To be ratified **PAG(M)(17)2**

NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE THIRTY-FIRST MEETING OF THE PANCREAS ADVISORY GROUP AT 10:30AM ON WEDNESDAY 1 NOVEMBER 2017 AT ODT, STOKE GIFFORD, BRISTOL BS34 8RR

PRESENT:

Mr John Casey	**Chair**
Mr Titus Augustine	Deputy Chair - Manchester Transplant Centre
Mrs Hazel Bentall	Lay Member Representative
Ms Jo Bunnett	Statistics & Clinical Studies, NHSBT
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation (Abdominal)
Dr Pratik Choudhary	King's College London Representative
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Mr Doruk Elker	Cardiff Transplant Centre
Dr Stephen Hughes	Islet Laboratory Representative
Mr Simon Harper	Cambridge Transplant Centre
Mr Ben Hume	Assistant Director – Transplant Support Services, NHSBT
Mrs Christine Jansen	Recipient Coordinator Representative
Prof. Paul Johnson	Chair – Pancreas Islet Steering Group
Mrs Rachel Johnson	Assistant Director - Statistics & Clinical Studies, NHSBT
Mr Anand Muthusamy	West London Renal & Transplant Centre (deputy)
Dr Andrew Sutherland	Edinburgh Transplant Centre
Ms Marian Ryan	Regional Manager and SNOD representative
Dr Rommel Ravanan	Renal Association Representative
Prof. James Shaw	UK Islet Transplant Consortium
Mr Sanjay Sinha	Oxford Transplant Centre
Prof. Steve White	Newcastle Transplant Centre (deputy)

IN ATTENDANCE:

Thomas Hodgett	ODT Hub Programme (observer)
Sam Tomkings	Clinical & Support Services, ODT

Apologies
Mr John Asher, Prof. John Dark, Mr Martin Drage, Prof John Forsythe, Prof. Susan Fuggle, Ms Anushka Govias-Smith, Mr Nicholas Inston,,Dr Edmund Jessop, Ms Sally Johnson, Dr Sian Lewis, Mrs Julia Mackisack, Prof. Rutger Ploeg, Mr Mick Stokes, 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 5 April 2017 – PAG(M)(17)1
Accuracy

2.1 The minutes of the meeting held on 5 April 2017 were confirmed to be a true and accurate record of that meeting.

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2.2 Action Points – PAG(AP)(17)2 **Action**

AP1 – PAG Clinical Governance Report
Following the inquest in May, an external review has been carried out and any learning outcomes will be shared with PAG. **J Forsythe**

Standard Listing Criteria
An email was circulated on behalf of S Sinha providing further information regarding the 2 Oxford patients who were included in the previous standard listing paper, as not meeting the criteria. S Sinha confirmed both patients had met listing criteria, but the information had not been recorded accurately on the supplementary form.

AP2 – Strategy
J Forsythe will be updating PAG with more details at the next meeting.

AP3 – Length of Donation Process
Refer to minute 3.1

AP13 – Retrospective Listing For Pancreas Patients
It was confirmed the change request for retrospective listing does cover both kidney and kidney/pancreas. Additional information is required from Stats/KAG and when this is complete an estimated delivery date will be provided.

AP14 – Any Other Business
A discussion took place at the previous PAG meeting regarding a patient waiting for a SPK transplant with a view to dual listing. Views at PAG were split; therefore J Casey discussed this issue at KAG. KAG were supportive in the dual listing recommendation, however it was identified the IT system would currently not allow dual listing. A lengthy discussion took place as it was identified a minimal amount of patients would meet the dual listing criteria of cRF ≥95% and waiting three years or more on SPK transplant list. B Hume confirmed dual listing can be achieved; however the details will need to be finalised before changes are requested and timescales discussed, J Casey will take this back to KAG. **J Casey**

2.3 Matters arising, not separately identified
The chair advised Mr Gabriel Oniscu has nominated Mr Andrew Sutherland to take over representation for Edinburgh Transplant Centre.

3. Associate Medical Director's Report

3.1 Developments In NHSBT:
B Hume presented an update on the following:

Lessons learned from the Lung Allocation roll out need to be incorporated and considered for the new Pancreas Allocation scheme, which will begin in 2018. It's likely that development to move the pancreas allocation scheme across to the new ODT Hub IT platforms will commence in 2018/2019 and this is an ideal opportunity to make any required changes to the scheme. Although the timelines for the development are variable, due to other projects, it was suggested that any changes to the pancreas allocation scheme should be proposed at the next PAG meeting for sign off.

Action

Following discussion, it was agreed for B Hume to liaise with J Asher to organise a meeting with relevant advisory group members to discuss and plan proposed changes. **B Hume**

The development phase of the new scheme is anticipated to take 6-9 months, followed by 2-3 months to train staff on the new system.

The 'go live' date for the new Liver Allocation Scheme has been delayed until March 2018, to allow sufficient time to train operational staff, a lesson learned from the Lung Allocation roll out.

J Casey provided an update on the length of donation process – work is ongoing, a number of actions have been taken to reduce delay, and these include a fast track system for higher risk organs.

A joint NHSBT and BTS consent in organ donation workshop is scheduled to take place on 15th November.

3.2 Governance Issues

3.2.1 Non-compliance with allocation

None reported.

3.2.2 Incidents for review: PAG Clinical Governance – PAG(17)24

A report was received showing 14 incidents directly linked to pancreases.

It was reported on a number of occasions, a request for extra vessels had been made, however the vessels had not been delivered. There appears to be variation in practice regarding vessels being dispatched with the incorrect organ, therefore consensus was reached that the communication process between retrieval and recipient surgeons requires improvement. A suggestion was made to introduce imaging of pancreases and vessels to help identify quality and damage of the organ at the time of retrieval.

J Casey to take the above issues and suggestions to NRG. **J Casey**

3.2.3 Summary of CUSUM monitoring following pancreas transplantation – PAG(17)25

C Counter presented a CUSUM report which monitors short-term patient outcomes following organ transplantation. One signal at Cambridge was noted.

NHSBT ODT was asked to carry out an external review of 4 pancreas graft losses which took place between November 2016 and February 2017. It was noted the heparin protocol for discharge of patients vary across units. The suggestion was made to have a standard heparin protocol for all centres to follow when discharging a patient.
In summary, the 4 cases reviewed produced reasonable outcomes and there was no pattern to the graft losses. It was highlighted the complexity of cases were dealt with during out of hours. Some centres have a 'backup' surgeon during out of hours who can be contacted which works well.

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3.2.4 Pancreas Damage Report – PAG(17)26 **Action**

A paper was received reporting organ quality and damage. There were 216 pancreas donor forms received. C Counter highlighted the importance of completing these forms to assist with monitoring organ damage.

The suggestion was made to consider the HTA B form instead of the pancreas donor forms to allow a comprehensive capture of overall surgical damage data for any future reports. **C Counter**

Members of the meeting were asked for suggestions on how to educate retrieval teams when assessing a pancreas as there is a concern in the variability across units when retrieving a pancreas.

The following recommendations were made:

- Organ Retrieval Workshop which runs annually in December
- Educate SNODs when communicating with Hub Operations, to enquire about pancreas anatomy
- Video/photographic evidence at time of retrieval
- Clinical Retrieval forum organised by Roberto Cacciola
- Increase engagement with units when a non-pancreas team is retrieving

Members also suggested for the deceased donor pancreas specific form to include an additional question requesting date/time on ice on back table. It was agreed in the meantime, to incorporate this information in the general comments box (section 9).

J Casey to raise the above suggestions at NRG. **J Casey**

4. Statistics & Clinical Studies Report

4.1 Summary from Statistics & Clinical Studies – PAG(17)27

C Counter updated members on recent presentations, publications, current and future work. R Johnson was congratulated on her new role as Director of Statistics and Clinical Studies

4.2 Transplant Centre Dashboards

A small working group was put together to look at the data produced on transplant centre dashboards.

The working group agreed the informal talk from the Recipient Co-ordinator to the patient is valuable. It was identified the information a patient receives differ across centres; therefore it would be useful to have electronic information centres can refer to.

Further work on this will take place and will be provided at the next PAG meeting. **H Bentall & J Mackisack**

4.3 Standard Pancreas transplant data set for data applications – PAG(17)28

A proposal was produced for a standard whole pancreas transplant dataset to be agreed by PAG, for provision in response to data applications that meet a set of criteria. R Johnson advised the standard data set will be uploaded to the ODT website and will include timescale of work for all advisory groups. The group was in

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Action

agreement that it is important to have standard data set.

A request was made for the number of previous pancreas and islet transplants, donor admission glucose and donor HEV status to be included in the data set. The suggestion was made that prior to submission for publications, papers should come back to the chair of PAG for information.

C Counter

5 Pancreas Transplant Activity

5.1 Transplant list and transplant activity – PAG(17)29

A paper was presented showing deceased pancreas and islet activity in the UK from 1 April 2007 – 31 March 2017 and number of donors, transplants and patients on the active transplant list at 31 March.

Members recognised the need to also include in the tables transplant centres where a DCD transplant has not occurred.

J Bunnett

5.1.1 Group 2 Patients Report

Up until the end of September 2017, there have been no Group 1 non-UK resident EU patient pancreas transplants and no Group 2 patient's pancreas transplants.

5.2 Transplant outcome – PAG(17)30

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

It was noted that the three year graft survival rate after first DBD PTA was under 50% however internationally the five year survival rate is 50%.

J Casey advised a discussion took place at the pancreatic forum, that a short term trial should take place to analyse metabolic outcomes in pancreas transplants after kidney transplants.

It was agreed for Oxford and Newcastle to discuss at the next forum meeting a potential protocol for analysing metabolic outcomes in pancreas after kidney.

S Sinha & S White

5.3 Fast Track Scheme – PAG(17)31

A paper was received auditing 21 months of activity of the revised fast track scheme. Overall the pancreas fast track scheme had resulted in 19 transplants, of which, 11 resulted in a whole pancreas transplant and there was follow up available for 8 of these transplants where only 1 had failed at 3 months.

Members agreed it would be useful for Hub Operations to document the reasons why the pancreases have entered the fast track scheme.

B Hume – Hub operations

Discussion took place on whether criteria should change for organs being entered into the fast track scheme. After various suggestions made, it was agreed a more detailed analysis will need to be completed before changes to the scheme can be implemented.

C Callaghan/ C Counter

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5.4 Discard of pancreases from 'ideal donors' – PAG(17)32

C Callaghan presented a report describing an approach to identify pancreases

offered from 'ideal' deceased donors and analyse the frequency of non-use and underlying reasons.

The paper highlights where there are significant concerns about utilisation decisions, NHSBT will write to clinical teams to seek further information. This approach has been adopted in kidney transplants centres and will be introduced to pancreas transplant centres.

It was acknowledged the data produced will continue to demonstrate a larger discard rate of pancreas when sent for islets. It was agreed the data should focus on an ideal pancreas donor not an ideal islet donor; however once the donor grading system in pancreas islets has been agreed, an outcome measure could be produced.

It was noted another aspect of organ utilisation is when an organ is sent for research. It has been recognised at the PAG Islet Steering Group, the re wording of the research forms have resulted in a decrease in organs being sent for research. PAG ISG is taking this forward.

6 Update from Organ Allocation (Working Group) – PAG(17)33

An update was provided from the organ allocation working group. The group considered criteria from low and high BMI donors.

After a lengthy discussion, it was agreed a donor with a BMI of ≥31.5 will not be accepted at a whole centre unless all islet centres have declined and a donor with a BMI below <21.5 will not be accepted at an islet centre unless all whole centres have declined. It was recognised donor age is a factor; however it was agreed this change can begin with immediate effect, implemented by the centres. The implementation of this within ODT Hub Operations would require some work to ensure when fast tracking these donors all centres can see all patients who match the donor. The group agreed if a donor is outside of the age limit, the organ would then be fast tracked which will be monitored. P Johnson, M Drage and C Counter to look at donor age categories and provide a proposal to help implement the age limit within the fast track scheme.

Action: P Johnson/ M Drage and C Counter

It was agreed donors with a lower age and higher BMI which is sent for islets, will be incorporated in the new pancreas allocation scheme.

The second part of the paper highlighted resource issues within Oxford gaining access to ITU beds and Edinburgh accessing operating theatres, respectively. It was noted the majority of transplants had an element of out of hours activity. J Casey agreed a letter should be sent from NHSBT/J Forsythe to Edinburgh and Oxford to help highlight the resource issues the transplant teams are experiencing.

7 Update from Organ Utilisation and Damage (Working Group) – PAG(17)34

A retrospective study took place looking at offers of solid organ pancreases over the last 10 years. During January 2005 and December 2015, 7367 pancreases were offered for transplantation, 38% of these were initially accepted but not used

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Action

due to a fatty pancreas or organ damage. Another 50% of organs declined were on the basis of donor history. The paper recognised the need for criteria for organs

which should be accepted by all centres.

The working group also produced a prospective study from July 2016 to January 2017, where an assessment took place by a consultant surgeon independent of the initial discard decision and involved a video recording before and after preparing the graft for implantation. Of the 53 pancreas which were photographed and recorded, 36% of them were deemed to be transplantable by transplant surgeons. This gives an indication that some organs being declined could potentially be transplanted in another centre.

Members were in agreement there is a need for imaging of pancreases at the time of retrieval to help enable earlier decision making and to aid a more thorough analysis of the organ retrieved. C Callaghan advised a pilot study of imaging kidneys will take place. The group felt imaging of organs should already be in place; therefore a pilot study may not be necessary. It was agreed C Callaghan will take the kidney imaging proposal to NRG and feedback to PAG. **C Callaghan**

A Sutherland advised Edinburgh is putting together recommendations for surgeons to use as a guide on acceptable tears within organs.

8 Update from national information and consent document working group - PAG(17)35

A national information booklet was produced with a form of consent incorporating evidence of potential complications within a transplant. Although it is acknowledged units vary in clinical practice, the aim is to have a generic document for all units to use. Future developments will include an online version and develop the information into a video.

It is recognised the document produced holds a large amount of information and the method of information may not be the most logical. The working group acknowledged all trusts would need to be engaged to help utilise this document.

It was suggested smaller sections of information may be easier to understand and the document could be part of the recipient co-ordinators process with the patient. J Casey advised further suggestions are emailed to A Sutherland.

It was discussed whether NHSBT logo or individual trust logos should be added to the document. Members agreed it would be beneficial to have one document, well evident which could continue to be updated.

9 Update on donor and recipient risk analysis working group

C Counter confirmed an electronic form has been circulated to units. S Sinha advised there is a large amount of data which will need to be entered into this form. R Johnson suggested there may be a possibility of a resource extract rather than a data input dependent on the type of data required. A further update will be provided at the next PAG meeting.

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10	**Pancreas Islet Transplantation**	

10.1 Report from the PAG Islet Steering Group: 4 October 2017

P Johnson provided a verbal update on arising matters from the PAG Islet Steering

Group meeting, held in October 2017.

It was agreed analysis will take place looking at outcomes from different cold ischemic times which vary across the UK.

A HTA storage licence will be purchased by Oxford to help enable islets which have reached expiry time to be stored longer.

An ongoing issue has been highlighted at PAG ISG, where HbA1C samples are not accompanying every donor pancreas to the correct islet centre. J Casey advised this should be incorporated as part of donor characterisation development. Centres agreed blood samples should be sent with every solid organ in an ETDA bottle.

10.2 Islet Transplantation – PAG(17)36

This paper was also produced at PAG Islet Steering Group showing islet transplant activity using the four key measures.

10.3 Islet isolation outcomes – PAG(17)37

A paper which was presented at the PAG Islet Steering Group was also agreed to be presented at PAG.

Further analysis will take place to help categorise donors into grades to produce centre specific isolation outcomes.

11. Standard Listing Criteria

11.1 Summary Data - PAG(17)38

There were 485 registrations between 1 April 2015 and 31 March 2017. Nationally the return rates for the supplementary form have reached 86% for whole pancreas registrations and 97% for islet registrations. One centre has a low return rate and the request for supplementary forms to be completed and returned was reiterated.

Of the 110 new supplementary forms received between 1 March and 31 August 2017, 4 (4%) patients did not meet the standard listing criteria and were not circulated to the Pancreas Advisory Group Exemptions Panel. It was acknowledged this could be due to recording errors. C Counter to contact Oxford regarding the 3 patients who did not meet the standard listing criteria. **C Counter**

11.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel - PAG(17)39

The group was provided with a spreadsheet indicating 2 patients which were submitted to the pancreas applications panel and approved.

11.3 Patient Selection Policy – PAG(17)40

The patient selection policy for pancreas was reviewed and members came up with the following recommendations:

- Add “Liver ultra sound for islet patient” under Radiology

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- Remove “Thrombophilia screen” under Haematology blood tests
- Add “HEV” Under Serology blood sample…

12 Any Other Business

A Sutherland requested a letter from PAG is sent agreeing for a 43yr old patient assed for SPK with a suitable BMI; however has previously had various complications including a bowel operation, incisional hernia repair and has impaired awareness of hypoglycemia. The patient is aware of the risks; however is still keen to have simultaneous pancreas/kidney transplant.

Discussion took place around various options for this patient; however the group felt listing for simultaneous pancreas and kidney should proceed.
The pancreas forum will be taking place in January 2018 and it was agreed this will be held in Cardiff.

P Johnson advised the 8th EPITA meeting will take place in January 2018 and having UK representation from pancreas members would be appreciated.

13 FOR INFORMATION ONLY

13.1 Transplant activity report: Sept 2017 – PAG(17)41
Noted for information.

13.2 Patient Consent Scheme Audit – PAG(17)42
Noted for information.

13.3 IT Progress report: Feb 2017 – PAG(17)43
Noted for information.

13.4 Current and Proposed Clinical Research Items – PAG(17)44a & PAG(17)44b
Noted for information.

16. Date of next meeting:
Wednesday 11th April 2018, 10.30-15:00, 12 Bloomsbury Square, London

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