NHS BLOOD AND TRANSPLANT
ORGAN DONATION & TRANSPLANTATION DIRECTORATE

THE FIFTEENTH MEETING OF THE MULTI-VISCERAL AND COMPOSITE TISSUE ADVISORY GROUP (FORMERLY BAG) MEETING AT 11:30 AM ON WEDNESDAY 15 MARCH 2017, IN THE BOARDROOM, FIRST FLOOR, WEST END DONOR CENTRE, 26 MARGARET STREET, LONDON, W1W 8NB

PRESENT:

Prof Peter Friend	**Chairman** (and Rep for National Retrieval and Liver)
Dr Elisa Allen	Statistics & Clinical Studies, NHSBT
Ms Carly Bambridge	Recipient Co-ordinator Representative
Dr Martin Barnardo	BSHI Rep
Mr Andrew Butler	Cambridge Intestinal Transplant Centre
Ms Melissa D'Mello	Lay Member
Prof John Forsythe	Associate Medical Director, ODT
Prof Sue Fuggle	Scientific Advisor, ODT
Dr Simon Gabe	Adult and small bowel and BAPEN Rep
Ms Jackie Green	Deputy for Lydia Holdaway, Recipient Co-ordinator Rep
Dr Susan Hill	Paediatric gastroenterologist and BSPGHAN Rep
Dr Jonathan Hind	King's Intestinal Transplant Centre
Prof Elizabeth Murphy	Lay Member
Dr Lisa Sharkey	Deputy for Dr Steve Middleton, Cambridge Intestinal Transplant Centre
Mr Mick Stokes	Deputy for Ms Anne Sheldon, Transplantation Support Services Rep
Prof Simon Travis	Oxford Intestinal Transplant Centre
Mr Hector Vilca-Melendez	King's Intestinal Transplant Centre
Ms Sarah Watson	Deputy for Dr Edmund Jessop, Public Health Advisor

IN ATTENDANCE:

Mrs Kamann Huang	Secretary, ODT

ACTION

Apologies were received from:
Prof John Dark, Dr Girish Gupte, Ms Lydia Holdaway, Dr Steve Middleton, Mr Khalid Sharif, Mr Srikanth Reddy, Ms Susan Richards and Ms Anne Sheldon

1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA – BAG(17)1

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

2 MINUTES OF THE BAG MEETING ON 12 OCTOBER 2016 – BAG(M)(16)2

2.1 **Accuracy**

2.1.1 The minutes of the meeting held on 12 October 2016 were agreed as an accurate record following the amendment below:

Page 1, Add 'Prof Sue Fuggle to the Attendance list'.

ACTION

Page 5:

- Item 7.1 last sentence. Remove '<' (less than) from '3 kg in weight'.
- Item 10.1 third paragraph, 3rd line 'critically clinically urgent' to be amended to 'Clinically critical urgent'.

Page 6, 13.1 'National Organ Donation Committee Rep' to be amended to 'National Retrieval Rep' in the title.

2.2 Action Points – BAG(AP)(16)2

2.2.1 All action points have been completed, are in hand or are referred to in the Agenda, apart from the following:

AP1: C Bambridge stated that there will be a nominated recipient co-ordinator to inform the DO within 72 hours what organs have been transplanted. At King' College this will be C Bambridge, Cambridge - J Green and Oxford - L Holdaway. A nominee is yet to be confirmed for Birmingham. **C Bambridge**

AP2: In the absence of G Gupte and K Sharif, H Vilca-Melendez agreed to come up with the contra-indications for the paediatric centres. **H Vilca-Melendez**

A Butler will provide the contra-indications for the adult centres, in the absence of S Reddy. **A Butler**

H Vilca-Melendez and A Butler will work jointly to come up with a hard set of generic contra-indications to restrict organ offers which are unrealistic.

Under the liver offering scheme there is a +/- kg margin in the recipient to donor matching criteria. A similar principle could be adopted for the Bowel, whereby a generic set of criteria with a filter of +/- kg margin for each recipient/donor combination is applied. **H Vilca-Melendez/ A Butler**

AP9: HLA DSA (Donor Specific Antibody) data for bowel will be collected prospectively from 2017 at a time point. S Fuggle will write a letter, jointly with P Friend, to all centres and laboratories requesting the information. The data will be embedded into the dataset to be held at NHSBT. **S Fuggle**

2.3 Matters arising, not separately identified

2.3.1 There were no matters arising.

3 ASSOCIATE MEDICAL DIRECTOR'S REPORT

3.1 Developments in NHSBT

J Forsythe updated members on the following:

- The Utilisation Strategy was launched at BTS. The slides can be accessed at the following link (number 6 in the list) http://www.odt.nhs.uk/uk-transplant-registry/slides-presentations-for-download/ Part of the Strategy is looking at the length of donation and the retrieval Process and issues regarding extended criteria and donor organs.
- Donor Characterisation Review has looked at two issues: Microbiology and Histocompatibility and Immunogenetics Recommendations are being drawn up to present to the NHSBT Board.

ACTION

- The NHSBT ODT Clinical Website is being updated which has received good feedback from across the UK.
- CMV (Cytomegalovirus) incident- disparate results not reported. A letter has been sent to all units requesting any disparate results in donor characterisation to be reported to the Duty Office (DO) and other recipient sites.

A Butler raised the question of priority regarding a case of a bowel delaying a heart transplant (CT) and where the priority should lie. It was agreed that priority should be with a SU liver recipient. Members were asked to consider this further and, if agreed, can be discussed with LAG.

P Friend raised the issue of the extended time taken for organs to leave the hospital after retrieval and there was discussion about comparative cold ischaemic time by international standards. J Forsythe and P Friend agreed that these timings could be examined in the review of the length of the donation process and P Friend agreed to get evidence for inferior CIT compared with other countries. **J Forsythe/ P Friend**

3.2 **Governance**

3.2.1 **Non-compliance with allocation**

3.2.1.1 There were no non-compliances reported with allocation.

3.2.2 **Detailed analysis of incidents for review – BAG(17)2**

3.2.2.1 There were no incidents brought up for review.

4 STATISTICS & CLINICAL STUDIES REPORT

4.1 **Summary from Statistics and Clinical Studies and Annual Report – BAG(17)3**

The main points reported by E Allen were:

- analysis is under way to measure geographical variation of registration and transplant rates on intestine transplantation for the NHSBT/NHS England Annual Report. E Allen thanked members for feedback received on the Annual Report.
- statistical support to the Small Adults Working Group, and
- support to S Fuggle on the HLA DSA data collection.

5 NATIONAL BOWEL ALLOCATION

5.1 **Performance report of the National Bowel Allocation Scheme – BAG(17)4**

Data showed that since the implementation of The National Bowel Allocation Scheme (NBAS) in 2013, there has been an increase in the proportion of patients transplanted and a decrease in the number of deaths within 1 year of listing. The median waiting time for patients with intestinal failure requiring a liver has reduced by approximately 4 months. Patients with intestinal failure who do not require a liver transplant have experienced a reduction in median waiting times of approximately 3 months, relative to pre-NBAS figures. The current median waiting time for intestinal failure patients requiring a liver is

comparable to that of adults on the liver transplant list, at about 5 months.

6 UPDATE FROM WORKING GROUPS

6.1 Update from the National Bowel Allocation Working Group – BAG(17)5

6.1.1 A Working Group was set up to address transplantation for disadvantaged small adults weighing more than 35 kg with a restricted abdominal cavity preventing them from receiving organs from most adult donors.

The recommendation is that such cases should be discussed at NASIT and then submitted through the Appeals process. If the appeal is accepted, the adult patient will be registered on the intestinal waiting list with entitlement to be offered paediatric donor organs, in the same way as paediatric recipients. The number and outcome of such appeals to be reported back to BAG annually. **P Friend/ E Allen**

The recommendation will be taken to LAG by PFriend, as it will have implications for liver transplant patients. If it is endorsed by LAG, this new type of registration onto the intestinal waiting list will be introduced by E Allen.

6.2 Update from the Quality of Life Working Group – BAG(17)6

6.2.1 S Travis presented data based on completed questionnaires from patients using specified methods. The data were reported as inconclusive. Data would be improved if the dataset were to be completed nationally, and at 6 and 12 month intervals. On the basis of this information EQ5D can be used as a generic instrument for comparison.

It was noted that EQ5D is simple and used by NICE, though it has not been formally validated in this context. BAG members agreed that the UK has a worthwhile opportunity to drive this forward for QoL. Data should be rigorously collected and be adopted in transplantation reporting protocols. This will require setting up a database.

C Bambridge reported that there are similar tools suitable for paediatrics. She will take this forward for paediatrics. **C Bambridge K Huang**

This item will remain a standing agenda item.

6.3 Update from the Working Group on NHSBT data and post-operative data collection – BAG(17)7

6.3.1 This was discussed in the absence of the WG lead, S Reddy. P Friend recommended that this Working Group links up with the QoL Working Group. The issue of membership and chairmanship of the group was raised. C Bambridge and J Green agreed to join H Vilca-Melendez and further discussions will take place outside the meeting to ensure that this group is able to deliver the necessary recommendations. Neither Lay Member was able to Chair this Working Group owing to current workloads.

Discussion took place on Group 2 transplants. J Forsythe emphasized that donated usable organs should always be offered to UK residents

ACTION

first before Group 2 patients, in order to comply with the governance rules: this is done automatically on the system.

BAG agreed that a report detailing any Group 2 transplants would be advisable and would show adherence to Group 2 transplant rules. **E Allen**

6.4 **Update from the Working Group on a patient information and consent document for intestinal transplantation – BAG(17)8**

6.4.1 A Butler presented members with a draft consent document. The following recommendations were made:

- waiting times and survival data at 30 days, 1 and 5 years should be included.
- any issues to be dealt with centrally, rather than locally, to avoid variation.
- provide more clarification in the information regarding blood transfusion to patients.
- do not use the phrase '1 or 2 patients' which does not give clarity on a statistical level.
- provide a separate Information Sheet to be used in conjunction with the Consent Document, to cover the details that a patient might wish to consider, including a 'what can go wrong section' before agreeing to transplantation. A Butler will circulate revised draft documents to members for comments. This will be discussed again at the next meeting. **A Butler/ K Huang**

It was suggested that it would be helpful to build up a series of videos covering topics e.g. Consent to bowel transplant, a surgeon talking to a patient regarding a number of topics e.g. microbiology.

7 PATIENT SURIVAL OUTCOMES

7.1 **Patient survival after intestinal transplantation – BAG(17)9**

7.1.1 E Allen reported national data on patient survival following intestinal transplantation from 1 January 2001 to 31 December 2016.

A significantly lower survival of adult patients at 90 days post-transplant in the recent era was noted compared to historical data. This result was discussed at length and comments included the change in case mix of patients with time (including the type of transplant – intestine only vs. multi-visceral – and the indication for transplantation), and the relatively small number of patients in the analysis. It was agreed that, if significance is observed again in the next report, E Allen will undertake further analysis. **E Allen**

8 ADOLESCENT TRANSITION IN SMALL BOWEL TRANSPLANTATION

8.1 There will be two Service Specifications; one for Paediatrics and one for Adults. The Paediatrics Specification requires more work. The process of transition should start at 12 years of age in line with NICE guidelines.

The issue of transitional care highlights the lack of a suitable NHSE funding stream for patients post 12 months. Whereas other transplant types (liver, kidney) devolution to a physician with the necessary

ACTION

specialist skills (gastroenterologist, nephrologist), there is no such national network of specialists with the necessary skills (yet) for patients who have undergone intestinal transplantation. As a result, a substantial workload remains with the transplant centres in the long-term.

S Watson is currently working on the Service Specifications to define what the service will provide. This will be approved early next year and will form the basis of a business case to be put to NHS England, which will then be in a position to undertake a compliance exercise with each of the centres on an annual basis. Regarding the funding of long-term care, there is no short-term solution. S Watson will look at the activity across the country to be built into the costing. S Watson will recirculate the Service Specification, to include QoL, to members for comment. **S Watson**

A Butler reported that following a costing for transition undertaken by Addenbrooke's there is a shortfall and the team is currently not permitted to accept these patients. The primary issue is the cost of looking after the patients following transplantation post 12 months, for which the Trust has received no reimbursement, rather than the costs of the actual transition process.

S Watson reported that Trusts are commissioned and should claim for reimbursement. This needs to be addressed by the Service Specification. Members were asked to inform S Watson of any obstacles for transitioning for their centres. Birmingham is believed to have the larger burden. Cambridge currently putting together a business case.

S Watson will send out an updated Service Specification for Paediatrics and Adults, incorporating the points listed above, with full clarification and details regarding transitional care. **S Watson**

9 APPEALS/PRIORITY

9.1 There were no appeals regarding bowel intestinal transplantation.

10 UPDATE ON ADULT AND PAEDIATRIC SERVICE SPECIFICATION

10.1 Refer to agenda item 8.1 above.

11 HAND/ARM TRANSPLANTATION

11.1 There will be two representatives on BAG for hand/arm. Simon Kay is the National Lead and will nominate the other representative. It will be helpful to brief BAG on the protocols. This is a new service so NHS England will be involved. S Watson to let P Friend know what the issues are. P Friend will arrange to meet with Simon Kay before next BAG meeting on 11 October. **P Friend/ S Kay** **S Watson P Friend**

C Bambridge raised the question of which was the correct form to use for a patient requiring an abdominal fascia transplant. E Allen will respond to C Bambridge on this. **E Allen**

ACTION

12 COMBINED INTESTINAL AND PANCREATIC RETRIEVAL – BAG(17)10a, 10b & 10c

12.1 When the small bowel is retrieved for isolated small bowel transplantation and the pancreas is retrieved separately (or separated from an en bloc retrieval on the back table) the superior mesenteric vessels are cut short, increasing the technical risk of the intestinal transplant. The current agreement is that the pancreas should be removed on the back table, preserving the full length of vessels with the intestine, and then utilising the pancreas for islet transplantation. This has caused concern amongst a small number of pancreas transplant surgeons.

After discussion, it was agreed that the technical risk of allowing the superior mesenteric vessels to be cut short was significant and that, given the small number of such cases, the existing practice should continue. P Friend agreed to take this to the forthcoming meeting of PAG. **P Friend**

13 INCONSISTENT USE OF HTA A FORMS IN BOWEL TRANSPLANTS

13.1 A Butler raised the issue of the absence of a dedicated HTA form for bowel transplants: this came up at an HTA inspection visit to Cambridge. The HTA classed this as an inconsistency. It was noted that it was not appropriate to use the Liver Transplant form to cover this. A Butler to communicate with the HTA and feedback to BAG. **A Butler**

14 NASIT FORUM

14.1 S Gabe circulated a paper regarding the constitution of NASIT and its Terms of Reference.

The primary aims of NASIT are to discuss patients specifically considered for transplantation, to provide a forum for discussing patients prior to transplantation. NASIT is currently held every two months. The question of whether the Paediatric Group was to join this forum was raised; J Hind felt that it may be more appropriate for this to take place on an annual basis.

After discussion, it was agreed that NASIT has an advisory role. The final responsibility for any decision regarding a patient rests with the clinician involved. S Watson will reflect this in the Standards document. **S Watson**

The function of NASIT and the above agreements will be reflected in an updated NASIT Terms of Reference document. **S Gabe**

15 ANY OTHER BUSINESS

15.1 **Proposal to rename BAG as the Multivisceral and Composite Tissue Advisory Group (MCTAG) and draft Terms of Reference – BAG(17)11**

The question of whether a separate BAPEN representative and/or more representation for intestinal failure, to provide pre-transplant focus, should be in attendance (currently covered by S Gabe) was raised. Following discussion it was agreed that in the event S Gabe is

unavailable a deputy should attend. This issue can be discussed further at NASIT if required.

The revised Terms of Reference for BAG were presented to members, following the inclusion of composite tissue transplantation. Members agreed that the Bowel Advisory Group (BAG) should be renamed Multivisceral and Composite Tissue Advisory Group (MCTAG). The following amendments are to be made: **K Huang**

- Section 1.2 Members:
  Voting members: last line - 'Two representatives from the national hand transplant service' to be amended to 'Two representatives for composite tissue'.

  Non-voting members: Change 'Lay Member Representatives' to 'Lay Members'.
- Section 4 – 'sub-committee' to be changed to 'Working Group' in the title.
- Section 7 - Take out the paragraph before 7.1.

The BAG minutes will be officially renamed as MCTAG at the next meeting on 11 October 2017.

15.2 **Nomination of Deputy Chair**
K Huang to send out an email to members asking for nominations. **K Huang**

15.3 Members were informed that the next Intestinal Bowel Forum will be held in Cambridge on December 5th 2017.

16 DATE OF NEXT MEETINGS:

- Wednesday 11th October 2017 - London

17 FOR INFORMATION ONLY:

Papers attached for information were:

- IT Progress Report – BAG(17)12

- Transplant activity report for January 2017 – BAG(17)13

- Minutes of LAG meeting : 23 November 2016 – BAG(17)14

- Intestinal Patient Data Record Consent – BAG(17)15

New Appointments:

- Ms Jazz Sehmi, Internal Communications Manager - January 2017.
- Mr Greg Methven, Director of Manufacturing and Logistics - 6 February 2017.
- Mr Steve Park, Assistant Director Communications - 6 March 2017, at Speke.
- Ms Jacqueline Newby, 12 month secondment as Head of Referral & Offering - 3 April 2017.
- Mr Mark Rogers, Interim Assistant Director for Business Transformation Services - April 2017.