NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE THIRTY-SECOND MEETING OF THE PANCREAS ADVISORY GROUP AT 10:30AM ON WEDNESDAY 11 APRIL 2018 AT 12 BLOOMSBURY SQUARE, LONDON WC1A 2LP

PRESENT:

Mr John Casey	**Chair**
Mr Titus Augustine	Deputy Chair - Manchester Transplant Centre
Dr Pratik Choudhary	King's College London Representative
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Mr Martin Drage	Guy's Transplant Centre Representative
Prof. Peter Friend	Oxford Transplant Centre Representative
Dr Stephen Hughes	Islet Laboratory Representative
Mrs Christine Jansen	Recipient Coordinator Representative
Mr Adam McLean	West London Renal & Transplant Centre Representative
Ms Laura Ramsay	Lead Nurse Recipient Co-ordinator, NHSBT
Ms Rachel Rowson	Regional Manager, ODT
Ms Marian Ryan	Regional Manager & SNOD Representative, ODT
Mr Andrew Sutherland	Edinburgh Transplant Centre Representative
Mr Michael Stokes	Head of Hub Operations, NHSBT
Prof. Steven White	Newcastle Transplant Centre Representative

VIA TELECONFERENCE: Prof. Susan Fuggle, Scientific Advisor, ODT

IN ATTENDANCE:

Ms Lisa Mumford	Statistics & Clinical Studies, NHSBT (part meeting)
Ms Maria Ibrahim	Organ Utlisation, NHSBT
Miss Sam Tomkings	Clinical Support Services

Apologies

Mr John Asher, Mr Argiris Asderakis, Mrs Hazel Bentall, Mr Chris Callaghan, Prof. John Dark, Prof John Forsythe, Ms Anushka Govias-Smith, Mr Simon Harper, Mr Ben Hume, Mr Nicholas Inston, Dr Sian Lewis, Dr Edmund Jessop, Mrs Julia Mackisack, Prof. Nizam Mamode, Prof. Paul Johnson, Ms Rachel Johnson, Ms Sally Johnson, Prof. Rutger Ploeg, Dr Rommel Ravanan, Prof. James Shaw, Dr David Turner

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 1 NOVEMBER 2017 – PAG(M)(17)2

2.1 Accuracy

The minutes of the meeting held on 1 November 2017 were confirmed to be a true and accurate record of that meeting.

Action Points PAG(AP)(18)1

AP2 – Developments in NHSBT

2.2 B Hume will liaise with J Asher to discuss changes to the Pancreas Allocation Scheme. **B Hume**

AP3 – Incidents for review: PAG Clinical Governance **Action**

Discussion around the proposal of introducing imaging of pancreases and vessels to assist with identifying quality and damage of the organ at the time of retrieval took place at NRG. Initial thoughts were to prioritise the kidney imaging pilot study first, as opposed to pancreas.

AP4 – Pancreas Damage Report

Members discussed the ongoing problem with high quality pancreases not being transplanted and the ways in which this could be improved. At the previous PAG meeting, the suggestion was made to raise this at NRG and to suggest introducing specific educational forums for retrieval surgeons. This would also support the requirement for imaging of pancreases at the time of retrieval to assist with assessing the quality of the organ and damage. Members agreed if a pancreas is damaged at the time of retrieval which could have been preventable, this should be reported as a clinical incident on the ODT website. Members also suggested if the pancreases have been retrieved and not assessed correctly and results in an organ not being transplanted, this should also be reported as a clinical incident. **All Centres**

AP8 – Transplant Outcome

An agreed protocol was made at BTS for analysing metabolic outcomes in solid pancreas transplantation to bring this in line with post-transplant assessment of islets. Some centres have taken this forward. P Choudhary will re circulate the agreement to centres. **P Choudhary**

J Casey requested for members to update at the next PAG meeting if their unit have implemented this. **All Centres**

P Choudhary will liaise with C Counter to ensure the follow up forms capture the outcome data. **P Choudhary / C Counter**

AP9 – Fast Track

Hub Operations are now recording reasons why pancreases are being fast tracked. C Counter and C Callaghan will be completing a detailed analysis in the summer and present this at the autumn meeting. **C Counter / C Callaghan**

AP10 – Update from Organ Allocation (Working Group)

The resource issues within Edinburgh and Oxford have been discussed to look at ways in which this could be improved. The suggestion was made for further data to be audited to look at detailed reasons why the pancreas was turned down and if this was as a result of lack of resources. In Manchester, organ transplantation his deemed an emergency procedure which has resolved logistical problems. Oxford feel mandating organ transplantation as an emergency procedure would assist with their access to resources.

The group acknowledge the logistical reasons differ in Oxford and in Edinburgh. If Edinburgh had an additional theatre available, the surgical resource would also have to be available. A Sutherland suggested a letter highlighting the number of organs declined due to lack of resources would be beneficial, and to consider extending theatre time to prevent declining an organ if there is a delay in the time of the organ arriving. **J Casey / J Forsythe**

2.3 Matters arising, not separately identified **Action**

None.

3. ASSOCIATE MEDICAL DIRECTOR'S REPORT

3.1 Developments in NHSBT:

J Casey outlined 3 main projects on behalf of J Forsythe which were raised at BTS:

- Consent and Information at the time of transplant. The current process of informing patients and taking consent are good but further improvements can still be made. Workshops were held last year on patient consent and included both legal and Lay Members' input. The next stage is to define the process better which will require a small group for each organ to specify the content and incorporate patient feedback for the different levels of information. The recommendation is to have a core amount of information with further levels of information should patients require it. Tools are being considered to help highlight this information and a request will be sent to PAG members requesting to support this. Chris Watson has been invited to act as chair for pancreas and islet consent working group.

- Donor Characterisation review led by S Fuggle. Recommendations have been accepted and this is now at the implementation stage. There are three working groups, one to look at the commissioning pathway, one to develop a service specification and the other to consider the IT infrastructure required with the first meeting to be held in May.

- Organ Retrieval. A new record of 1500 donors in the UK was achieved for the first time. Keith Rigg will be chairing the review for demand and capacity for organ retrieval in the UK.

3.2 Governance Issues

3.2.1 Non-compliance with allocation

None reported.

3.2.2 Incidents for review: PAG Clinical Governance – PAG(18)2

A Clinical Governance report was received showing 9 incidents which were related to the pancreas, fewer than in the previous period. There were 3 organs not transplanted because of retrieval damage.

In the first case, the pancreas was lost because all available vessels had been sent with the liver. As the split liver would only require one set of vessels, it was noted vessels should be transported with the pancreas whether being used for solid organ or islets.

One organ was not used because of presumed contamination from an untied bile duct. It has been reported that bile duct was left untied and transport fluid was bile stained, therefore the organ was not transplanted but accepted for research.

In another case, the portal vein was cut very short (.5cm) requiring an extension graft.

3.2.3 Summary of CUSUM monitoring following pancreas transplantation PAG(18)3

C Counter presented a CUSUM report which monitors short-term patient outcomes following organ transplantation. This report shows the last two runs in the CUSUM

monitoring. There were no signals in December but one in March which is currently under investigation. **Action**

3.2.4 Pancreas Utilisation – PAG(18)4

A paper was submitted and presented on behalf of C Callaghan displaying the pathways by which individual solid organ pancreas utilisation decisions will be monitored. Further work has taken place on how to define an 'ideal donor'. PAG are asked to consider the pathways and agree the summary data on letters sent to units will be presented to PAG.

P Choudhary raised, based on the recent work taken place in Manchester, could insulin use in ITU be incorporated.

M Drage added data is available on patients with a high alcohol intake and high amylase which could affect this.

P Friend highlighted all the criteria are continuous variables which is why the DRI system is in place for all organs.

The group agreed monitoring utilisation is worthwhile, however the way this should be monitored should be refined. Using a bigger analysis, may also be required and the DRI should be considered. J Casey will feed this back to C Callaghan. **J Casey**

4. STATISTICS & CLINICAL STUDIES REPORT

4.1 Summary from Statistics & Clinical Studies PAG(18)5

C Counter provided an update from Statistics and Clinical Studies and a summary of recent presentations, publications, and current and future work in the area of pancreas transplantation.

A news article showed 2017/18 was another record breaking year for donors and transplants performed.

The interim islet and pancreas transplantation report from April 17 to Sept 17 was published on the ODT website: http://www.odt.nhs.uk/statistics-and-reports/organ-specific-reports/ . The recent presentations presented at BTS are also available on the ODT website.

C Counter advised if anyone is interested in setting up a clinical trial to email: CTU@nhsbt.nhs.uk.

The contract with NHS England has funded two clinical fellow posts, one is a post in cardiothoracic transplantation, the second post is vacant and will be advertised to work in abdominal transplantation. Additionally, Maria Ibrahim is an NHSBT funded clinical fellow working alongside Chris Callaghan in organ utilisation.

4.2 Transplant Centre Profiles – PAG(18)6

NHSBT are standardising the transplant centre profiles, initially named dashboards, across the organs. Members were asked if the draft profile provided is a useful presentation of pancreas transplantation data.

It was felt as pancreas is a low volume organ, the one year outcome could

potentially be misleading to patients. The Lay Members felt the information provided within the profiles could make patients feel they should go to a centre with average waiting time and best success rate. The suggestion was made to have some sort of measure which combines risk aversion and outcomes. **Action**

Members agreed the data and how it is presented in a league table way is not very reassuring for patients.

J Casey would like the Lay Members to work alongside NHSBT to develop the pancreas transplant centre profiles. **J Mackisack & H Bentall**

5 Pancreas Transplant Activity

5.1 Transplant list and transplant activity – PAG(18)7

C Counter presented a paper reporting activity over the last 10 years.

Since 2007 there has been a 42% increase in pancreas donors from 336 to 478 in 2017. The proportion of DCD donors increased from 11% in 2007 to 25% in 2017. The total number of pancreas and islet transplants has fluctuated over the 10 years with a peak of 249 transplants in 2013. There were 214 transplants in 2017 which was an overall increase of 11% on the previous year; a 10% increase in DBD transplants and a 14% increase in DCD transplants.

5.1.1 Group 2 patients report

There have been no group 2 or group 1 non-UK EU resident transplants.

It was highlighted individuals within the EU are aware of the pancreas transplantation program. There have been two recent cases where these individuals moved to the UK to receive a pancreas transplantation.

P Choudhary requested clarification on what NHSBTs policy is on Group 2 patients. C Counter to find out. **C Counter**

M Drage will circulate the report which is the most recent summary on Group 2 potential recipients. **M Drage**

5.2 Transplant outcome – PAG(18)8

C Counter presented the Pancreas Transplant Outcome report.

There was no significant difference in pancreas graft survival following SPK transplants from DBD or DCD donors between the two time periods. There was no significant difference in pancreas graft survival following pancreas only transplants from DBD and DCD donors between the two time periods.

5.3 Fast Track Scheme – PAG(18)9

C Counter presented a paper which audits activity since the revised fast track scheme was introduced in December 2015.

There have been 327 (35%) deceased pancreas donors offered through the scheme. Of those offered through the scheme, 23% were offered and accepted for transplantation, 22 of all accepted pancreases were transplanted, 13 as whole organs and 9 as islets. Of the 13 whole transplants, the follow up information

available showed 1 graft failed at 3 months, 8 had a functioning graft recorded at 3 months and 4 had functioning graft recorded at 12 months. Of the 9 islet pancreas transplants 6 were routine islet grafts, 2 were priority and 1 was an SIK transplant and follow up on these have been reported for 5 of the transplants and none of these had failed. Hub Operations have started recording fast track trigger points and once enough data is recorded, this will be analysed to identify why the organs are entering the fast track scheme. **Action**

A concern was raised regarding the high number of pancreases entering the fast track scheme and not being allocated. A small internal study in Oxford has identified a large number of phonecalls taking place for offers made via fast track, which suggests ways to improve efficiency should be considered when reviewing the pancreas allocation scheme.

During the two year period, only 3 out of 94 DCD pancreases offered through the fast track scheme were transplanted, therefore the question was asked if DCD pancreases should continue to be offered through the fast track scheme. It was suggested that these pancreases should be offered directly to islet centres to identify if it is a viable organ and have shorter cold ischemia times. Although the workload for islet labs was a concern if isolating a DCD meant they weren't able to isolate a preferable DBD pancreas. If agreed, a change to the policy would take a few months. Discussion took place if all fast track offers should be considered for islet transplantation. The group agreed further details are needed why the organs are entered into the fast track scheme with a view to reducing the number offered.

6 New Kidney Allocation Scheme

L Mumford presented changes to the new kidney offering scheme and what implications this may have on pancreas transplantation. This will also provide an insight into the upcoming process to change the pancreas allocation scheme.

The following questions were asked for PAG to consider:

1. Should SPK/SIK patients who meet Tier A criteria be included in the Kidney Matching Run?
2. Should there be an age restriction the same as the pancreas matching run: – DBD 0 – 65 – DCD 0 - 55
3. Should SPK / SIK recipients have the option to only accept the kidney if included in Tier A?

Members agreed SPK/SIK patients should appear in Tier A and there should not be any age restriction in Tier A only. Members also agreed the option to accept just a kidney only will be available.

KAG has agreed the following;

- Earliest of dialysis start date or activation on the kidney transplant list.
- If re-transplant then waiting time calculated from point of graft failure or reactivation on the kidney transplant list.
- If graft fails within 180 days then waiting time from prior to transplant is added to current waiting time.

PAG are asked should the waiting time start from dialysis for SPK/SIK patients. **Action**

Initially, this was being introduced for kidney only patients. After a lengthy discussion, the group felt the impact on the islet and pancreas alone patients would be high, therefore the waiting time to dialysis will not be changed for SPK/SIK patients in the pancreas matching run. Patients in the new Tier A will have waiting time from start of dialysis.

7 **7 Year Review National Pancreas Allocation Scheme – PAG(18)10**

C Counter presented a paper showing there have been over 1577 transplants, 22% of those were from DCD donors. Of those 1577 87% were whole pancreas transplants and the majority were SPK and 5 SIK. The centres performing the most transplants were Oxford and the centre performing the most islet transplants was Edinburgh.

Of the 211 transplants performed last year, 52% of patients were waiting 12 months or more and 3% had a CRF sensitisation of 95% or more 57% were male.

The median waiting time of those patients transplanted by transplant demographics showed 51 patients with a CRF of 95% or more had a median waiting time of over 1 ½ years compared to 1 year and 1 month with those with a CRF of less than 10%. The median waiting time for transplant type shows those patients receiving a SPK had a median waiting time of 1 year and 3 months and those patients requiring an islet graft waited 5 months.

The donor BMI by transplant type showed 14 pancreas islet transplants were from donors with BMI of 22 or less and 14 whole pancreas transplants from donors with a BMI of 32 or over.

M Drage highlighted that at the last PAG meeting, PAG agreed organs with a high BMI would be offered to islets and those organs with a low BMI would be offered as a solid organ. C Counter advised this is not something which can be implemented due to restraints within the IT system but it is down to the centres to make that decision themselves. J Casey advised with the possibility to change the National Pancreas Allocation Scheme, this is something which could be implemented. P Friend suggested as BMI is not the most evidenced based way of predicting a pancreas transplant outcome, should PAG consider other simple measures, such as looking at waist circumference data.

Cold ischemic time ranges for DBD organs 10hrs to 13hrs, and for DCD organs 9 and ¾ hours to over 13 hours. P Choudhary queried why there are data lines showing minimum cold ischemia time as zero, C Counter advised this is around 30 minutes but would check the times with centres concerned. **C Counter**

The median waiting time for all patients has reduced from 402 days to 219 days.

8 **Timeline for changes to National Pancreas Allocation Scheme**

M Stokes informed the group that analysis has started on the kidney and pancreas allocation schemes. The development of both schemes will begin in July with the aim to complete this by March 2019. Members were encouraged to look at the current scheme and propose changes by July 2018.

J Casey would like for a working group to look at the current pancreas allocation scheme and list any changes and reasons and distribute these urgently to PAG for consideration. The group will consist of J Casey, M Drage, P Johnson, C Watson, S Fuggle, C Counter, H Bentall and J Mackisack. **Action** **J Casey**

9 Update from Organ Utilisation and Damage (Working Group) – PAG(18)11

A working group was put together to look at the utilisation of solid organs. The group recognised the high decline rate prior to retrieval due to donor age and BMI but also a high decline rate following retrieval where 50% of declined pancreases were due to fatty appearance and a significant proportion due to organ damage.

Part of the study was to take video recordings of the pancreas and approach 5 surgeons to evaluate the videos which resulted in a significant difference between the surgeon's acceptance criteria based on viewing the video.

The suggestion made is for a short video recording of the pancreas to be taken at retrieval and provided to the recipient surgeon, and should there be a change in the way organs are allocated to centres which are more likely to utilise the higher risk organs.

Members suggested pictures may be an easier and quicker process, however it was felt a more in-depth evaluation would be available from a recording. Logistically, Hub Operations are able to send pictures but not recordings. Hub Operations indicate via EOS that there are pictures available to centres. The group agreed it would be easier to take pictures and upload these routinely, however a protocol for what pictures are required has to be identified. **J Casey**

Members feel it would not be appropriate to change the way higher risk organs are allocated to centres. The recommendation was made for centres to regularly audit their reasons for declining an offer. C Counter suggested the monthly 'offer decline' reports circulated to centres of organs subsequently transplanted could name the transplanting centre which would make liaising with the centre easier. PAG members feel this would be useful to include. **C Counter**

10 Update from National Information and Consent Document (Working Group) – PAG(18)12

A working group was set up to develop a patient consent booklet. The initial development of the booklet identified a number of concerns, such as the booklet being a lengthy document and how the consent is presented. The group has since developed a more straight forward booklet and members are asked to consider this and feedback their comments to A Sutherland. Once the content is agreed, the logo will need determining. **All Members**

11. Update on Donor and Recipient Risk Analysis (Working Group)

T Augustine reported Cambridge have returned 197 forms, Cardiff have returned approximately 57 forms and Guy's have begun collating and return the forms. Manchester centre will collate their forms and forward these as a group.

T Augustine advised Manchester have an external trainee who could assist centres with the collection of data.

Action

All centres were encouraged to participate in providing data. **All Centres**
T Augustine will arrange a date to analyse the data once this has been provided. **T Augustine**

12 Pancreas Islet Transplantation

12.1 Report from the PAG Islet Steering Group: 8th March 2018

S Hughes reported on behalf of P Johnson a summary of discussion points from the PAG Islet Steering Group on 8th March 2018.

- Edinburgh laboratory is transferring to a new facility and necessary down time as result of the move will require laboratories across the UK to provide cover.
- Good progress has been made with the new grading system for pancreas islet donors.
- Recording of donor blood glucose on admission has been variable which is required when accepting islets for transplantation. This information should be captured on the core donor form. J Shaw identified in one weekend, there were 9 offers made where the donor blood glucose was not recorded on the form.
- It was identified at PAG ISG that the ETDA sample is not always sent with the pancreas. PAG members agreed ETDA should be sent with every pancreas.

12.2 Islet Transplantation – PAG(18)13

Members noted a paper from C Counter summarising islet transplant activity and outcome.

The question was raised if there is enough islet recipient data available to look at sensitisation. J Casey confirmed those data are available and D Turner and S Fuggle are in the process of analysing this.

12.3 Islet Isolation Outcomes – PAG(18)14

C Counter presented a paper which provides information on the outcome of pancreases retrieved with the intention to transplant as pancreas islets and includes a summary by islet isolation centre.

Once the donor grading system is in place, this could be used to compare isolation centre outcomes. Discussion took place around the quality of pancreases sent for islets.

13 Standard Listing Criteria

13.1 Summary Data – PAG(18)15

Members noted a paper on the audit of standard criteria for listing. Of the 142 supplementary forms received between 1 September 2017 and 31 January 2018, one (1%) patient did not meet the standard listing criteria and was not circulated to the Pancreas Advisory Group Exemptions Panel. However, on checking with the centre involved, it was found that this was a data recording error and the patient had met the standard listing criteria.

Action

Members are reminded that patients who no longer meet the requirement for a priority islet listing will need ODT Hub Information Services to remove the patient from the priority list and list them on the routine transplant list in order to preserve the patient's waiting time. Management of a centre's priority islet list is essential to ensure the benefit of receiving a "top-up" graft soon after the first graft is achieved.

It was raised if a patient who is on the SPK list, receives a live donor kidney transplant but remained suspended on the pancreas transplant list, will the pancreas waiting time be carried over from the SPK list if the patient required a pancreas or islet transplant after kidney. C Counter confirmed if a patient moves from one pancreas transplant list to another, the waiting time accrued will transfer, but the transfer between lists needs to be completed by ODT Hub Information Services.

13.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(18)16
Noted for information.

14 Any Other Business
M Drage asked how funding would be obtained from commissioners for SIK transplants. T Augustine confirmed the charge for islets and pancreas are separate.

P Choudhary raised if it is possible for C-peptides to be measured, if so, is it possible to collect data on this and should there be a C-peptide cut off for SIK. A McLean advised if C-peptide is measured, a pair of blood glucose will also be required. The suggestion was made to include C-peptide recording on the standard listing form as this data is already captured for PTA.

A recent case was discussed where a European patient entitled to NHS healthcare would require a multivisceral transplant which included a small bowel and pancreas from the UK. Members supported this request.

15 FOR INFORMATION ONLY

15.1 Transplant activity report: February 2018 – PAG(18)17
Noted for information.

15.2 Patient Consent Scheme Audit – PAG(18)18
Noted for information.

15.3 IT Progress Report: February 2018 – PAG(18)19
Noted for information.

15.4 Current and Propose Clinical Research Items – PAG(18)20
Noted for information.

15.5 QUOD Statisical Report – PAG(18)21
Noted for information.

16 Date of Next Meeting:
Thursday 15th November, Stoke Gifford, Bristol 11am