NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE THIRTY THIRD MEETING OF THE PANCREAS ADVISORY GROUP AT 11:00AM ON THURSDAY 15th NOVEMBER 2018 AT ODT, STOKE GIFFORD, BRISTOL, BS34 8RR

PRESENT:

Mr John Casey	**Chair**
Mr John Asher	Medical Health Informatics Lead – ODT
Mr Titus Augustine	Deputy Chair - Manchester Transplant Centre
Ms Cliona Berman	Regional Manager & SNOD Representative (deputy)
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation
Dr Pratik Choudhary	King's College London Representative
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Mr Martin Drage	Guy's Transplant Centre
Mr Doruk Elker	Cardiff Transplant Street
Prof John Forsythe	Medical Director, NHSBT
Prof Susan Fuggle	Scientific Advisor, NHSBT
Mr Simon Harper	Cambridge Representative
Mr Ben Hume	Assistant Director TSS, NHSBT
Dr Stephen Hughes	Islet Laboratory Representative
Prof Paul Johnson	Pancreas Islet Steering Group Chair
Mrs Julia Mackisack	Lay Member
Mr Anand Muthusamy	West London Renal & Transplant Centre (deputy)
Mr Simon Northover	Recipient Co-ordinator
Ms Isabel Quiroga	Oxford Transplant Centre (deputy)
Dr Rommel Ravanan	Renal Association Representative
Mr Andrew Sutherland	Edinburgh Transplant Centre
Prof. Stephen White	Newcastle Transplant Centre

IN ATTENDANCE:

Mrs Lizzie Abbot-Davies	Clinical & Support Services (observer)
Mr Willis George Olsen	NHSBT (observer)
Miss Sam Tomkings	Clinical & Support Services

Apologies

Mrs Hazel Bentall, Prof. John Dark, Miss Kirsty Duncan, Ms Roseanne McDonald, Mr Nicholas Inston, Dr Sian Lewis, Prof. Nizam Mamode, Ms Rachel Johnson, Prof. Rutger Ploeg, Dr David Turner, Ms Sarah Watson

Action

1. DECLARATIONS OF INTEREST IN RELATION TO THE AGENDA

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

2. MINUTES OF THE MEETING HELD ON 11 April 2018 – PAG(M)(18)1

2.1 Accuracy

The minutes of the meeting held on 11 April 2018 were confirmed to be a true and accurate record of that meeting.

2.2 Action Points PAG(AP)(18)2 **Action**

Action points with a verbal update were discussed below.

AP2 – Transplant Outcome
It was agreed at last meeting to recirculate and review which units had implemented the standard follow up and monitoring processes. P Choudhary circulated the Igls criteria and the associated document which the majority of units confirmed are following these processes. P Johnson asked if the meal tolerance test is part of the current proposal. A Sutherland advised the meal tolerance test can be achieved at the end of admission after transplant, however it can be difficult to obtain the outpatient follow up, particularly if patient is not followed up at the unit where the transplant took place. This is similar for most units. J Casey added there are resource issues regarding meal tolerance testing in whole pancreas transplantation. Members acknowledged that pancreas solid organ function is not monitored as well as it should be and that it is an essential part of the transplant process.

J Shaw enquired if there has been success in reversing the trend if a patient experienced rejection. M Drage advised this has been possible in some patients. J Shaw suggested a more interventional trial to identify patients who are beginning to lose function.

J Casey suggested reviewing the follow up data held within NHSBT data and if appropriate to take the proposal for a UK wide clinical trial to the Pancreas Forum. **P Choudhary**

M Drage suggested as Guy's hold the largest number of biopsies it would therefore be useful to present the safety data at the Pancreas Forum. **M Drage**

AP 2 - Update from Organ Allocation (Working Group)
J Forsythe and J Casey have discussed how to address units declining pancreas offers due to logistical issues. Raised at the Transplant Policy Review Committee (TPRC) was the issue of the duty of candor to patients, particularly those organs turned down due to lack of resource. From this, it was agreed to include as part of the policy a statement where NHSBT would inform patients if an offer was made and refused as a result of logistical issues.

C Callaghan added that the pancreas ideal donor scrutiny scheme which will begin in the next few months to look at the reason an offer has been declined from an ideal donor and had met certain criteria will result in that unit receiving a letter requiring a response for the reason it was declined. This will help highlight units experiencing logistical issues. This scheme has commenced for kidney at the next KAG meeting the next steps regarding the responses received will be discussed. KAG has already set up a short term working group to consider the responses.

AP3 – Pancreas Utilisation
The suggestion was made at the last PAG to consider using the pancreas DRI to help monitor pancreas utilisation, however it was found the DRI would not have significant benefit as the variables would not be useful.

AP5 – Group 2 patients report **Action**

The NHSBT directions state that "No person in Group 2 shall receive an organ for which there is a clinically suitable person in Group 1". Group 2 patients currently appear in the centre specific summary report, not in the main matching run, although there are no Group 2 patients listed at the moment. KAG have recently agreed that Group 2 patients will not appear in any matching runs and will not be eligible to receive a transplant until they obtain Group 1 status, although they can still be listed in order to accrue waiting time points.

2.3 Matters arising, not separately identified

3 ASSOCIATE MEDICAL DIRECTOR'S REPORT

3.1 Developments in NHSBT

J Forsythe updated PAG on the current developments within NHSBT.

The Scottish bill for Opting Out has been published and it is anticipated this will come into force by April 2020. The English Opting Out legislation is from a private members bill which has been accepted and has now moved to the House of Lords where a debate will take place on 23rd November 2018. If it is agreed without amendments, this could be in place in England by 2020. Impact assessments have been completed for both legislations which has suggested the requirement for additional resources for communications, retrieval and novel technologies.

The retrieval service is under significant pressure and there is a requirement for increase in capacity. There have been meetings held to discuss this and NHSBT have written to the retrieval teams inquiring if more capacity could be entered into the system and if this could be achieved. All units have now responded, and this will be discussed at the capacity and demand meeting.

Sustainability was discussed at the joint BTS and NHSBT meeting in June and the next phase is to hold regional meetings. The first meeting will be held in the region of London at the end of November to identify if there are ways to collaborate better and identify the resource required to move forward.

Doug Thorburn has been appointed as the new chair of the Liver Advisory Group.

3.2 Governance Issues

3.2.1 Non-compliance with allocation

None reported.

3.2.2 Incidents for review: PAG Clinical Governance – PAG(18)23

J Forsythe presented the Clinical Governance paper which identified two incidents, one regarding the anatomy of the kidney that went as part of a SPK, however the findings suggested the offering had been completed correctly that the highest ranking person would receive the left kidney. The right kidney could be requested but would require the other centre to agree and would be required due to major clinical need. This has been raised at both PAG and KAG.

The second incident related to islet isolation process from the pancreas and concerns that the condition of the pancreas did not reflect what had been documented on the HTA A form, although following review of the HTA A form it was agreed the description of the trauma was sufficient. S Hughes added this

pancreas was described as bruised but on processing, the actual description wasn't quite accurate. **Action**

J Forsythe referred to the guidance available around photographs of organs which is available on the ODT website.

3.2.3 Summary of CUSUM monitoring following pancreas transplantation PAG(18)24

There were no CUSUM signals in the last 6 months.

3.2.4 Organ damage – PAG(18)25

C Counter presented a paper investigating the level of damage reported on the HTA B form on grade of surgical damage for pancreases that were accepted for whole pancreas transplantation.

C Counter reminded members that fully completed forms are essential and to ensure these are returned to NHSBT.

Both damage to the pancreas and vessels are significant issues and this has been raised at the National Retrieval Group (NRG) and requested that Rutger Ploeg, chair of NRG take this forward. In addition, J Casey made the request to raise this issue at the NRG education meetings to ensure pancreases are retrieved in the appropriate way.

As most retrieval teams have a similar level of damage, J Casey asked for suggestions how this can be improved to help reduce the level of damage caused. A suggestion was made to consider the level of damage caused by the grade of surgeon which may highlight the need to reinforce training and to ensure surgeons attend regular workshops. I Quiroga confirmed this training is covered as part of the Organ Retrieval Masterclass held once a year. I Quiroga queried if a record of surgeons attending courses is held. J Forsythe advised that no record is held and that it is down to centres to establish a surgeon's competency, however units are monitored and if a retrieval team had a higher organ damage rate, this would be investigated. C Counter reminded members if an organ is damaged due to surgical error at retrieval, this should be marked on the HTA B form and a clinical incident should be raised.

The use of organ imaging may improve cases such as the recent incident regarding the bruised pancreas sent for islet.

In summary the group agreed to:

- Continue emphasis in educational training meetings
- Continue to raise at NRG particularly if degree of severe damage hasn't reduced
- Continue monitoring through PAG

3.2.5 Update on organ imaging pilot

A national pilot scheduled to take place for imaging of kidneys had been delayed due to ensuring a secure pathway to send images, which has now been resolved

by IT. The national kidney imaging pilot will begin once the SNOD teams are happy to incorporate the change. **Action**

The next scheme to be piloted will be pancreas which members are keen to bring forward particularly due to the level of pancreas damage and therefore asked if there was a possibility to introduce this as a simultaneous scheme for kidney and pancreas. C Callaghan feels this may put additional pressure on retrieval teams and SNODs. C Callaghan recommended initially piloting the kidney only imaging as the pancreas imaging requirements were not as far advanced.

P Johnson stated the data produced from Sham Dholakia, suggested that the imaging of fatty pancreases may not be beneficial identifying infiltrated fat.

3.2.6 Update on offer decline scrutiny schemes

C Callaghan updated PAG on the offer decline scrutiny scheme which is based on the criteria set on the core donor data form. If an offer decline or organ discard from a donor who has met the "ideal donor" criteria is identified, this information will be sent to C Callaghan for review. This scheme will begin in the next 6-8 weeks.

The question was raised why DCD pancreas offers are not included, C Callaghan advised DCD offers may have different outcomes therefore it was decided to begin with DBD offers. Members agreed DCD offers should be included within this scheme. **C Callaghan**

3.2.7 Late notification of pancreases split from potential MVT blocs – PAG(18)26

C Callaghan presented a paper on behalf of the Cambridge unit who have identified potential multivisceral transplant (MVT) patients with extensive portal vein (PV) thrombosis, for whom at the point of transplant may only require a liver transplant due to PV thrombosis being less extensive that originally thought. This results in the pancreas not being utilised.

Andrew Butler and C Callaghan produced a proposal suggesting that if Cambridge accept a multivisceral bloc for PV thrombosis patient, a pancreas matching run is initiated, and the pancreas is provisionally offered via the offering scheme. A kidney would be held back from offering until the destination of the pancreas was known.

C Callaghan asked PAG if this proposal is acceptable. Members agreed this is a good way to ensure pancreas utilisation and accept this proposal on the basis KAG agree.

3.3 Developments in IT

3.3.1 Organ Quality eForms update – PAG(18)27

A paper was received from J Asher on the organ quality HTA eForms where an electronic replacement for the HTA form A and B will begin. The development of the provisional form B is on track and will be rolled out in December. The development of form A is scheduled to start in April 2019. The forms will be built within the donor path and will help streamline various forms and the collection of data. Both forms will be hosted within the CRM platform. The aim of this project

is to minimize duplicating data collection and to assist clinicians with completing the correct forms which will be available in one platform. **Action**

J Forsythe requested this information is relayed to centres and if clarification is required to liaise with B Hume or J Asher. **All Representatives**

J Forsythe suggested renaming the eForms to avoid confusion with the current HTA A and B forms.

I Quiroga queried as part of the pilot, there were three donor identifiers, and as the pancreas does not have a HTA A number will this therefore no longer be required. J Asher advised the HTA A form is primarily used to track and link the HTA B form. Going forward the ODT number used as the primary identifier.

3.3.2 Recording reasons for pancreas decline or non-use – PAG(18)28

J Asher submitted a paper to help define the recording of reasons for pancreas decline or non use. The reasons have been divided into categories. The list has been kept using the same numbers across all organs therefore may not appear in a logical order. Appended within the lists are reasons for decline and in italic are additional reasons for decline. J Asher included for reference, the kidney and pancreas reasons.

J Casey encouraged members to review the list and take back to their units and feedback comments to J Asher. **All Representatives**

C Callaghan felt poor weather is a transport issue and A3 – high risk lifestyle could be reworded to increase in infection risk.

4. Changes to National Pancreas Allocation Scheme – PAG(18)29

The Kidney Allocation Scheme has been significantly revised which involve SPK patients within that scheme and therefore this was discussed at the last PAG meeting. As part of the new IT platform, it was agreed to introduce appropriate changes to Pancreas Allocation Scheme.

C Counter produced various simulations which were circulated in June this year and the changes to both schemes will be implemented next year.

Incorporated into tier A of the new Kidney Offering Scheme are SPK or SIK patients with 100% cRF, matchability score 10 or kidney waiting time ≥7 years. Ranked by descending matchability score and then ascending waiting time.

The Pancreas Offering Scheme will be divided into three tiers. Tier A - Pancreas or islet alone patients with 100% cRF or matchability score 10 and any pancreas patient with pancreas or islet waiting time ≥3 years. Ranked by descending matchability score and then ascending waiting time. Tier B - Blood group identical and highly sensitised compatible patients ranked by descending total points score (TPS) and Tier C - Other blood group compatible patients ranked by descending TPS. The exclusion criteria are: Donors aged <25 years and BMI <25 kg/m^2 not offered to islet patients and Donors with a BMI ≥31 kg/m^2 not offered to whole pancreas patients.

Action

J Shaw queried how this would affect highly sensitised priority islet patients removed from the priority list after 12 months and listed as routine. C Counter confirmed if the patient was 100% sensitised or had a matchability points score of 10 they would be in Tier A of the offering scheme. [Post meeting note: Additionally, accrued waiting time on the priority list is carried over to the routine registration and once that reached three years the patient would meet the criteria to be in Tier A.]

S Hughes queried the current maximum age for DBD islet groups was 60 and not 61. C Counter advised the maximum age is 60 and 364 days.

C Callaghan asked if the DCD criteria aged equal to 51 not offered to islet patients include SIK patients. C Counter confirmed it does include SIK patients and C Callaghan suggested this could result in a SIK patient missing out on good kidney offers. J Casey added consideration to lower islet yield for SIK patients has been discussed but it is important that the patient has a good chance of getting islets with the kidney.

After extensive discussion, it was agreed to monitor this and to re consider increasing the DCD age criteria for islet patients to increase access to a kidney and islet transplant.

5 Pancreas Transplant Activity

5.1 Transplant list and transplant activity – PAG(18)30

A paper was received showing the activity over the last 10 years.

There were 211 transplants 2017/18 and 481 donors. At the end of March 2018 there were 218 patients on the waiting list and 29 of those were islets or SIK patients.

J Casey asked if members agreed that the new technologies for diabetes is reducing the number of referrals for SPK transplants. R Rommel added that early detection of diabetes within patients and managing this is likely to have an impact on the number of referrals.

5.1.1 Group 2 patients report

There has been no Group 2 or Group 1 non-UK EU resident transplants.

5.2 Transplant outcome – PAG(18)31

C Counter presented a paper showing graft and patient survival for simultaneous pancreas kidney and pancreas only transplants performed between April 2013 and March 2017.

There was a significant improvement in 1 year graft survival following SPK transplants from DCD donors. There was no significant difference in graft survival from DBD donors within this period.

5.3 Fast Track Scheme – PAG(18)32a & PAG(18)32b **Action**

Two papers were received, one auditing the activity within the Fast Track Scheme (FTS) and, due to high numbers of donors entering the FTS, a second paper reported on an in-depth study.

Over a 33 month period, a total of 470 (36%) of all deceased donor pancreases have been offered through the FTS, 122 pancreases were accepted for transplantation, and 41 (9%) were transplanted through the FTS.

An in-depth analysis of donors offered via the FTS in a six-month time period and all donors whose pancreas was transplanted after a fast track offer in a 30-month time period was presented.

These analyses showed that organs with a trigger for fast track of "deemed unusable" and those organs with a cold ischaemic time (CIT) of more than 8 hours had not resulted in a transplant. Of all those organs transplanted via the fast track scheme none had a CIT of more than 6 hours.

The recommendation is to implement a restriction on fast track offers based on the criteria of CIT or the organ being deemed unusable. From these analyses, not offering via the FTS if the CIT is more than 8 hours at the time of potential fast track offer, would reduce the number of fast track offers by 19% and have no negative impact on the number transplanted. If the decision is also to not offer organs deemed unusable there would be a further 12% reduction in fast track offers.

After discussion around the difficulties in defining "unusable", members agreed that pancreases would not be offered via the FTS if the CIT at time of potential fast track was more than 8 hours. C Counter agreed to liaise with Hub Operations and Regional Managers regarding the implementation of this and the calculation of CIT, as members emphasised that the CIT must be calculated from time of cold perfusion to ensure accuracy. **C Counter**

6 HCV positive donor organ for HCV negative recipients

J Casey has taken part in various teleconferences discussing the utilisation of organs from HCV donors to negative recipients. J Casey sought the views from PAG on whether units would consider organs from HCV positive donors for pancreas and islets and how this could be implemented.

J Forsythe confirmed Scotland and Wales have agreed to fund the DAA's and this is being considered by NHS England. NHBST is keen to implement this across the UK.

A position statement is available regarding HCV positive organs into negative recipients which include stipulations centres must follow.

Most units have discussed accepting HCV positive kidneys but have not considered this for pancreas. J Casey requested units discuss this as a priority and identify which units are willing to take part in this proposal and feed this back to J Casey. **All Units**

A Sutherland highlighted the concerns raised by patients when considering accepting a HCV positive organ. J Casey added patient information and education can assist with informing patients. **Action**

7 Update from Organ Utilisation and Damage (Working Group)

A Sutherland reported back to the working group the suggestions made at the previous PAG meeting regarding the use of photographs rather than recordings. Another part of the working group was to analyse the damage of declined pancreases and involve a wider group of surgeons which is still in progress.

Key pictures have been produced which the group agreed should be sent to the recipient centres. Gabi Oniscu is keen to collaborate with C Callaghan's work on organ imaging and consider if this should begin with kidney and later rolled out to all organs.

C Callaghan agreed to liaise with A Sutherland and Gabi Oniscu and agree on a clear description of what is required and pass this onto Maggie Stevens, SNOD operations. Pancreas imaging will follow kidney as there is a 3-month roll out. **C Callaghan**

8 Update from National Information and Consent Document (Working Group) – PAG(18)33

The National Information document has been separated from the consent document as this is being looked at by another group. A Sutherland incorporated the suggestions made at the last PAG meeting.

J Mackisack felt graft survival and patient survival outcome is not clearly distinguished and that the illustrations should state where within the body the illustrations are referring to. A Sutherland will incorporate the suggested changes and re circulate and add to the ODT website. **A Sutherland** J Mackisack requested the terminology be similar to that being used within the consent document for consistency. P Choudhary suggested passing the document to Diabetes UK to ensure the terminology is appropriate. A Sutherland will liaise with C Watson who is part of the consent group. **A Sutherland**

I Quiroga felt the document does not provide enough detail regarding complications. A Sutherland added as part of the original form the list of risks was removed as this is captured within the consent document.

M Drage highlighted that portal vein is spelt incorrectly and information regarding a living kidney donor being an alternative for SPK patients, who are well enough, should be stated. **A Sutherland**

9 Update on Donor and Recipient Risk Analysis (Working Group)

T Augustine provided an update on the current progress with the donor and recipient risk analysis. C Counter informed Oxford and Cambridge have completed all forms required and that Edinburgh, Newcastle, WLRTC and Manchester have not returned any forms. The remaining centres are near completion.

T Augustine will follow this up. **T Augustine**

10 Pancreas Islet Transplantation **Action**

10.1 Report from the PAG Islet Steering Group: 2nd October 2018

P Johnson provided a verbal update from the PAG Islet Steering Group meeting held in October.

The Edinburgh islet isolation laboratory has re-opened and is operating.

Centre specific isolation data is beginning to be produced where all isolation data will be presented at the next PAG ISG.

All islet facilities have purchased a HTA storage license to ensure islets that have been distributed and expired can return and accepted back to the islet laboratory and re cultured.

10.2 Islet transplant activity and outcome – PAG(18)34

C Counter presented the islet transplant activity and outcome report.

Transplant activity in 2017/18 shows 26 transplants in total, 16 routine and 10 priority, compared to 34 in the previous year. As of the 31st March 2018 there were 29 islet patients on the waiting list, 24 of those were routine including 10 SIK patients.

One year graft survival following routine islet transplantation was 88% and at one year post transplant there were reductions in annual rate of severe hypoglycaemic events, HbA1C and insulin dose.

10.3 Islet Isolation Outcomes – PAG(18)35

C Counter presented a paper looking at data on 121 donors in the last financial year where a pancreas was accepted for islet transplantation.

Of the 121 donors analysed the islet page was completed and returned for 85% of cases. Of the 116 organs indicated to have arrived at an isolation laboratory and used for islet isolation, 104 (90%) had isolation completed. However 57% did not meet the release criteria using post isolation counts or information was missing. Of the 45 that met the release criteria, 18 (40%) were transplanted.

Following PAG ISG a request for retrospective data, in order to obtain complete data for all organs arriving at an isolation laboratories, has been made. This will enable a more accurate picture to be presented.

J Casey asked for the final product count to be used where it is reported instead of the post isolation count in order to categorise whether the islet prep met the release criteria. **C Counter**

10.4 Discussion with the HTA regarding Islet Transplantation

A meeting took place in October with the HTA and members of the clinical and islet laboratory leads. The aim of the meeting was to discuss the process of organ offering across the UK of pancreas solid organ and islets.

It was agreed to work towards providing the HTA with accountability for the organ at different stages, from offering to transplantation. The HTA recognised the

acceptance criteria for solid organ and islet transplantation differ, therefore suggested it would be beneficial to become more similar. **Action**

Confirmative testing is something which is solvable, however this is a legal requirement. Concerns were raised from the isolation laboratories regarding the increase in resource. J Casey confirmed there is the potential for re testing and if there were a difference in the results, there could be potential for errors within that system.

P Johnson added that the Edinburgh laboratory is designed to complete second testing however Kings and Oxford are technician led and therefore would be responsible for interpreting results' which the HTA understood adds vulnerability to the Kings and Oxford laboratories.

11 Standard Listing Criteria

11.1 Summary Data – PAG(18)36

There were 512 registrations between 1 April 2016 - 31 March 2018. Nationally the return rates for the supplementary form have reached 95% for whole pancreas registrations and 100% for islet registrations. All patients with forms returned in the latest six months, met the listing criteria.

The standard listing criteria for SIK patients was discussed. P Choudhary and A Sutherland agreed to review the patient selection policy standard listing criteria and will feedback comments to J Casey. **P Choudhary & A Sutherland**

11.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(18)37

Noted for information, no recent appeals.

12 Any Other Business

Guy's Hospital have a 16-year-old patient, potentially group 2 which may be considered as a Group 1 category patient if classified as a child with severe complications. M Drage will email J Casey once clarity is sought from the lawyers.

The suggestion was made to hold the next Pancreas Forum at Hammersmith Hospital. A Muthusamy suggested a joint meeting in April next year.

13 FOR INFORMATION ONLY

13.1 Summary from Statistics & Clinical Studies – PAG(18)38

Noted for information.

13.2 Transplant activity report: September 2018 – PAG(18)39

Noted for information.

13.3 IT Progress Report: October 2018 – PAG(18)40

Noted for information.

13.4 Current and Propose Clinical Research Items – PAG(18)41

Noted for information.

13.5 QUOD Statisical Report – PAG(18)42

Noted for information.

14 Date of Next Meeting:

Wednesday 1st May 2019 10:30am, 12 Bloomsbury Square, London