To be ratified **PAG(M)(16)2**

ORGAN DONATION AND TRANSPLANTATION DIRECTORATE
NHS BLOOD AND TRANSPLANT

MINUTES OF THE PANCREAS ADVISORY GROUP MEETING HELD ON WEDNESDAY, 2ND NOVEMBER 2016 AT ODT, STOKE GIFFORD, BRISTOL

PRESENT:

Mr John Casey	Chair
Ms Joanna Bunnett	Statistics & Clinical Studies, NHSBT
Mrs Hazel Bentall	Lay Member Representative
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation (Abdominal)
Dr Vaughan Carter	British Society for Histocompatibility Representative
Ms Dawn Chapman	Recipient Co-ordinator Representative
Dr Pratik Choudhary	Deputy for Prof J Shaw, UK Islet Transplant Consortium
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Mr Martin Drage	Guy's Transplant Centre
Mr Doruk Elker	Deputy for Mr A Asderakis, Cardiff Transplant Centre
Prof John Forsythe	Associate Medical Director, ODT
Prof Sue Fuggle	Scientific Advisor, ODT
Mr Simon Harper	Cambridge Transplant Centre
Dr Stephen Hughes	Islet Laboratory Representative
Mr Nick Inston	Kidney Advisory Group Representative
Prof Paul Johnson	Chair – Pancreas Islet Steering Group
Mrs Julia Mackisack	Lay Member Representative
Dr Adam McLean	West London Renal & Transplant Centre
Prof Rutger Ploeg	National Clinical Lead for Organ Retrieval, ODT
Dr Rommel Ravanan	Renal Association Representative
Mr Sanjay Sinha	Oxford Transplant Centre
Mr Mick Stokes	Deputy for A Sheldon, Head of Referral & Offering, NHSBT
Mr Andrew Sutherland	Deputy for Mr Gabriel Oniscu, Edinburgh Transplant Centre
Ms Marian Ryan	Regional Manager, Organ Donation Services, NHSBT
Prof Steve White	Newcastle Transplant Centre

IN ATTENDANCE:

Mrs Kathy Zalewska	Clinical & Support Services, ODT

Apologies

Mr Argiris Asderakis, Mr John Asher, Mr Titus Augustine, Ms Rachel Brodie, Dr Catherine Coyle, Prof John Dark, Mr James Gilbert, Mr Ben Hume, Mrs Christine Jansen, Dr Edmund Jessop, Ms Sally Johnson, Mr Gabriel Oniscu, Prof Jim Shaw, Ms Anne Sheldon, Mr Anthony Snape, Ms Helen Tincknell and Ms Sarah Watson.

1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA – PAG(16)20

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

2 MINUTES OF THE MEETING HELD ON 20TH APRIL 2016 – PAG(M)(16)1(Am)

2.1 **Accuracy**

The minutes of the meeting held on 20th April 2016 were agreed as a correct record.

2.2 **Action points – PAG(AP)(16)1**

AP1 – Clinical governance incidents:

- C Counter confirmed that a letter to centres had been drafted reminding them to complete incident forms.
- J Casey confirmed the suggested solutions to the packing issues had been passed to NRG.
- A protocol to standardise the preparation of the duodenum had been written for consideration at NRG.
- The agreed wording for dealing with a right hepatic artery arising from the SMA will be included in the NORS standards at the next iteration.

AP2 – Interim peer review: Refer to minute 3.2.4 below.

AP3 – Annual review of pancreas selection and allocation policies: These policies went live in July.

AP4 – **Transplant outcome:** Refer to minute 5.2

AP5 – Update from organ allocation working group: Refer to minute 6.

AP6 – Islet transplantation: Refer to minute 11.2.

AP7 – Update on simultaneous islet and kidney transplantation: A letter has been sent to centres re monitoring of simultaneous islet and kidney transplants.

AP8 –Uterine transplantation: PAG approval for the proposed pilot study has been fed back to NRG.

- Utilisation of both the small bowel and pancreas from the same donor: BAG is keen to ensure that bowel retrieval is optimised as much as possible. Members discussed the question of prioritisation of small bowel and pancreas and the fact that it is feasible to retrieve both safely although each case is dependent on both the donor and recipient nephrology. J Casey agreed to discuss this off line with P Friend, BAG Chair, together with input from C Callaghan and A Butler.

2.3 **Matters arising, not separately identified**

There were no other matters arising.

3 ASSOCIATE MEDICAL DIRECTOR'S REPORT

3.1 **Developments in NHSBT:**

J Forsythe reported on the following developments:

- Cardiothoracic allocation: The new urgent and super-urgent heart allocation schemes went live on 26th October. Revisions to the lung allocation scheme will be the next priority, followed by the allocation scheme for liver and then kidney.
- Donation and retrieval process: There is strong data to indicate that the pathway for both DBD and DCD donors has lengthened since 2012. The donor characterisation project is looking at aspects of H & I, microbiology, virology and pathology. In addition work is taking place looking at better quality and safety issues and data is being gathered on the donation and retrieval processes to try to ascertain where the delays are.
- Organ utilisation: Centres are being contacted for information on infrastructure problems which may cause barriers to utilisation.
- The final go-ahead has been given to upgrade the ODT website. Members were asked to comment on ways to improve the website.
- **SaBTO developments:**
  - The updated SaBTO microbiology safety document has now been produced in draft form. J Forsythe agreed to ensure that the document was circulated to Advisory Group Chairs and other interested parties for comment.

- Although not formally agreed, SaBTO is likely to recommend to Ministers that HEV testing should be carried out on donors shortly after organ donation. Centres will need to ensure that any positive test results are dealt with appropriately.

In response to a query re incorporating minor changes to allocation algorithms, it was noted that unless these were already accounted for they were unlikely to be prioritised due to the major IT changes currently in progress.

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 Clinical Governance Report – PAG(16)21**

A report was received on the ten incidents related to the pancreas during the past six month period. The majority of these incidents related to minor HLA discrepancies or transcription errors in donor date of birth whilst the loss rate due to damage or perfusion issues were a little higher than normal. Discussion took place on variability in perfusion practice with some retrieval teams not adhering to the nationally agreed perfusion protocol. This will also be discussed at the next meeting of the National Retrieval Group.

P Johnson reported that between April and the beginning of October 2016 there were eleven pancreases with poor perfusion/damage, which was a dramatic increase from last year. In addition, S White reported on an occasion when vessels were retrieved and packaged correctly but did not arrive together. J Casey questioned whether these were reported as incidents as they were not apparent within the overall clinical governance report.

One significant incident reported was the death of a pancreas recipient from CMV infection. The donor was designated as CMV negative, probably in error due to a mix-up of specimens from another donor. The pancreas was transplanted into a CMV negative recipient, as were both the kidneys. Both renal centres re-tested and treated their recipients appropriately. Unfortunately there was no communication from either centre so the donor status was unknown until the pancreas patient was admitted with overwhelming CMV infection. J Forsythe wrote to all transplant centres in early October asking them to have a mechanism to communicate immediately any discrepancy resulting from re-testing. If re-test results were advised to the ODT Duty Office these could be relayed to the relevant recipient centres. It was noted that the issue of donor characterisation is currently undergoing a detailed review.
S Fuggle confirmed that there is currently a process in place for reporting HLA discrepancies. J Mackisack suggested that consideration be given to including the date of the inquest for this incident in an open communication such as the monthly Associate Medical Director's bulletin or Cautionary Tales. This would serve to reassure patients on the openness of the investigative process.

3.2.3 **Summary of CUSUM monitoring following pancreas transplantation – PAG(16)22**

Over the six month period since the last Pancreas Advisory Group meeting there were no signals to report in pancreas transplantation CUSUM monitoring.

3.2.4 **Interim peer review process**

Concerns had been expressed re pancreas transplant issues being considered secondary to kidney transplant issues at review. However, representatives from those centres already reviewed did not feel this was the case and stated this was a fair and balanced process.

4 STATISTICS AND CLINICAL STUDIES REPORT

4.1 Summary from Statistics & Clinical Studies – PAG(16)23

C Counter updated members on recent presentations, publications, current and future work. C Callaghan requested the inclusion of utilisation data in the pancreas organ specific report. Due to the fact that centres are currently being contacted re infrastructure problems which may impact on utilisation, it was agreed to wait for the outcome of these calls and review this issue at the next meeting. In the meantime there is a need to maintain consistency across all organs in the data reported so C Counter agreed to discuss with colleagues the possibility of adding this data to the report.

5 PANCREAS TRANSPLANT ACTIVITY

5.1 Transplant List and Transplant Activity – PAG(16)24

Members noted a report showing that between 1st April 2015 and 31st March 2016 there were 468 pancreas donors resulting in 216 transplants. As at 31st March 2016 there were 227 patients registered for a pancreas transplant, 184 of which were registered for a kidney/pancreas transplant and 28 for islet transplantation.

5.2 Transplant Outcome – PAG(16)25

C Counter presented national data on outcomes following vascularised pancreas transplantation. Members considered the possible reasons for the significant fall in pancreas graft survival following SPK transplant between the time periods 2011 – 2013 and 2013 – 2015. Comparison of the two time periods showed no difference for donor age, donor BMI, recipient age or recipient waiting time. The report was noted and the situation will be monitored. It was also suggested that a clinical discussion on variations in practice takes place at the next Annual Pancreas Transplant Forum at Oxford in January 2017.

5.3 Fast Track Scheme – PAG(16)26

A paper auditing activity within the first nine months of the new pancreas fast track scheme was presented. Members queried the accuracy of the data indicating that 98 of the 99 organs offered on the fast track scheme were accepted. C Counter agreed to check the figure and notify members.
Post meeting note: A revised paper was circulated to members with clarification of these data.

C Callaghan queried the benefit of the fast track scheme which involved considerable extra work for a relatively low yield of 6 %. Members commented that it would be useful to have more information, such as data on outcomes and why and when they were turned down initially, on the six organs which were transplanted via the fast track scheme.

6 UPDATE FROM ORGAN ALLOCATION WORKING GROUP – PAG(16)27

6.1 M Drage thanked both C Counter and S Fuggle for their contribution to the group. The Group looked at three particular areas of concern:

- Low BMI donors being used for islet patients:
  There were 32 donors with a BMI of less than 26 whose organs were offered to islet patients between 1 December 2010 and 30 November 2015. Thirteen of these were direct offers to islet patients. Of the remaining 19 where at least one offer was made to a whole pancreas patient, 10 were offered to just one centre. Fifteen of the 19 offers were declined for centre resource issues. Further work will take place looking at all pancreas declines where lack of centre resource is cited. Another concern is the fact that 108 pancreases were lost due to failed isolations, 86% of which were due to insufficient yield. Of these 108 pancreases, 60% were previously

turned down by at least one centre for whole pancreas transplantation.

- Patients waiting longer than two years for a whole pancreas transplant: During the period 1 December 2010 to 11 October 2016 nineteen patients were identified as having waited longer than two years, 15 of which had a cRF ≥75. Of the 19 patients, 10 required a kidney as well as a pancreas. Twelve of the 19 were blood group O whilst seven were blood group A.
- Highly sensitised patients waiting for a transplant (defined by a cRF≥75): Of 1,410 patients registered for a pancreas or kidney/pancreas transplant since 1 December 2010, 131 were highly sensitised with a cRF of 75% or more. Of these patients, 36 had a cRF of 99 or 100%. As at 12 September 2016 there were 77 HSPs still active/suspended or were removed or died on the transplant list. Fifty seven of these patients have matched at least one donor and 41 have received an offer of an organ. PAG members were asked if they might, in the future, wish to decide on a threshold for the number of offers to a highly sensitised patient beyond which a report would be required. A discussion on what the threshold should be took place and it was suggested that patient groups should be asked for their opinion.

Members discussed the joint allocation scheme and the acceptable BMI cut off for islet donations. It was suggested that pancreases from low BMI donors should not be offered for islet isolation unless they have been offered and declined for whole pancreas transplantation. P Johnson agreed to join the group. It was noted that any changes to the existing algorithm could take up to two years to implement.

7 UPDATE FROM ORGAN UTILISATION AND DAMAGE WORKING GROUP – PAG(16)28

7.1 G Oniscu updated members on the progress made to date:

- Review of current declines database – The database had been cleaned and work was in progress to determine centre specific declines, including islet offer declines, and to identify patterns. This will be presented at the next meeting.
- Utilisation of organs for islets – The database is being pulled together for interrogation in due course.
- Prospective evaluation of discarded organs – Evaluation started in July 2016 in Edinburgh and Oxford. Between 21st July and 30th September 23 discarded pancreases were potentially suitable for evaluation, 19 of which subsequently underwent evaluation (12 in Edinburgh & 7 in Oxford). Twenty of the 23 organs had consent for research, 19 of which were accepted for further research. Three of the pancreases assessed in Edinburgh underwent MRI scanning as per the agreed protocol. Given the small numbers of organs recovered, an extension to the study for an additional 3 months had been agreed.

8 UPDATE FROM NATIONAL INFORMATION AND CONSENT DOCUMENT WORKING GROUP – PAG(16)29

8.1 S Sinha reported on behalf of J Gilbert on the progress of the working group. Responses on the proposed final consent form are currently awaited from surgical colleagues. A list of the risks involved will also be included within the booklet. It was acknowledged that a list of up to 800 risks is too much for patients to take in but is a legal requirement. J Mackisack and H Bentall suggested a shortened bullet point list of the key risks backed up by a more extensive list. In addition, an audio version would be advantageous, particularly due to the problems that some patients awaiting a pancreas transplant have with their eyesight.

J Forsythe highlighted the recent Royal College of Surgeons' document produced in light of the Montgomery case and also mentioned that the

NHSBT/BTS policy on consent was now scheduled for review. Members discussed whether there should be different forms of consent accessible by patients; possibly videos which could be accessed via the website. Members recognised the difficulty of incorporating all types of transplant (SPK, PAK, islet, etc) in one document. J Casey agreed to liaise with J Forsythe to look at having a proposal ready in time for the National Pancreas Transplant Forum in January.

9 UPDATE ON DONOR AND RECIPIENT RISK ANALYSIS WORKING GROUP – PAG(16)30

9.1 Three centres have yet to confirm to T Augustine who will be the contact for their centre on this work. All centres were encouraged to participate in providing data.

10 UPDATE ON CLASSIFYING PANCREAS FUNCTION AFTER TRANSPLANTATION – PAG(16)31

10.1 Members noted a paper received from P Choudhary with an updated proposal for classifying pancreas function after transplantation.

11 PANCREAS ISLET TRANSPLANTATION

11.1 **Report from the PAG Islet Steering Group: 27 September 2016 – PAG(16)32**

P Johnson gave a summary of discussion points from the PAG Islet Steering Group on 27th September:

- Agreement had been reached for PAG ISG to be the forum for monitoring of islet auto activity
- There has been a significant increase in poorly perfused and damaged pancreases received by the islet isolation facilities over the past six months. Unless these are reported as incidents it is difficult to assess the problem. The assessment and reporting of damage will be discussed at the next meeting of PAG ISG. Photos are an important tool for assessing damage.
- Funding has been made available for a reference laboratory for mixed meal tolerance testing in Exeter, which it is hoped will lead to good outcome predictions in the future.
- A number of high weight patients on the waiting list are failing to be transplanted due to the very high islet requirement on the transplant waiting list. It was felt that the current threshold of 5,000 islet equivalents per kg was too rigid and members had agreed this should not be an absolute requirement for a first graft, allowing centres to transplant using lower yields dependent upon the individual patient.

- Commissioning is currently available for two isolations per transplant. As more marginal pancreases are being accepted work is taking place exploring costs as isolations are more numerous.
- The quality of organs being sent to islet laboratories is decreasing as laboratories are being encouraged to isolate the more marginal organs. The basic scoring system used for measuring successful/unsuccessful isolations on a centre specific basis is being reviewed.

11.2 **Islet transplantation – PAG(16)33**

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

12 STANDARD LISTING CRITERIA

12.1 **Summary data – PAG(16)34**

Members noted a paper on the audit of standard criteria for listing which were

agreed at a previous meeting. Adherence to the criteria was audited via the Supplementary Pancreas/Islet Registration form from May 2012. Of the 137 new supplementary forms received between 1 March and 30 September 2016, three SPK patients were recorded as having eGFR >20 and one SPK Type 2 diabetic patient was recorded with a BMI larger than 30. Members were asked to review the registrations that did not meet the standard listing criteria. S Sinha agreed to check those relating to Oxford centre and submit one particular case to the PAG Exemptions Panel.

13 ANY OTHER BUSINESS

13.1 **Thrombophilia:** M Drage introduced a paper recommending the removal from the national guidelines of thrombophilia screening from the work up process for pancreas transplant patients. It was agreed that at the next review of the guidelines either thrombophilia screening should be removed and replaced with coagulation screening or details of the criteria for thrombophilia screening included.

13.2 **National Pancreas Transplant Forum 2017:** S Sinha reminded members that the Forum was scheduled for Friday, 20th January 2017 at the Said Business School, Egrove Park, Oxford. Further details would be circulated shortly.

14 FOR INFORMATION ONLY

14.1 **Transplant activity report: October 2016 – PAG(16)35**
Received for information.

14.2 **Update on Simultaneous Islet & Kidney Transplantation – PAG(16)36:**
From 1st July 2016 centres were able to register patients for a SIK transplant with NHSBT through ODT Online.

P Choudhary highlighted that the assessment process for both PTA and ITA patients should be the same. S Sinha added that work was in progress to set up a PTA clinic in Oxford which would tie in with the Birmingham clinic. Patients would then attend a beta cell clinic and then decide whether they wished to register for islet transplantation or solid organ transplantation.

P Choudhary reported that at the last UKITC meeting new questions were added to the islet database to help to identify hypoglycaemic exposure, looking at assessment being more standardised. Details would be circulated to centres. It was suggested that minimal diabetology assessment takes place prior to listing.

14.3 **Update on the Patient Consent Scheme – PAG(16)37**
Received for information.

14.4 **IT Progress Report – PAG(16)38**
Received for information.

14.5 **Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(16)39**
Received for information

14.6 **Current and proposed clinical research items**
No papers or research items were reported.

15 DATES OF MEETINGS IN 2017
Wednesday 5th April – Association of Anaesthetists, Portland Place, London
Wednesday, 1st November - ODT Bristol