NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE THIRTIETH MEETING OF THE PANCREAS ADVISORY GROUP AT 10:30AM ON WEDNESDAY 5 APRIL 2017 AT THE ASSOCIATION OF ANAESTHETISTS 21 PORTLAND PLACE, LONDON W1B 1PY

PRESENT:

Mr John Casey	Chair
Mr Titus Augustine	Manchester Transplant Centre
Dr Pratik Choudhary	UK Islet Transplant Consortium
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Mr Martin Drage	Guy's Transplant Centre
Prof John Forsythe	Associate Medical Director, NHSBT
Prof. Peter Friend	Representing Oxford Transplant Centre
Prof. Sue Fuggle	Scientific Advisor, ODT
Mr Simon Harper	Cambridge Representative
Dr Stephen Hughes	Islet Laboratory Representative
Mrs Christine Jansen	Recipient Coordinator Representative
Dr Edmund Jessop	NHS England
Prof. Paul Johnson	Chair – Pancreas Islet Steering Group
Mrs Julia Mackisack	Lay Member Representative
Dr Adam McLean	West London Renal & Transplant Centre
Mr Gabriel Oniscu	Edinburgh Transplant Centre
Mr John Richardson	Head of Health Informatics, NHSBT
Ms Marian Ryan	Regional Manager – ODT
Prof. James Shaw	UK Islet Transplant Consortium
Mr David Turner	Consultant Clinical Scientist, Edinburgh
Prof. Steve White	Newcastle Transplant Centre

IN ATTENDANCE:

Heather Crocombe	Clinical Support Services
Sam Tomkings	Clinical Support Services

Apologies

Mr Argiris Asderakis, Mrs Hazel Bentall, Ms Joanna Bunnett, Mrs Dawn Chapman Prof. John Dark, Mr Ben Hume, Mr Nicholas Inston, Mrs Rachel Johnson, Ms Sally Johnson, Prof. Derek Manas, Prof. Rutger Ploeg, Dr Rommel Ravanan, Mr Sanjay Sinha

Action

1. Declarations Of Interest In Relation To The Agenda

1.1 There were no declarations of interest in relation to the Agenda

2. Minutes Of The Meeting Held On 2 November 2016 – PAG(M)(16)2

2.1 Accuracy

The minutes of the meeting held on 2 November 2016 were confirmed to be a true and accurate record of that meeting.

Action

2.2 Action Points - PAG(AP)(17)1

AP1 – Clinical Governance Incidents
R Ploeg has taken forwards the agreed wording for dealing with a right hepatic artery arising from the SMA and will incorporate this within the NORS standards. **Completed**

AP8 – On agenda, point 13. **Completed**

PAG Organ Specific Report
C Counter commented that utilisation data is included in the transplant activity report and is being considered for inclusion in the annual pancreas report. **Completed**

PAG Clinical Governance Report
J Forsythe asked that certain points be reworded. Also, make sure any shared learning points are spread as far as possible (after the inquest, which is believed to be taking place in May). **J Forsythe**

Fast Track Scheme – on agenda, point 5.5.3

AP6. Liaise on how to produce a proposal incorporating the different types of consent required which could be discussed at the National Pancreas Transplant Forum in Jan.

More can be done to improve the consent processes around the country, including use of videos and other techniques. A joint group between ODT and the BTS will be set up to look at issues of consent in transplantation.

AP7. Standard Listing Criteria
Check those registrations relating to Oxford centre and submit one particular case to the PAG Exemptions Panel. **Ongoing. H Crocombe to contact S Sinha for an update**

2.3 Matters arising, not separately identified
There were no other matters arising.

3. Associate Medical Director's Report

3.1 Developments In NHSBT:

3.1.1

- Hoping with SaBTO Biological Guidelines there will be further clarification on guidance, and that the SaBTO aide memoire can be uploaded to the website
- Hoping to have a section of the ODT site which will be login/password protected in order to try to improve communication (eg. a list of all retrieval surgeons with easy contact numbers) That way it would be relatively quick to get hold of someone if you need to.
- In terms of clinical incidents and governance, incidents could

be put on password protected website. No change to current incident reporting system. Incidents to be put on the microsite as more of an accessible forum.

3.1.2 Strategy

Utilisation Strategy in place, J Forsythe will be returning to PAG with more action points. **J Forsythe**

3.1.3 Length of Donation Process

Consultation process completed, action points produced, J Forsythe happy to provide more detail at next PAG Meeting **J Forsythe**

3.1.4 Donor Characterisation Review

J Forsythe thanked S Fuggle for her work on Donor Characterisation and advised a report will soon be produced for review. The report will go to the NHSBT Board at the end of May and we will await recommendations.

3.2 Governance Issues

3.2.1 Non Compliance with Allocation

There were no instances of non-compliance to report.

3.2.2 Incidents for Review – PAG(17)2

There were 47 reported incidents where the word 'pancreas' was mentioned. Because of multi organ retrieval, the word 'pancreas' crops up in incidents where there is no direct relevance to the organ. On closer analysis, 20 incidents were related to pancreases, which is double the number in the previous six months. Most of the incidents reported are relating to minor HLA discrepancies, issues with the ODR or transcription errors.

M Drage reported one incident where a scalpel blade was left in a pancreas box. The pancreas was deemed untransplantable, re-bagged and sent on for research. The scalpel blade was left embedded in polystyrene. Process has now been changed to ensure that scissors only are used for opening boxes.

J Forsythe would like confirmation that all HLA incidents are sent to Olive McGowan and her team to identify these issues and to ensure that they are dealt with.

There is no "CUSUM" system in place in regards to retrieval. J Forsythe questioned how we would monitor a retrieval team. He has suggested to retrieval leaders that that we might try to implement something similar to CUSUM in future. Will pick up particular issues within any teams. P Friend fully backed that idea.

M Drage and C Counter shared a report which identified organ damage. M Drage queried what the feedback route is, when one unit is shown to have a much higher damage ratio than others. Can extra training be provided? Feedback is informal at the moment, more of a

formal method needed. J Forsythe asked R Cacciola how we might do this with governance colleagues.

G Oniscu said that formal evidence must be taken by retrieval teams at the point of damage occurring rather than just having the 'word' of surgeons involved. All damage must be recorded on HTA forms.

Martin Drage volunteered to look into this. **M Drage**

Microbiology should be carried out on transport fluid on every occasion. This needs to be discussed with microbiologists to decide on a procedure for incident reporting on positive cultures.

Conclusions
Generic retrieval issues being addressed at NRG
Generic issues regarding damage are being addressed
Issues with microbiological cultures are being looked into at NHSBT

3.2.3 Summary Of CUSUM Monitoring Following Pancreas Transplantation - PAG(17)3

C Counter presented a report which monitors short-term patient outcomes following organ transplantation through centre specific cumulative sum (CUSUM) analyses.

Over the six month period since the last Pancreas Advisory Group Meeting there have been three signals in pancreas transplantation CUSUM reporting, two of which required investigation.

PAG members discussed the changes to data that triggered these signals later than would have been expected. These data changes were partly due to an historic issue with the data application not being able to record the code for patients who died with a functioning graft and also due to inaccurate reporting of the data to NHSBT. Data corrections have been made over the last 6 months and there are still outstanding queries for some centres to respond to. P Friend made the point that he thinks the current coding system from NHSBT is correct.

Guy's CUSUM Report

M Drage ran through his report, which showed investigations into 7 graft failures within 30 days of transplant triggering CUSUM signals. The graft failures could have been due to technical reasons; the main technical factors where improvements are needed are warm ischaemia time and cold ischaemia time. In order to reduce cold ischaemia time further, a system is now in place where two surgical consultants are always present in theatre.

3.2.4 Interim Peer Review Process

J Casey confirmed that the reports from the Interim Peer Review have been received, this can therefore be removed from the Agenda **H Crocombe**

Action

4. Statistics & Clinical Studies Report

Summary From Statistics & Clinical Studies - PAG(17)4

4.1 C Counter updated members on recent presentations, publications, current and future work.
Prof. Dave Collett has announced that he will be retiring at the end of June 2017.

4.2 Transplant Centre Dashboards – PAG (17)5

A report was received regarding NHSBT introducing more information about organ donation and transplantation that is accessible to the public. Example layouts were given in Appendices 1 and 2
J Forsythe understood that feedback from patients has suggested that the information provided is difficult to understand.

A working group should be put together to look at data produced on transplant centre dashboards. This will be chaired by the PAG lay members. **Lay Members**

5. Pancreas Transplant Activity

5.1 Transplant List And Transplant Activity - PAG(17)6

A paper was presented showing deceased pancreas and islet activity in the UK from Jan 2006-Dec 2016 and number of donors, transplants and patients on the active transplant list at 31 Dec. It was noted that the number of pancreas transplants performed was 17% less than in the previous year.

M Drage advised he has carried out an internal audit which identified resource issues, especially lack of intensive care beds. J Forsythe has been working on a resource 'scan' across transplant units and confirmed a report will be produced from this and sent to the commissioners. **J Forsythe**

Discussion took place around resource issues and allocation issues. J Casey asked if PAG are able to assist units regarding the problems with resource issues. It was felt it may be beneficial for PAG to send a letter of support to P Friend.

E Jessop stated it is not entirely clear to commissioners why organs are declined. C Counter reminded the group reasons for centres declining organs and how they are recorded in the duty office are being reviewed.

J Casey would like a specific audit for a six month period to identify why organs are being declined.

5.2 Transplant Outcome - PAG(17)7

C Counter presented national data produced from the pancreas transplant outcome paper.

It was identified that there was no significant difference in pancreas graft survival following SPK transplants from DBD or DCD donors between the time periods 2012 2013 cf. 2014-2015, p=0.5 and p=0.96 respectively. Three year pancreas graft survival following SPK transplant in 2012 and 2013 was 84% for DBD donors and 75% for DCD donors.

There was no significant difference in pancreas graft survival following pancreas only transplants from DBD donors between the time periods 2012-2013 and 2014-2015

5.3 Fast Track Scheme - PAG(17)8

Brief summary of the paper received regarding the 15 month audit activity of the new scheme from Dec 2015 to Mar 2017.

Table 1 shows that over the 15 months, a total of 199 deceased donors have been offered through the revised fast track scheme, 34% of all deceased donors. Of those offered through the scheme, 41 (21%) pancreases were accepted for transplantation, of which 20 were accepted for islets. 12 (29%) of all the accepted pancreases were transplanted, five as islets.

Of the seven whole pancreas transplants, follow-up information was available for five (71%) and all were functioning at 3 months. Of the five islet pancreas transplants, three were routine islet grafts and two were priority grafts. Follow-up has been reported for one routine graft and it was functioning at 3 months.

P Friend suggested this is a failure into the system as a 3rd of all deceased pancreas donors were offered through the fast track scheme and a very small proportion resulted in transplants. J Casey confirmed the reasons as to why the organs were offered through the fast track scheme and reasons why the organs were not transplanted need to be identified.

G Oniscu volunteered to work with C Counter to look at the reasons and whether this fast track scheme is useful. **G Oniscu/ C Counter/M Drage**

6. Update On NPAS: National Pancreas Allocation Scheme - PAG(17)9

C Counter updated the group on the National Pancreas Allocation Scheme providing data from Dec 2010-Nov 2016.

It was requested that C Counter break the data on sensitisation down further to distinguish those very highly sensitized patients in the next report. **C Counter**

S Fuggle advised that a similar study has been carried out under the kidney scheme and data needs to be read in percentage points.

C Counter highlighted that the standard pancreas criteria SPC is only based on age, and does not show BMI

Action

7. Update From Organ Allocation Working Group - PAG(17)10

M Drage updated the meeting on the paper which M Drage, C Counter and S Fuggle have been working on after the 5 year review of the national allocation scheme.

Use of low BMI pancreases for islet transplantation was reviewed as the allocation scheme should preferentially allocate these for solid organ transplantation. There were 29 islet transplants of pancreases from donors with a BMI <25kg/m^2 in the six years of the scheme and in 7 (24%) cases the islet patient was ranked first. Use of high BMI pancreases (BMI≥32) for transplantation as a solid organ is very low Following on from this review, M Drage would like to look at low BMI pancreases sent for islet isolation but not transplanted.

Going forward, P Johnson, M Drage, C Counter and S Fuggle are to meet and discuss data produced from organ allocation working group. **P Johnson/M Drage/ S Fuggle**

8. Update From Organ Utilisation And Damage Working Group - PAG(17)11

G Oniscu produced a paper regarding the utilisation and damage of organs.

G Oniscu advised that there has been a pilot scheme running whereby a video evaluation was taken at the time of retrieval. A short video was produced with commentary, sent to the surgeons for assessment and if declined, this could avoid the need for the organ to travel to the centre. This seems to be a valuable tool but will require evaluation in a prospective way.

From the initial work, it was identified that a large number of organs are discarded unnecessarily. All surgeons involved were able to identify damage from video evaluation.

A complete video assessment of the 53 discarded pancreases is in preparation. Taking into account suggestions from the pilot video evaluation, these will be circulated to every single transplant surgeon in the country. This will enable us to assess the variability in acceptance criteria between centres and individual surgeons and better inform potential utilisation of the grafts.

9. Update From National Information And Consent Document Working Group - PAG(17)12

This will be updated at the next meeting.

Action

10. Update On Donor And Recipient Risk Analysis Working Group - PAG(17)13

Cambridge Newcastle and Cardiff yet to suggest someone to collect data from pre-transplant forms – one page document. Ideally resource can be made available from middle grade staff member to collect the data – T Augustine's research fellow is currently going through this. T Augustine will be circulating the form within the next couple of days. Essentially co-morbidities and cardiovascular data on more than 1700 transplant patients.

This could be listed as a research project and would then receive funding/resources.

11. Pancreas Islet Transplantation

11.1 Report From The PAG Islet Steering Group: 14 March 2017 – PAG(17)14

The minutes from the last PAG ISG Steering Group will be circulated when finalised. It was agreed that M Drage would attend future PAG Islet Meetings **HC to invite M Drage to meetings**

Referring to PAG ISG Minutes, PJ advised that only in 50% of cases does the correct blood bottle arrive with organs. It had been suggested at PAG ISG that Anthony Clarkson pick this point up and contact centres. PAG agreed. **A Clarkson**

5,000 islets per kg had previously been agreed – patients, especially those with higher weights, are waiting a prolonged period to get this figure, so members agreed on a figure of 4,000 islets per kg.

(IPITA) 2017 Conference – booking via website.

11.2 Islet Transplantation

C Counter produced an Islet transplant activity paper.

Islet transplant activity and end of year transplant list for the last three calendar years were analysed. Data on 157 (99 routine and 58 priority) islet transplants performed in the UK where the routine transplant was performed between 1 April 2010 and 31 December 2015 were analysed from the UKTR. Outcome data are reported for all routine transplants.

The number of islet transplants and patients on the transplant list at the end of the year fell slightly in 2016. Graft survival, reduction in rate of severe hypoglycaemic events, reduction in HbA1c and reduction in insulin dose at one, two and three year post routine transplant have been reported.

It was agreed the new PAG ISG Islet laboratory isolation paper would also be included at future PAG meetings. **C Counter**

Action

12. Retrospective Listing For Pancreas Patients - PAG(17)16

Chris Watson had asked S Harper to raise this. Change request has been submitted to ensure that policy is amended to show waiting time is accrued from the time of starting dialysis and/or the start of being added to the transplant list. J Richardson will check the specification to ensure that this shows kidney and kidney/pancreas. J Richardson will circulate a copy of the change request and update PAG as to when this has been completed. **J Richardson**

13. Utilisation Of Both The Small Bowel And Pancreas From The Same Donor – The Feasibility Of Retrieving Both Organs Safely

P Friend presented a verbal report of the utilisation of both the small bowel and pancreas and the feasibility of retrieving both organs safely.

The question of what happens to the pancreas when a patient donates the small bowel only has recently been referred back to BAG. A consensus was reached that the pancreas should be referred preferentially for islets as it is too much of a waste to discard a perfectly usable pancreas. View was reasserted by members that there was no wish to increase the technical risk of the procedure, and the bowel community would prefer not to change previously agreed rules.

14. Standard Listing Criteria

14.1 Summary Data - PAG(17)17

There were 1245 registrations between 1 May 2012 and 31 December 2016. Nationally the return rates for the supplementary form have reached 95% for whole pancreas registrations and 99% for islet registrations.

Of the 130 new supplementary forms received between 1 July 2016 and 31 December 2016, 2 (2%) patients did not meet the standard listing criteria and neither was circulated to the Pancreas Advisory Group Exemptions Panel.

Discussion took place regarding the review of the registrations that did not meet the standard listing criteria.

14.2 Pancreas Transplant Listing Exemption Requests And Outcome Of Previous Applications To Appeals Panel - PAG(17)18

No comments.

Action

15. Any Other Business

A letter was received from Andrew Sutherland regarding a patient who had remained active on the Simultaneous Kidney and Pancreas waiting list since 2012.

Discussion took place as to whether the patient would benefit from dual listing but members agreed that the patient would not.

Research had been carried out some time ago and the conclusion was reached that highly sensitised patients would not have benefitted from being dual listed.

i. Need to ensure that kidney/pancreas recipients do not receive an unfair advantage over kidney recipients
ii. Risk of confusing patients as to what we're recommending

J Casey asked whether 95% sensitization would be enough to dual list patients – however, C Counter advised that currently the IT system wouldn't allow dual listing so this is currently a moot point.

J Forsythe feels it would be beneficial to have a member of PAG attend KAG to discuss dual listing. J Casey will discuss this with the KAG Chair. **J Casey**

16. Date Of Next Meeting:

Wednesday 1st November 2017, 10:30 – 15:00, Meeting Room CS2, ODT, Bristol.