NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE THIRTY FOURTH MEETING OF THE PANCREAS ADVISORY GROUP AT 10:30AM ON WEDNESDAY 1st MAY 2019 AT 12 BLOOMSBURY SQUARE LONDON WC1A 2LP

PRESENT:

Mr John Casey	**Chair**
Mr John Asher	Medical Health Informatics Lead, ODT
Mr Titus Augustine	Deputy Chair - Manchester Transplant Centre
Dr Richard Baker	National Clinical Governance Lead, ODT
Miss Joanna Bunnett	Statistics & Clinical Studies, NHSBT
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation (Abdominal)
Ms Cliona Berman	Regional Manager & SNOD Representative (deputy)
Dr Pratik Choudhary	King's College London Representative
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Mrs Kirsty Duncan	Recipient Coordinator Representative
Prof. John Forsythe	Medical Director, NHSBT
Prof. Susan Fuggle	Scientific Advisor, NHSBT
Mr Simon Harper	Cambridge Transplant Centre
Mr Nicholas Inston	KAG Representative
Prof. Paul Johnson	Pancreas Islet Steering Group Chair
Mrs Julia Mackisack	Lay Member Representative
Dr Adam McLean	WLRTC and Hammersmith Hospital
Mrs Jacqueline Newby	TSS/Hub Operations
Mr Simon Northover	Recipient Coordinator Representative
Prof. James Shaw	UK Islet Transplant Consortium
Mr Sanjay Sinha	Oxford Transplant Centre
Mr Andrew Sutherland	Edinburgh Transplant Centre
Dr David Turner	BSH Representative
Ms Sarah Watson	NHS England Representative
Prof. Stephen White	Newcastle Transplant Centre

IN ATTENDANCE:

Miss Sam Tomkings	Clinical & Support Services

Apologies

Mrs Hazel Bentall, Mr Martin Drage, Prof. Nizam Mamode, Ms Roseanne McDonald, Dr Stephen Hughes, Dr Rommel Ravanan

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 15 November 2019– PAG(M)(18)2

Accuracy

2.1 The minutes of the meeting held on 15 November 2018 were confirmed to be a true

and accurate record of that meeting subject to the following change: **Action**

- Add Prof. Jim Shaw to the attendance list of the November 2018 meeting.

2.2 Action Points PAG(AP)(19)1

All action points had been completed or were included on the agenda.

2.3 Matters arising, not separately identified

3 ASSOCIATE MEDICAL DIRECTOR'S REPORT

3.1 Developments in NHSBT

J Forsythe provided an update on the current developments within NHSBT.

The English Opt out legislation has been agreed and will take effect in Spring 2020. Over the next year, a wide-ranging public awareness campaign will take place. It is anticipated that an increase in donor numbers and potential transplant numbers will put additional pressure on the service. The requirement for additional resources for retrieval teams, novel technologies and commissioning of transplants are being considered.

A successful meeting was held to discuss sustainability and consider ways in which kidney and pancreas transplant centres could collaborate. The work will initially focus on kidney transplant units and will be rolled out to other areas. S Sinha added that Oxford and Coventry have worked collaboratively for the past 12 months which has worked well and therefore would welcome and support further initiatives across the country.

The figures for organ utilisation are available for 2018/19. The deceased donation figures have increased to another highest record however, the number of transplants has not risen to match this. It was noted there is a significant down turn in heart and lung transplantation.

3.1.1 Transplant Centre Profiles – PAG(19)2

The Transplant Centre Profile was initially developed to provide the public with information on Organ Donation and Transplantation. It has since been decided due to the patient focused work taking place at the Winton Centre, that the Transplant Centre Profile information will be provided to transplant centres to compliment the annual report but will also be accessible to the public on the website.

C Callaghan requested that the alignment of the key to the graph is adjusted and that the colours on the graph have more distinction between them. **C Counter**

It was noted that as this profile may be accessed by the public, some patient focused aspects will remain.

Members felt that Islet activity should be incorporated within the information sheet. Members agreed a more accurate title for the graphs at the bottom is required and the suggestion was made to title the graphs 'What are the chances of me being alive at 5 years' and 'What are the chances of my pancreas graft functioning at 5 years'. **C Counter**

Action

3.2 Governance Issues

3.2.1 Non-compliance with allocation

None reported.

3.2.2 Incidents for review: PAG Clinical Governance – PAG(19)3

J Forsythe presented the PAG Clinical Governance report.

An inaccuracy was noted within the paper which states there are 7 pancreas transplant centres in the pancreas fast track scheme but that there are 8 centres within the scheme.

An incident was raised where the Hub Operations was unable to make contact with a transplant centre to make an offer for a named patient. Members acknowledge it is the centres responsibility to ensure someone is available to accept these offers 24/7. A McLean advised the person that takes the offers at WLRTC is also responsible for calls from ITU and theatre and that there are areas within the Hospital where mobile phones do not work, therefore a bleep system has been provided. A proposal within this unit has been made within the transplant group to change the system for who is responsible for taking the organ offers. As the majority of centres have a Recipient Coordinator it was felt this would be the most appropriate person to take the initial call.

3.2.3 Summary of CUSUM monitoring following pancreas transplantation PAG(19)4

There were no CUSUM signals in last 6 months, however a previous CUSUM was raised where a team visited the unit involved where various discussions resulted in recommendations being made. J Forsythe requested if necessary, that a lessons learned document is produced to share with other units. **J Casey**

3.2.4 Pancreas Offer Review Schemes – PAG(19)5

A report presented by C Callaghan provided the early experience of these schemes since they have been introduction in February 2019. PAG were asked to consider a change of terminology to 'High quality pancreas donors' rather than 'ideal pancreas donors'. PAG agreed with the proposed name change. J Casey suggested including in future reports the outcome of the organs transplanted. **C Callaghan**

Three letters have been sent to units and two responses were received.
S Northover advised that Oxford had declined an offer due to an ICU bed capacity issue but that the named recipient has since received a transplant.

N Inston expressed concern that pancreas units may accept all SPK offers made but later decline the pancreas which will have increased the cold ischemia time (CIT) for the kidney which is offered on. To address this concern, J Forsythe suggested taking a number of cases where the pancreas was declined, and the kidney was offered on to identify if there is evidence of this happening. It was also highlighted that NHSBT will monitor the time the organs arrive, and the length of time taken for the unit to inspect the organ. **C Counter**

3.2.5 Pancreas imaging pilot

The kidney offering pilot has begun and the use of taking images of the organ on explant and sending these images to the implanting centre will aim to improve

decision making and organ utilisation. NHSBT SNOD teams have numerous IT changes but it is anticipated the pancreas imaging pilot will begin mid-summer. **Action**

C Callaghan will liaise with Ian Currie to decide if this is something which could be incorporated in the Organ Retrieval Masterclass taking place in December. **C Callaghan**

3.3 Developments in IT

3.3.1 Organ Quality eForms update

J Asher informed the committee that funding for the electronic A and B integrated forms to be sent to the commercial developer is not available, therefore this project is on hold.

There has been a gradual increase in the electronic form B which replicates the paper form. Local security IT policies have been an issue with accessing the cloud. Michael Gumm from NHSBT visited Guy's Hospital to assist with the IT issues.

J Asher requested feedback from units using this form which should be emailed to J Asher's nhs.net email address. Oxford is using the form which is working well, however there are a number of mandatory boxes which will not let you progress through the form in circumstances such as taking the kidney out of ice. **All centres**

3.3.2 Recording reasons for pancreas decline or non-use – PAG(19)6

A paper was received showing the catergorised reasons for decline which has been expanded into 8 categories. Members of PAG agree with the list of reasons in each category.

4. Pancreas Offering Scheme

4.1 8 year review of the National Pancreas Allocation Scheme – PAG(19)7

C Counter presented an 8-year review of the Pancreas Allocation Scheme.

Since the scheme began there have been 1800 transplants, 23% were from DCD donors, 13% were Islet transplants and 87% were whole pancreas transplants.

As of 1 December 2018, there were 193 whole pancreas patients waiting on the transplant list and 34 islet patients on the waiting transplant list.

In future reports, it is intended that the information for utilisation of whole pancreas and islets will be separated.

J Shaw suggested looking at the conversion rates now that data is available for donors over 50 years of age vs less than 50 and the outcomes. **C Counter**

The number of registrations in Manchester for Islet transplants have increased. T Augustine stated there has been a focus drive to increase the numbers and that a large proportion of these are SIK. A request was made to look at SIK as a separate entity. **C Counter**

4.2 Changes to the scheme and timescales

A letter and FAQs document were circulated to members of PAG in April. The changes to the Pancreas Offering Scheme will be implemented this summer.

Incorporated into Tier A of the new Kidney Offering Scheme are SPK or SIK patients who are 100% sensitised or a matchability score 10 or kidney waiting time over 7 years. Those patients will be offered a pancreas and kidney but could accept the kidney and not the pancreas. **Action**

4.3 Declined offers due to logistical reasons – PAG(19)8

C Counter presented a paper looking at reasons where whole pancreases were declined or accepted but not used.

In 2018 calendar year, there were 765 solid organ donors whose pancreas was offered for whole organ transplantation. 392 subsequently became pancreas donors, of those, 53% resulted in transplantation. Of the offers in 2019, 79% were declined, 12% were accepted and not used, and 9% were accepted and transplanted. Of those offers declined, logistical reasons were stated in 277 (17%) of cases, with no access to beds/staff/theatre stated in 12% of those cases.

Members agreed that 17% of offers being declined due to logistical reasons is a high percentage.

NHSBT will be introducing an expectation by centres that the named patient will be made aware of an offer which is declined solely due to logistical reasons.

Members discussed if a patient should be made aware if it is not possible for a unit to do a pancreas and liver transplant at the same time.

Each advisory group will define what is a reasonable workload and advise NHSBT of this.

Members agreed that a small working group should look at reasons classed as 'logistical' for use if a transplant centre declines a pancreas for a named patient. S White will lead the group and provide recommendations and suggestions to NHSBT. **S White**

5. Review of the Patient Selection Policy – PAG(19)9

The Patient Selection Policy was circulated to members for review. Comments were received and will be discussed at the next Transplant Policy Review Committee (TPRC) in June.

A teleconference organised by J Shaw was held to discuss listing for simultaneous islet and kidney transplantation and what level of C-peptide pre-transplant should be considered and whether a pre-transplant MMTT be undertaken. It was agreed that, in the presence of glucose >10mmol/l, a C-peptide <50pmol/l means a pre-transplant MMTT is not required. If C-peptide >50pmol/l but <100pmol/l an MMTT is required. If the MMTT stimulated levels of <100pmol this is still C-peptide negative for ITA or SIK. If the C-peptide is above 100pmol/l this would need to be discussed via the exemption panel but that the clinician would be allowed to list this patient which will be included in the selection criteria.

A lengthy discussion took place regarding whole pancreas transplant units completing a MMTT for pre-transplants and the listing of SIK patients. It was felt a steer from the SIK group is required regarding SIK patient listing, therefore the

suggestion was made to include in the criteria for listing that for all SIK patients who are Type 1 diabetics and have a positive C-peptide level of >50pmol/l but <100pmol/l an MMTT is required. J Casey highlighted that these patients who receive a SPK assessment and by SPK definition have Type 1 diabetes but are then considered listing for SIK but no longer meet the criteria for baseline C-peptide. A Sutherland felt the threshold of C-peptide above 100pmol will result in a number of patients being considered for exemptions. **Action**

It was agreed for the criteria to remain as is and to continue listing for SIK for those patients who are not eligible for SPK listing. It was also agreed to consider data collection but mandate MMTTs and to not remove patients from the list who are already listed. This will be discussed further at the pancreas forum.

6. Pancreas Transplant Activity

6.1 Transplant list and transplant activity – PAG(19)10

J Bunnett presented a paper reporting activity and transplant listing in the UK over the last 10 calendar years.

In the last calendar year there has been an increase in pancreas donors to 500. 78% were from DBD donors and 22% from DCD donors which equates to 7.6 per million population.

There has been a slight increase in the number of pancreas transplants to 223 where 73% were from DBD donors and 27% were from DCD donors.

At the end of December 2018, there were 218 patients on the active waiting list, 33 of these were islet patients and around half of these were SIK patients.

6.1.1 Group 2 patients report

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

6.2 Transplant Outcome – PAG(19)11

J Bunnett presented the Pancreas Transplant Outcome report.

There was no significant difference in one-year pancreas graft survival following first SPK transplants from DBD or DCD donors between the two time periods.

There was a significant difference in one-year kidney graft survival following first SPK transplants from DBD donors between the two time periods. There was no significant difference in one-year pancreas graft survival for pancreas only transplants from DBD donors between the time periods.

6.3 Fast Track Scheme – PAG(19)12

C Counter presented the Fast Track Scheme paper which audits activity within 39 months of the Pancreas Fast Track Scheme (FTS) which was introduced in December 2015.

Over the 39 months, there has been 567 deceased donors offered through the fast track scheme which equates to 37% of all deceased donors. Of those offered, 144 (25%) of pancreases were accepted for transplantation, of which, 62 were accepted for islets. Overall 9% of those offers made through the FTS were transplanted.

Action

These data do not take into account the rule change around not offering pancreases with a CIT at 8 hours via the FTS which became effective on 1 April 2019.

S Sinha expressed that in his experience the 8-hour CIT limit was too long and should be shorter. C Counter advised this will continue to be reviewed.

7 HCV positive donor organ for HCV negative recipients

A letter circulated to all units and discussed at the previous PAG meeting was whether units would consider accepting offers from an HCV positive donor for HCV negative recipients. One reply was received from Cardiff who are currently piloting HCV kidneys and advised depending on the outcome from these, Cardiff will trial pancreas HCV organs.

There have been issues with funding the antivirals in England however Scotland, Wales and Northern Ireland have secured funding. J Forsythe added that Welsh and Scottish patients receiving treatment in England are funded for receipt of DAAs. S Watson advised that NHS England are developing the policy and it will be taken to the Clinical Priorities Advisory Group for a decision. A McLean asked if this budget would cover a patient whose inability was to complete the course of antivirals. S Watson will ensure the draft policy is circulated to PAG when available for stakeholder testing to allow PAG/individual members to feed comments into the process of drafting. J Casey agreed this would be useful. **S Watson**

All units would consider accepting these organs on the basis that the antiviral funding is available. J Forsythe added NHSBT have established routine testing of higher infectious risk donors and units who want to accept these organs should contact Ahmed Elsharkawy who is leading this to ensure appropriate oversight. A Programme Monitoring Committee has been set up through the Liver Advisory Group to monitor this as this develops.

8 Working group re: SIK

Raised at the recent PAGISG meeting was the need for further discussion on assessment and follow up for SIK patients and to consider the logistics of how this is accessed across the UK. It was therefore agreed that a small working group led by David Van Dellen including islet representation and solid organ will gather evidence and create a number of proposals for the questions surrounding SIK and feedback to PAGISG and PAG. **D Van Dellen**

9 Update from Organ Utilisation and Damage (Working Group)

The recommendations made to the last PAG meeting were to consider video recordings of the pancreas at time of retrieval to consider whether the pancreas was suitable for solid organ transplant and if not, divert the organ to islets. PAG felt it was not practical to do this and agreed to incorporate this work into C Callaghan's organ imaging work. It was agreed that a panel of photographs should be taken at the time of retrieval which are sent to the accepting surgeon for a decision. P Johnson added that it would be useful to incorporate this with the islet photographs taken within the islet facilities.

J Casey asked how this would be monitored, A Sutherland confirmed C Callaghan

and Gabi Oniscu have liaised and agreed this will sit within the organ imaging work and that feedback from surgeons obtaining the pictures would be appreciated. **Action**

10 Update from National Pancreas Information Booklet (Working Group)
A Sutherland took the suggestions made at the PAG meeting in November, incorporated the changes and the information booklet has now been submitted to NHSBT for upload to the website.

P Choudhary suggested liaising with Martin Rutter at Manchester regarding the DUK information sheet which is due for review. **A Sutherland**

11 Update on Donor and Recipient Risk Analysis (Working Group)
T Augustine informed members that there has been 100% data returns from 4 centres. Data from Edinburgh, WLRTC and Oxford has been partially received, however no data from Newcastle has been received. S White advised there is no support available to provide this data.

12. Pancreas Islet Transplantation

12.1 Report from the PAG Islet Steering Group: 2 April 2019 – PAG(19)13
P Johnson provided an update on the main points discussed from the PAGISG meeting held on 2 April 2019.

A coherent strategy was agreed for the acceptance of donors with meningitis across the islet facilities.

A number of pancreas sent for islets have been declined as a result of the lack of isolation capacity. The addition of SIK and the Edinburgh facility which is closed at weekends and at night means the islet facilities are strained.

The Auto Programme for islets will be monitored under the PAG remit and the post-transplant follow up will be the same as the ITA process.

12.2 Islet transplant activity and outcome – PAG(19)14
C Counter presented the islet transplant activity and outcome for 2018.

There were 29 islet transplants performed and the number of patients on the waiting list at the end of December 2018 was 33, 30 routine and 3 priority compared with 28 patients in 2017.

Following first islet transplant, one-year graft survival was 89% and 5-year graft survival was 50%. Five-year graft survival for a patient receiving a routine and priority graft was 60% survival compared with 33% for those receiving a routine only graft, this difference was statistically significant.

The annual rate of severe hypoglycemic events, the level of HBA1C and the insulin dose for patients had all reduced at 1 year post-transplant. A request was made at PAGISG to split these graphs by those receiving a routine only and a routine and priority graft.

S Sinha asked at what stage would NHSBT and the islet community want to

contribute to the national data. P Johnson will present this information at the IPTA meeting in July. J Shaw suggested whether the HBA1C data and hypoglycemic data should be collected on pancreas patients, A Sutherland advised these data are collected and returned to NHSBT. **Action**

12.3 Islet isolation outcomes – PAG(19)15

The islet isolation outcome data was presented for 2018.

Of the 111 donors where there was an offer of islet accepted and the organ was retrieved and arrived at an isolation facility, 98% were used for islet isolation. Of the 93 with islet isolation completed, 49 met the release criteria defined using the final product information if available. Of these 49, 24 were transplanted giving a conversion rate of 49%, 25 were not transplanted mainly due to insufficient islet yield. Of the 44 that did not meet the release criteria, 5 were transplanted, 2 were SIK.

The donors received at each isolation facility were 44% at Oxford, 23% at Edinburgh and 33% at King's. 98% had isolation started and in 85% of cases were completed. S White highlighted that Oxford have the highest number of isolations started and not completed. P Johnson advised Oxford has experienced more poorer quality pancreases where the isolation should not have started but that the criteria for starting an isolation has been reviewed. It is not known whether all facilities have similar criteria for stopping an isolation mid isolation.

S White requested additional columns are included in Table 1 for met release criteria and transplanted by isolation facility. C Counter confirmed those data are available and will be added and categorised by donor grade.

P Choudhary stated it would be useful to show how many SIK were under the 100,000 IEQ release criteria.

It was asked whether photographs are taken of pancreases that are not isolated, P Johnson confirmed that pictures are taken for auditing, but that it would be good to link this up with C Callaghan's work. J Casey asked how auditing these data and differences in outcomes can be monitored. P Johnson suggested at the PAGISG meeting that laboratory managers meet every 3 months to ensure the laboratories are assessing in the same way.

13. Standard Listing Criteria

13.1 Summary data – PAG(19)16

A paper was presented showing there were 523 registrations between January 2017 and 31 December 2018 and that the return rates for supplementary forms were 93% for whole pancreas registrations and 100% for islet registrations.

Of the 135 new supplementary forms received between 1 August 2018 - 31 January 2019, two (1%) of patients did not meet the standard listing criteria and were recorded to be not receiving dialysis and have an estimated GFR >20mls/min. One patient was listed as suspended and has subsequently met the criteria and has been activated. The second patient has subsequently been removed from the list following suspension as they still did not meet the criteria.

Action

A Sutherland asked that if a patient is listed with a GFR 19 but 3 months later have a GFR 21 should that patient be suspended. C Counter's concern with the patient at Manchester was that the patient's GFR did not meet criteria at listing and would therefore have gained a year's waiting time. J Casey confirmed that if a patient meets the criteria at listing they do not need to be suspended.

S Sinha highlighted an error in appendix 1 which states 'b. patients listed with type 2 diabetes must have a BMI of <30kg/m2' but this should not be in the PTA section and should state in 'a. all patients must have type 1 diabetes'. The >4 mmol/l under ITA b. should be changed to >10 mmol/l. **C Counter**

13.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(19)17
There have been no new exemption requests submitted.

14 Any Other Business
Members discussed funding for the Pancreas Forum. It was agreed that to help reduce costs, the hotel and meal the evening before will not be included in this year's forum.

J Casey asked the committee what they feel are PAG priorities and what are the areas this group should focus on. The suggestion was made to consider how the median to long term outcomes are optimised, how rejection is diagnosed and how graft function is monitored. P Choudhary volunteered to look at partial function and weight gain post-transplant. **P Choudhary**

Members agreed that there is a shortage of data regarding quality of life study and that capturing secondary complications data would be useful. A PHD student in Oxford is looking at prospective and retrospective data within the Oxford cohort. J Shaw suggested adding this to the Islet remit. J Shaw agreed to take this forward. The ATTOM project had a quality of life aspect included. Gabi Oniscu and Rommel Ravanan will have further analysis on this. **J Shaw**

Newcastle has a 60-year-old male patient with Type 1 diabetes who has no hypo awareness and recurrent life-threatening hypos and has had two previous islet transplants, most recent in March 2014. The patient is now C-peptide negative and has progressive renal decline. His GFR is 28 and has fluid retention. The patient has been listed for ITA but clinicians now feel he is not safe for ITA because of renal decline and therefore would like to list this patient for an SIK but above the threshold of 20 GFR. The suggestion was made to email this request to C Watson. **J Shaw**

15 FOR INFORMATION ONLY

15.1 Summary from Statistics & Clinical Studies – PAG(19)18
Noted for information.

15.2 Transplant activity report: March 2019 – PAG(19)19
Noted for information.

15.3 IT Progress report: February 2019 – PAG(19)20
Noted for information.

15.4 Current and Proposed Clinical Research Items – PAG(19)21
Noted for information.

15.5 QUOD Statistical report – PAG(19)22 **Action**

Noted for information.

16. Date of Next Meeting:

Tuesday 5th November, 11am at ODT, Stoke Gifford, Bristol

May 2019