Approved 17.03.21 MCTAG(M)(20)2

NHS BLOOD AND TRANSPLANT ORGAN AND TISSUE DONATION AND TRANSPLANTATION DIRECTORATE

THE TWENTY SECOND MEETING OF THE MULTI-VISCERAL AND COMPOSITE TISSUE **ADVISORY GROUP MEETING** AT 11:30 AM ON WEDNESDAY 21 OCTOBER 2020. **VIA MS TEAMS VIDEO CONFERENCING**

PRESENT:

Prof Peter Friend Chairman (and Rep for National Retrieval and Liver)

Deputy Chair & Birmingham Intestinal Transplant Centre Rep Dr Girish Gupte

Dr Ayesha Ali NHS England

Oxford Intestinal Transplant Centre Dr Philip Allan Dr Elisa Allen Statistics and Clinical Studies Ms Carly Bambridge Recipient Co-Ordinator Rep

Mr Andrew Butler Cambridge Intestinal Transplant Centre Mr Ian Currie National Lead for Organ Retrieval, ODT

Prof John Dark **Guest Presenter**

Ms Samantha Duncan Recipient Co-Ordinator Rep

Prof John Forsythe Associate Medical Director, NHSBT Dr Simon Gabe Adult small bowel and BAPEN Rep

Dr Susan Hill Paediatric gastroenterologist and BSPGHAN Rep

King's College Hospital Dr Jonathan Hind

Ms Rachel Hogg Statistics and Clinical Studies

Ms Heather Howe Recipient Co-Ordinator

Mr Craig Jones Lay Member

Ms Victoria Gauden National Quality Manager, ODT

Prof Simon Kav Composite Tissue Rep

Lav Member **Prof Elizabeth Murphy** Ms Sarah Peacock **BSHI** Rep

Specialist Nurse Organ Donation Rep Ms Lyn Robson Specialist Nurse Organ Donation Rep Ms Angie Scales Dr Lisa Sharkey Cambridge Intestinal Transplant Centre Mr Hector Vilca-Melendez King's Intestinal Transplant Centre

Ms Sarah Watson NHS England

Ms Julie Whitney **ODT Hub Rep**

IN ATTENDANCE:

Mrs Kamann Huang Secretary, ODT

ACTION

Welcome

Andrew Butler will be the new Chair of MCTAG from 1 November 2020.

John Forsythe and members expressed their thanks to P Friend for his time and the work undertaken as Chair of MCTAG.

Apologies were received from:

Prof Derek Manas and Mr Khalid Sharif.

- 1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA MCTAG(19)16
- 1.1 There were no declarations of interest in relation to the agenda.
- 2 MINUTES OF THE MCTAG MEETING ON 11 MARCH 2020 - MCTAG(M)(20)1
- 2.1 **Accuracy**
- 2.1.1 The minutes of the meeting held on 11 March 2020 were agreed as an accurate record.
- 2.2 Action Points MCTAG(AP)(20)2
- 2.2.1 <u>Liaise with HTA regarding the classification of abdominal fascia in the context of intestinal transplantation and inform J Forsythe to confirm if further action is required (AP2 24.10.18)</u>

AP1 – The HTA regard fascia as a tissue and, not an organ, thereby requiring different regulations for testing, storage and utilisation. There is no substantial HTA concern regarding the use of fascia in patients who are undergoing transplantation of a solid organ from the same donor, but there is concern if the fascia is to be used in a patient not undergoing transplantation of a solid organ. In particular, this raised issues of traceability of the fascia; if this issue is resolved then there is no underlying problem with the use of the fascia as a third-party graft.

The issue of retrieval was discussed: at present, only Cambridge, King's College Hospital and the Royal Free Hospital retrieval teams are trained to retrieve isolated abdominal fascia. There are plans for a training video.

There have been discussions with the NHSBT Tissue Bank in Liverpool regarding the storage of fascia.

It has been proposed that the retrieval of fascia will be carried out in a pilot region (East Anglia) first and, if successful, extended to the rest of the UK. A Butler and V Gauden to put together the plan and A Butler to circulate this when finalised.

A Butler/ V Gauden

AP2 – <u>Priority of hepatoblastoma and intestinal recipients in the</u> paediatric setting

Refer to minute 4.2.1.

AP3 – Establish if post-transplant DSA data collection can be simplified S Peacock has proposed a system of data collection that was presented to MCTAG in Spring 2020. The Addenbrooke's lab has implemented this in Cambridge – it involves programming in Excel to interrogate recipient and donor HLA data and extract reported DSA in the right format. Oxford has a similar set up and S Peacock thinks that it would be possible to implement this in Oxford. Once the adult data are collected it will be interrogated for the development of antibodies post- transplant and the implications of someone developing multiple antibodies. Adults will be analysed independently to paediatrics using in-house expertise at Cambridge.

Data exists for paediatrics but requires more work to retrieve the required data. There is still a need for a system that works nationally. S Peacock will advise further regarding paediatric data.

S Peacock

AP4 – Extending the donor criteria for the offering of intestine-containing grafts

The current criteria for bowel donation for a DBD donor is an age limit of 55 years and a weight limit of 79 kilograms. At the last MCTAG meeting it was agreed that as the general population is living longer and getting heavier the age limit should be extended to 59 years and a maximum weight of 89 kilograms, but to use the evidence in the UK Transplant Registry to quantify the number of extra bowel transplants that such a change would result in.

Over the last 5 years, based on the current criteria, on average there has been one transplant per year using donors aged 50-55 years and for donors weighing 70-79 kg over the same period. There have been on average four transplants per year. Assuming the same consent and utilisation rates as those observed for donors in this age range, the proposed extended age criteria would amount to an extra 0.6 transplant per year, average, from donors aged 56-59 years. Likewise, the proposed extended weight criteria would result in 3.5 extra transplants per year, average, from donors weighing 80-89 kg. E Allen will speak to R Taylor to discuss possible impact for liver recipients and communicate the change to LAG. MCTAG agreed to extend to the new criteria.

E Allen

AP5 – <u>Proposal for a national audit of intestinal transplant units with internal bench-marking</u>

NHSBT documents outlining the system used for the peer review of Kidney and Pancreas transplant units have been circulated to H Vilca-Milendez and G Gupte. Each centre is assessed according to pre-defined standards. There was discussion about the purpose of peer review, with the consensus that this should be an informal process intended to share best practice and to assist units resolving logistics and other issues. It is therefore proposed that the two paediatric centres will visit each other and the same process to be undertaken with the adult centres. The details of this will be discussed more fully at the National Intestinal Forum in January. It was recommended that IF representation should be at the Forum.

2.3 Matters arising, not separately identified

2.3.1 There were no matters arising.

3 ASSOCIATE MEDICAL DIRECTOR'S REPORT

- 3.1 Governance
- 3.1.1 Non-compliance with allocation
- 3.1.1.1 There were no non-compliances reported with respect to allocation.
- 3.1.2 Detailed analysis of incidents for review MCTAG(20)20
- 3.1.2.1 There was one incident reported, over the last 12 months, regarding retrieval damage as part of a multi-visceral retrieval. Following

investigation, it was confirmed that the damage occurred due to unexpected abnormal donor anatomy.

NB:

There has been discussion regarding a possibility of the four units undergoing an external review facilitated by NHSBT but this has been put on hold due to COVID-19. This will be looked at again next year.

3.1.3 Organ donation and transplantation after COVID-19 surge

3.1.3.1 Clinical Team meetings, which includes all the Chairs of the Advisory Groups and senior managers from NHSBT, are continuing to be held on a weekly basis, in conjunction with weekly meetings with all the commissioners for transplantation across the UK, in order to monitor and manage the pandemic and to plan for the second wave. Data from NHSBT are presented at these meetings to provide as accurate a picture as possible nationwide.

NHSBT has access to ICNARC (Intensive Care National Audit & Research Centre) data to help the planning of donation and retrieval activities.

The second surge document sent to Centre Directors, accessed via the ODT clinical website, provides advice on virology for transplant centres to help them remain open as far as possible.

The bulletins sent out to Clinical Directors contain important information for the clinical community and should be circulated appropriately.

4 STATISTICS AND CLINICAL STUDIES REPORT

4.1 Summary from Statistics and Clinical Studies – MCTAG(20)21

Some key points of the update were:

- The 2019/20 Annual Report on Intestine Transplantation has been published on the ODT clinical website.
- An update in the staff responsibilities within the department for organs and tissue.
- POL193 and POL194 will be updated to provide guidance to register multi-visceral patients with hepatoblastoma and prioritise them for offering.
- POL194 will be updated to describe a process to inform NHSBT about patients registered for an intestinal transplant but transplanted with an isolated liver only.

4.2 POL193 Intestinal Allocation Policy & POL194 Draft Intestinal Registration – MCTAG(20)22 & MCTAG(20)23

4.2.1 POL193 - One change relates to the registration and transplantation of multi-visceral (MV) patients with hepatoblastoma. This is not currently viewed as an indication for MV transplant, and such (rare) cases therefore require approval from the intestinal national appeals panel before registration; detailed in the registration policy. Hepatoblastoma MV patients are not prioritised for offering in the national bowel allocation scheme. Following discussions, it was agreed to give additional waiting time points to these patients; it will be the responsibility of the transplant centre to seek approval for registration

and the additional waiting time points. Prioritisation will be guaranteed only within the donor to recipient blood group preference tier of the national combined liver and intestinal waiting list. Therefore, a non-hepatoblastoma intestinal patient who is blood group preferable to the donor will be prioritised over a hepatoblastoma MV patient who is only blood group compatible. A MV hepatoblastoma patient will only be prioritised within the national combined liver and intestinal waiting list and never within, or above, the national hepatoblastoma list of liver patients.

Following a lengthy discussion, some members would like MV hepatoblastoma patients to have the same, or higher, priority as liver hepatoblastoma patients on the basis that liver hepatoblastoma recipients can have split livers whereas MV cannot. J Whitney and E Allen explained that IT changes to the allocation systems would not be simple. It was concluded that MV hepatoblastoma registrations will be individually discussed with other intestinal and liver centres to consider offering at the same priority level as liver hepatoblastoma registrations.

POL194 – This policy will be updated to include information related to registering patients for a MV intestinal transplant but only transplanted for an isolated liver. As the registration is done via the intestinal route, the process results in transplantation of a liver only, they are not automatically followed up; this can also cause problems if patients need to be re-registered. To ensure that such cases are captured correctly, the process is for the transplant centre to inform the NHSBT Statistics team by emailing Statistical Enquiries statistical.enquiries@nhsbt.nhs.uk). The transplant centre should also notify ODT Hub Operations at the transplant notification stage.

E Allen will implement the edits presented on POL193 and POL194.

5 NATIONAL BOWEL ALLOCATION

5.1 Performance report of the National Bowel Allocation Scheme (NBAS) – MCTAG(20)24

A report was presented showing patients active on the transplant list between 1 January 2020 and 30 June 2020 with a comparison of one year post-registration outcomes over time, median time to transplant, and prolonged registrations.

Data showed that there has been a prolonged waiting for paediatrics. No definite reasons could be given for this so G Gupte will take this issue up outside of the meeting to see what has changed in the paediatric population setting.

G Gupte

5.2 Meeting criteria before registering liver for a multi-visceral transplant – MCTAG(20)25

5.2.1 This issue was raised because of very long waiting times for paediatric multi-visceral transplants and will be followed up by discussion between the two paediatric units.

H Vilca-Melendez/ G Gupte

6 GROUP 2 BOWEL TRANSPLANTS

6.1 Group 2 bowel transplants – MCTAG(20)26

Data showed there was one Group 2 intestinal transplant performed in the UK between 1 February 2020 and 31 August 2020 for a paediatric patient, aged 9 years from UAE, at King's College who received a bowel-only transplant.

There were no Group 1 non-UK resident EU patient intestinal transplants performed in the UK for the same period.

7 POTENTIAL BOWEL DONORS AND LOCATION – MCTAG(20)28

7.1 A paper was presented looking at the pathway from identification of potential bowel donors to transplantation of the bowel and the points at which potential bowel donors are "lost".

Members were asked to inform Stats of any amendments/updates that need to be included.

Table 2 – R Hogg to send J Whitney the history details for the 15 donor bowels not offered.

R Hogg

8 REFERRAL CRITERIA STRATEGY FOR INTESTINAL TRANSPLANT

8.1 The aim of increasing awareness of intestinal transplantation as well as other treatments in intestinal failure was raised a year ago. This has traditionally been undertaken via publications and conferences. One option is to hold virtual conferences aimed at referrers at a multidisciplinary level and to involve patient support groups, NHS Statistical expertise and M&F Health (a communications company) involved with BAPEN raising malnutrition awareness. Unfortunately, owing to COVID-19 little progress has been made. The next step is to ask Trevor Smith (BAPEN) to approach M&F to initiate the awareness campaign which will involve a cost. It was recommended that NHS England should also be involved to publicise educational awareness.

S Watson

Post Meeting Note:

Carly Bambridge, Susan Hill and Phil Allen have offered to be involved in the team undertaking the work. Other members to be approached are Carolyn Wheatley (Chair of PINNT), Nicola Birch, a BAPEN executive, a dietitian, and pharmacist (to be decided) in order to scope the issue with M&F Health. P Allen/P Friend to approach Nicola Birch.

P Allen/ P Friend

9 TRANSFER OF UK INTESTINAL DATA TO THE INTERNATIONAL INTESTINAL TRANSPLANT REGISTRY (ITR) – MCTAG(20)29

9.1 The data we currently collect needs to be amended for the ITR. A spreadsheet was presented with five tabs: Tab 1 – Proposed fields, Tab 2 – Current NHSBT data fields, Tab 3 – Current ITR data fields. The key tabs are 1 – 3. Attendees were asked to give feedback on the data presented; the next step will be to agree with NHSBT IT regarding operational feasibility.

J Whitney will discuss this further after the meeting with E Allen and others.

J Whitney

10 UPDATE FROM THE WORKING GROUPS

10.1 Quality of Life Working Group: data collection

10.1.1 Adults

Collection continues at all centres in working towards a unified QoL package.

10.1.2 **Paediatrics**

A meeting was planned in Birmingham in January this year between the four centres but owing to COVID-19 this did not take place: the work is continuing.

10.2 Update from the Working Group on NHSBT data and postoperative data collection

10.2.1 This will essentially be using the ITR information once it has been finalised to populate the registry. The registry is now transitioning to TTS (which will give it international status). J Hind will restart communication with TTS.

J Hind

10.3 Update from the Working Group on a patient information and consent:

10.3.1 Patient & Consent document for intestinal transplantation MCTAG(20)30

A Butler suggested that the generic adult document might be based on an amendment of the Oxford document presented below (Item 10.3.2).

It will not be feasible to use the adult document for paediatric cases, which will have to be a separate document. Work previously undertaken between G Gupte and J Hind (whilst at the Children's Liver Disease Foundation) for an overview leaflet on intestinal transplantation and a patient information leaflet could be reviewed to form the paediatric document. C Jones agreed to be part of the team to work on this along with H Howe, A Butler and P Allan.

10.3.2 Generic Adult document – MCTAG(20)31

The Oxford patient intestinal transplantation information document was presented.

11 DONOR SIMVASTATIN TREATMENT – MCTAG(20)32a & 32b

11.1 The details of a donor management trial, comprising the randomisation of multi-organ donors to receiving treatment with simvastatin or placebo, were presented by Professor John Dark. Members were requested to keep this information confidential until the end of the month.

In a previous study, the use of simvastatin (which has anti-inflammatory properties) in heart donors showed improved cardiac survival and reduced early complications and reduced rejection. In the same study, kidneys showed no difference, livers demonstrated a lower ALT at day 7, lungs showed improved primary graft dysfunction grade: no multi-visceral transplants were undertaken.

This 4-year study will use 2600 randomised DBD adults, following consent for donation to receive a single dose of 80 mg simvastatin. The

recipients will not be known; this is a donor intervention management study. The concept of the study has been presented to a number of PPI groups who have all approved and is being presented at all relevant Transplant Advisory Groups.

There is an advantage of undertaking the study in the UK owing to the national transplant services being coordinated centrally. MCTAG approved the study.

12 KING'S CURRENT PRIVATE PATIENT LISTED FOR ISOLATED SMALL BOWEL AND COLON TRANSPLANT

12.1 Refer to agenda item 6.2.

13 APPEALS/PRIORITY

13. There were no appeals reported regarding bowel intestinal transplantation.

14 UPDATE ON NASIT

14.1 It was reported that the monthly meetings have been working well via MS Teams meetings during the pandemic with the involvement of IS centres.

G Gupte reported that a meeting is being held early next year which will provide more information for the equivalent for paediatric teams. He will provide an update at the March 2021 meeting.

G Gupte

15 HAUL – VCA Service – MCTAG(20)33a & MCTAG(20)33b

15.1 Professor Simon Kay presented an update of the UK Hand Transplant service. This was temporarily suspended earlier in the year amid fears over immunosuppression risks during COVID-19 and has now reopened.

As more information is known about the virus now it was felt that undertaking hand and upper limb transplantations in the younger age group, who are otherwise fit and well, would lower the co-morbidity risk. However, the decision to go ahead with transplantation in each individual case will be based on full explanation of risks and potential benefits to the patient. The consent process is complex and typically taking a year and including four long interviews.

Feedback is welcomed from MCTAG members regarding the decision to re-open this service and the basis upon which the risk/benefit balance is arrived at.

S Kay will report back at a later stage on how we quantify QoL and weighing this up against risk.

16 FEEDBACK FROM THE LIVER ADVISORY GROUP MEETING ON 20TH MAY 2020

16.1 There were no major issues raised which required the attention of MCTAG.

17 ANY OTHER BUSINESS

17.1 New Chairs:

Gavin Pettigrew for RINTAG from 1st November 2020 Steve White for PAG from 1st December 2020

18 DATE OF NEXT MEETINGS:

Wednesday 17th March 2021 Wednesday 13th October 2021

19 FOR INFORMATION ONLY:

Papers attached for information were:

19.1 ICT Progress Report - MCTAG(20)34

19.2 Transplant activity report for September 2020 - MCTAG(20)35

19.3 Minutes of LAG meeting: 20 November 2019 - MCTAG(20)36

Administrative Lead: Kamann Huang October 2020