The Specification of Tissues

A Chandrasekar and R Lomas attended from Tissue Services to seek support from NRG for:

i) Improving the quality of tissue allografts retrieved during organ retrieval
ii) The retrieval of new types of tissue allograft during organ retrieval
iii) Dissemination of this information to organ retrieval teams

- A Chandrasekar stated that hearts were currently retrieved by organ retrieval teams and sent to heart valves banks for processing

- The aortic and pulmonary valves, with associated vessels, were banked but it was important that longer lengths of pulmonary artery were left attached to hearts taken for valve donation
- Based on data from April - October 2015, 15% of pulmonary grafts obtained from hearts retrieved by organ retrieval teams were too short (<1cm) to be of clinical use. At least 2cm of each pulmonary artery is needed
- There was an unmet clinical need for this type of graft, which is used for repair of congenital defects of the RVOT
- Every graft discarded for this reason was logged with the ODT clinical incident reporting system and this was a widespread issue
- Also important to have longer lengths of aorta left attached to hearts taken for valve donation, ideally including the thoracic aorta to the level of the diaphragm

- Tissue Services bank aortic arch and superficial femoral artery grafts but an intermediate diameter size graft was also required
- Sufficient length (at least 5mm) of each intercostal artery needed to be left attached to the thoracic aorta to allow for ligation
- There are requests for bifurcated abdominal aorta including iliac arteries for the replacement of infected prosthetic vessels. If these are retrieved from deceased tissue donors in a mortuary they would be contaminated and therefore need to be retrieved at the time of organ retrieval
- Ideal to have 3 - 5 grafts in the bank
- Unused iliac vessels taken at the time of organ donation could be sent to Tissue Services for cryopreservation within 48 hours of cross clamp, to support organ transplantation
- Whole trachea and larynx, including sections of bronchii were required for the preparation of life saving acellular tracheal allografts. This was a new service – providing trachea for clinical use from deceased donors. Surgeons had requested that tracheas from organ donors also be considered. If this was feasible, they would speak to the SNODs regarding consenting appropriate donors
- The committee asked if a video could be circulated to teams demonstrating how to remove the heart appropriately and dissection showing where it is too short as well as details on how to access the new service
- V Gauden expressed concern that surgeons would not be licensed to retrieve the trachea – more discussion is required
- A Chandrasekar to talk to CTAG once the licensing is agreed
- V Gauden and E Billingham to talk to A Chandrasekar outside the meeting

10 Commissioning

10.1 NORS Review Implementation

J Mehew presented a paper which showed retrieval team attendances split by each team and scout attendances –

- There were 4 cases where scout attendances were made by teams that were not on duty (Glasgow on 9th and 19th April and Papworth on
- 19th and 22nd April)
- There were two further cases whereby scout attendances occurred on NORS rota handover days however RTI/ORI/PDA data have not yet been received in order to check against the cardiothoracic NORS rota
- J Mehew talked about the deployment of a fourth team and the data showed that there was no change in decline rates with the new rota
- This was based on 5 weeks of data and there would be more detail in

future. The data would be reviewed at the next implementation board
- E Billingham would review the criteria
- K Quinn asked E Billingham to lead a proposal to bring back to next NRG to review triggers for increased capacity **E Billingham**

10.2 Annual Report on the National Organ Retrieval Service 2015/16

J Mehew presented the main finding of the NORS Annual Report for 2015/16.

- Activity has increased slightly for most teams in this financial year compared with last financial year; the average change in the number of abdominal and cardiothoracic team attendances was 6%
- On average, 4.7 potential donors were attended by a retrieval team per day, which has increased slightly from last year (4.6 last year)
- On average, abdominal teams attended at least one donor on 55% of days in the year, while cardiothoracic teams attended at least one donor on 24% of days
- The proportion of out of zone attendances ranged from 13% (Scotland) to 45% (Royal Free) for abdominal teams and from 4% (Scotland) to 29% (Harefield) for cardiothoracic teams
- There were statistically significant differences in the mean number of cardiothoracic organs retrieved and transplanted per DBD donor across retrieval teams but this was not the case for abdominal organs
- A very high proportion of abdominal organs accepted for transplantation were retrieved; 100% for DBD and DCD kidneys across all teams
- The proportion was lower for cardiothoracic organs accepted (69% to 93% for DBD cardiothoracic donors across the six teams)
- The transplantation rates for retrieved organs were variable across organs, ranging from 51% for DBD pancreases, up to 97% for DBD hearts. Additionally, 21 DCD hearts were retrieved, 19 of which were transplanted in the time period
- J Mehew was asked to include the quality matrix in future reports **J Mehew**

10.3 Commissioning Performance Report

Attention was drawn to the fact that this report went to the Communications team. It included 10 objectives:

1 - Increase the number of living donors
2 - Increase the number of pre-emptive living donor kidney transplants
3 - Increase efficiency in the National Living Donor Kidney Sharing Schemes
4 - Increase the number of organs retrieved and transplanted
5 - Minimise organ retrieval damage
6 - Maximise DCD organ retrieval by meeting stand-down target
7 - Timely dispatch of retrieval teams to donor hospital
8 - Timely arrival of retrieval teams at donor hospital
9 - Minimise wait at donor hospital prior to retrieval
10 - Monitor activity across NORS teams

There was discussion around minimising the waiting time at the donor hospital prior to retrieval – this was being monitored to get a better understanding and E Billingham will provide a summary of the issues to the next NRG meeting. **E Billingham**

10.4 Feedback from Contract Review meetings

- E Billingham explained that the meetings had not started for 2016 so she was presenting from a paper that summarised the key themes and issues arising from last year's Contract Review Meetings (between May and November 2015) with the National Organ Retrieval Service Teams (NORS Teams) which were:
    - Training and Competencies
    - Organ damage reporting
    - KPIs
    - NORS Review
    - New developments
- There was a question about the organ damage report from statistics which will be circulated shortly – this will be a regular item going forward **J Mehew**
- E Billingham explained that it had been a challenge to get responses from NORS leads to complete the registration documents so that competencies and registrations could be verified
- R Ploeg stressed that all NORS leads must complete the registration documents
- E Billingham will liaise with Trudy Monday who is working on updating all of the registrations **E Billingham/ T Monday**

11 Any other business

There were no other items of business to report.

12 FOR INFORMATION ONLY:
NRG Workplan – noted.

13 Dates for 2016 meetings:
Wednesday, 9th November 2016 – Coram, Brunswick Square, London