NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE THIRTY SIXTH MEETING OF THE PANCREAS ADVISORY GROUP AT 10:30AM ON TUESDAY 28th APRIL 2020 VIA MICROSOFT TEAMS MEETING

PRESENT:

Mr John Casey	**Chair**
Dr Arthi Anand	BSHI Representative
Mr Titus Augustine	Deputy Chair & Manchester Transplant Unit
Dr Richard Baker	National Joint Clinical Governance Lead
Mrs Hazel Bentall	Lay Member Representative
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation (Abdominal)
Mrs Claire Counter	Statistics & Clinical Studies, NHSBT
Dr Pratik Choudhary	King's College London
Mr Ian Currie	UK Clinical Lead Organ Retrieval
Mr Martin Drage	Guy's Transplant Unit
Mrs Kirsty Duncan	Recipient Coordinator Representative
Mr Doruk Elker	Cardiff Transplant Centre
Prof. John Forsythe	Medical Director, NHSBT
Ms Anushka Govias-Smith	NSD Scotland
Ms Susan Hannah	Regional Manager
Mr Simon Harper	Cambridge Transplant Centre
Dr Stephen Hughes	Islet Laboratory Representative
Prof. Paul Johnson	Pancreas Islet Steering Group Chair
Mrs Julia Mackisack	Lay Member Representative
Dr Adam McLean	WLRTC & Hammersmith Hospitals Representative
Ms Katie Morley	Lead Nurse Recipient Co-ordination
Mr Anand Muthusamy	WLRTC & Hammersmith
Mr Simon Northover	Recipient Coordinator Representative
Dr Tracey Rees	Chief Scientific Officer, ODT
Mr Sanjay Sinha	Oxford Transplant Centre
Mr Andrew Sutherland	Edinburgh Transplant Centre
Ms Sarah Watson	NHS England
Prof. Steven White	Newcastle Transplant Centre
Mrs Julie Whitney	Head of Service Delivery, ODT

IN ATTENDANCE:

Miss Sam Tomkings	Clinical & Support Services
Mr Joseph Parsons	Statistics & Clinical Studies, NHSBT

Apologies

Prof. James Shaw, Mr David Van Dellen

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 5 November 2019– PAG(M)(19)2

2.1 Due to recent COVID-19 events, it was decided to hold this meeting as a Microsoft Teams Meeting. The papers were circulated in advance and there was an opportunity to raise questions on each paper during or after the meeting.

Accuracy

The minutes of the meeting held on 5 November 2019 were confirmed to be a true and accurate record subject to a minor change to paragraph 3.2.2. Once this change has been made the minutes can be approved. **J Casey**

2.2 Action Points PAG(AP)(20)1

All action points had been completed or were included on the agenda. Those with a verbal update are listed below.

AP1 – Raised at the previous meeting was the issue of anesthetist support at Hammersmith Hospital. A McLean confirms this continues to be a concern and this will be revisited once service resumes.

AP2 - Hepatitis C positive donors to Hepatitis C negative recipients
J Casey reminded members to complete the paperwork which must be returned to Prof David Mutimer and NHSBT if their centre would like to receive such organ offers.

AP3 - Incidents for review: PAG Clinical Governance Report
I Currie confirmed communication was circulated to all abdominal retrieval teams regarding the staplers and confirmed all teams in the UK are using green staplers for both ends of the pancreas graft.

AP4 - Organ Damage
Raised at the Retrieval Advisory Group (RAG) was the standard of pancreas retrieval and loss of graft because of technical injury. I Currie has been considering ideas on how a pancreas retrieval workshop will be taken forward. The options include for pancreas centres to decide how a pancreas should be retrieved which would be a collaborative approach from centres who retrieve pancreases and centres who transplant pancreases and consider input from members of PAG to provide some recommendations. R Baker added Derek Manas has expressed his concern and noted the variability in the retrieval of pancreases. C Callaghan highlighted that the BTS website has guidelines regarding retrieval techniques which may be useful. S White added that if some retrieval teams have a larger number of damaged organs than others, could this be an indication there is a problem with accreditation of surgeons. I Currie has revamped the process of how surgeons are accredited, and that the responsibility of accreditation now lies with the NORS lead who registers the surgeon as independent. I Currie confirmed there may be pressure to sign surgeons off before they are fully independent. R Baker confirmed whenever an incident takes place, the centre will have this fed back to them. R Baker will suggest that an audit is undertaken to investigate this. As part of looking at organ damage for RAG, Derek Manas and I Currie are working on using pancreas as the pilot organ and running a CUSUM system for organ damage.

AP6 Retrieving vessels for pancreas
All the various issues were formalised at RAG and the NORS guidelines has been updated and will be published in the next few weeks. **Action**

AP9 – Contact and Offering
C Counter looked at the last 4 calendar years where the first three centres which were offered the organ declined the offer for the same reason and what proportion of those were subsequently transplanted. 8% of donors where the pancreas was offered were declined by the first three centres for the same primary reason, which was 272 cases and 4% of those were subsequently transplanted. Of those not subsequently transplanted, the reasons given for declining the organ was donor unsuitable due to past medical history, 64% and donor unsuitable age in 21%. C Counter mentioned that organs are fast tracked if 4 centres decline a DBD donor through a donor or organ specific reason and organs are fast tracked if 3 centres decline a DCD donor. C Counter added that it has been agreed to reduce the upper age limit to 60 and when that is implemented, that will reduce some of the organs which are currently fast tracked.

S Northover has had an email discussion with Mick Stokes (Head of Hub Operations) and provided him with a list of key information which gave a clearer idea of why organs are being fast tracked.

AP13 - Quality of Life working group
J Casey reminded members if they are interested in participating in this working group to email J Shaw.

2.3 Matters arising, not separately identified

3 MEDICAL DIRECTOR'S REPORT

3.1 COVID-19

J Forsythe thanked all members for their cooperation and collaborative approach across the community over the past few weeks.

A large number of meetings have taken place including daily meetings with commissioners and regular meetings of the extended medical team and all chairs of the advisory groups. Out of those meetings have come the COVID-19 bulletins and the decisions which have been made across the whole of transplantation.

As of today, cardiothoracic and liver are continuing to transplant highly urgent and super urgent patients. 5 adult kidney transplant centres remain open with the potential to re-open more and 2 paediatric centres are open. No solid organ pancreas transplants have been carried out for some time and a few urgent patients were on the waiting list for a second islet transplant.

The recovery period is now being considered where the decision for a program to re open or extend is a local decision which must consider local resources and local COVID profile. NHSBT felt it is important to have a level of local guidance and support, therefore C Callaghan and colleagues have circulated a document which will be widely shared. The second part to the recovery phase is the decisions that have been made over the course of the pandemic will be individually reviewed to consider whether the decisions should be reversed or partially reversed or whether some should be left in place such as the changes to the offering sequence which

have resulted in speeding up the process. **Action**

S Watson added a transplant paper was taken to the National Incident Response Board regarding restoration and recovery and to help provide instructions to regions. S Watson has been asked to provide some briefing notes about the risks and mitigation and what information should be provided from pancreas transplantation. J Forsythe added that a COVID free area has been the reason why some of the transplant centres have remained open which features heavily in C Callaghan's central guidance. J Forsythe also highlighted a rapid paper will be made available from the Renal Registry demonstrating how potentially life threatening COVID is to patients on unit hemodialysis and suggested S Watson contact an author of the document to make a request that the data is shared.

J Mackisack asked what communication is being provided to patients. J Forsythe added that the COVID-19 bulletin is shared with a wide number of people including patient group representatives and that this is part of C Callaghan's document. S Watson added that all of the transplant patients would have been given advice on being shielded. S Sinha added that Oxford has provided constant communications to their patients on the waiting list and those who have been suspended.

3.1.2 Opt Out update

The date for Opt Out to be implemented in England remains the 20th May. Scotland have agreed to delay the mechanisms of the passing of the Opt Out process which is now delayed until 2021.

3.1.3 ODT Strategy update

J Forsythe advised that the ODT Strategy has been put on hold.

4 COVID-19

4.1 Individual centre report

J Casey emailed all centres to ask for some consideration for potential plans and what the barriers may be for individual centres to reopen. A verbal report was provided by each representative.

WLRTC and Hammersmith Hospital – A McLean

Both units have experienced a big outbreak in their dialysis population where mortality is the same as the mortality of the transplant recipients recently reported by Cornell and Columbia which is 24% of all comers. The high dependency unit (HDU) which would usually be utilised by transplant recipients is being used as a ventilated area and is an important resource to dialysis patients. That area will be required and capacity on the intensive care unit (ICU) to support the immediate post operative period to consider re opening for pancreas transplantation. An agreement will need to be put in place with ICU that if a transplant patient is operated and re appear in the early post op period with COVID-19 pneumonitis that they are accepted.

Guy's Hospital – M Drage

M Drage reported that they have gone from having 2 ICU's to 10 ICU's across the two sites and their COVID free site is HCA Hospital London Bridge. The plan is to start with kidney paediatric transplantation at GOSH and possibly Evelina. The concerns Guy's Hospital have with restarting pancreas transplantation is that there

Action

are currently not enough ICU facilities to look after the patients. Clinicians are considering whether an interim rule could be put in place to allow patients to receive a kidney alone transplant rather than a SPK and also consider restarting kidney adult transplantation. Virologist for the Trust anticipate another peak in 3 weeks time.

Oxford – S Sinha
Oxford continue with kidney transplantation in a limited way; however, it is unlikely that pancreas transplantation will be reinstated any time soon due to access to intensive care. There are also constraints to anesthetic resource. In light of the epidemic, a change to the immunosuppression protocol for pancreas transplantation has been put in place from using Campath to Simulect. S Sinha would like as a group to discuss this further. Oxford have written to their Nephrologist who have patients on the SPK list and currently have patients on dialysis to seek their opinion before approaching the patients.

Cambridge – S Harper
Cambridge have managed to keep the transplant unit and transplant HDU separate. In the final week before lockdown, Cambridge successfully transplanted a couple of SPK but have since stopped. In this period around 25 kidneys have been transplanted and two of those kidney patients contracted COVID but both patients are fine. There is a possibility that Cambridge could restart pancreas transplantation. S Harper confirmed that kidney patients are receiving standard immunosuppression.

Cardiff – D Elker
Cardiff transplant unit and ward has been kept COVID free. Since the program has been suspended no kidney transplants have taken place. Now redeployed staff are beginning to come back to the unit the plan is to begin with kidney transplantation and to ensure a COVID free pathway is in place. Letters will be sent to patients and discussions will take place regarding the risks. Pancreas transplantation is not managed on ICU but on the ward with one to one care. Immunosuppression used in Cardiff for pancreas transplantation is ATG but there is an internal debate about whether a shortened course should be used.

Manchester – T Augustine
Manchester have stopped transplanting as the transplant ward is currently being used as a COVID/dialysis area. Elective surgery has not yet started therefore access to theatres will be a problem. The consent process for the pandemic is being discussed and the centre is looking at the kidney list to identify patients who are more straightforward to transplant. Pancreas is further down the line.

Newcastle – S White
Newcastle has been kept open for renal transplantation, but a transplant has not taken place since the first week of April however a recent successful liver transplant has taken place. The aim was to keep the Freeman Hospital COVID free, but the ICU has since been divided into two sections resulting in half of ICU being used for COVID patients meaning pancreas transplantation will be a problem because of access to ICU beds. S White advised until this reduces, pancreas transplantation will not be able to go ahead. A meeting will take place tomorrow to discuss how the unit can reopen kidney transplantation as kidney patients tend not to require ICU.

Edinburgh – A Sutherland **Action**
Both pancreas and kidney transplantation are suspended. The islet program is open for one priority patient awaiting a second islet transplant who is already on immunosuppression. Liver is open for super urgent transplants. ICU capacity was full but has since reduced and 24 out of 40 beds are occupied. The unit still has access to a COVID free ICU and HDU area. The transplant ward has been reconfigured into COVID positive and negative ward. The unit is discussing restarting the kidney transplant program and will navigate a COVID free pathway and initially keep patients on the transplant HDU and not on the general ward. The team are considering kidney patients of a lower risk and age but are some way off restarting the pancreas program. The unit is considering offering the SPK patients a kidney alone.

Islet transplantation – P Johnson
All the clinical leads met to discuss a united policy which acknowledged that Manchester, Bristol and Royal Free had already been told to close. For the rest of the islet units the decision was made to suspend new patients and for those patients in the process who were not requiring a second dose of Campath were kept on the list. There were three patients on the list two in Edinburgh and one in Newcastle. One patient in Edinburgh has been transplanted. The islet units in Edinburgh and Oxford are open for those specific patients. In terms of reopening, the group will look at this together and consider centre specific decisions. The implication for islet alone patients is life threatening hypoglycemia.

4.2 Strategy for restarting pancreas transplantation post COVID-19 – PAG(20)17
C Callaghan requested this document is not disseminated at the moment as it is still in draft form as a letter was received from NHS England which raised the issue of screening asymptomatic patients for COVID meaning the guidelines had to be reworded.

The underlying principles of the document is to acknowledge the variation of the impact of COVID on units and for those units who wish to consider reopening the programs, that a phase reopening is the appropriate way forward. It is anticipated that any decisions the units make will likely need regular review.

C Callaghan advised this is an overarching document and is not organ specific. Organ specific guidance will be provided by the chairs of the advisory groups. There is some new virological advice within the document and overall this is to be considered as an aide memoir.

M Drage highlighted that one of the issues we have is that there is a very high mortality of patients that receive dialysis in dialysis centres. For pancreas patients who receive dialysis at home or in a centre are relatively similar in comorbidity. M Drage would be keen to consider prioritising patients who have in centre dialysis during the pandemic. R Baker highlighted that only 20% of dialysis patients are on the transplant list and a lot of the dialysis patients who have died would not have been on the transplant list. J Forsythe advised R Baker ask the Renal Registry for an update of their data and added that NHSBT are trying to make sure the transplant registry data is linked to PHE and ONS to provide more information about transplant patients and listed patients.

R Baker added on behalf of Derek Manas who has suggested restarting first time islet patients with hypoglycemia. S White added for those centres using Campath for that group of patients it may not be sensible to reactive those patients if it is anticipated we may reach another peak in the new few weeks. P Choudhary added there is one patient who has had 6 severe hypos and 2 fractures in the last week and therefore would be happy to consider transplanting that patient. **Action**

S Watson recommended that a set of principles could be drawn up for centres to operate as local environments allow. J Casey added that going forward, for the majority of centres, restarting whole organ pancreas transplantation in the immediate future is not likely to happen apart from in Cambridge. J Casey suggested holding regular meetings with the clinical leads to form some sort of strategy. Members agreed this would be useful on a fortnightly basis. **J Casey**

5 Governance

5.1 Non-compliance with allocation

There has been no non-compliance with allocation.

5.2 Incidents for review: PAG Clinical Governance Report – PAG(20)2

R Baker advised of an incident in an islet facility which resulted in a fatality back in July. More information on this will be provided once the centre has approved this. R Baker will look at an audit of pancreas retrieval and will feed back on this. **R Baker**

5.3 Summary of CUSUM monitoring following pancreas transplantation – PAG(20)3

There were no CUSUM signals in the last 6 months.

5.4 Pancreas Imaging Pilot

C Callaghan advised that the most recent audit showed an uptake in pancreas imaging which has improved from 20% up to 50%.

6 Pancreas Offering Scheme

6.1 POS first 6 months report – PAG(20)4

C Counter presented the first 6 months from 11th September 2019 until 6th March 2020 of the new Pancreas Offering Scheme (POS).

The number of pancreas and islet transplants performed in that period were 102 transplants, 75 of those were from DBD donors. 86% were whole pancreas transplants and 14% were islet transplants. Of those 102 transplants, 4% were patients in either Tier A of the Kidney Offering Scheme (KOS) or the POS which is compared to 7% that would have been in those tiers in the previous year up until 10th September 2019.

As at 1st March 2020 there were 237 patients waiting for a pancreas or islet transplant and of those 9 (4%) were in Tier A of the KOS and 14 (6%) were in Tier A of the POS. 88% of those patients were waiting for a SPK or pancreas alone transplant. 28 patients (12%) were waiting for an islet transplant.

The overall median waiting time for those on the list as at the 1st March 2020 were comparable to those on the list as at 1st September 2019 which is 229 days and 228 respectively.

Action

7 Pancreas Transplant Activity

7.1 Fast Track Scheme – PAG(20)5A & PAG(20)5B

Paper A audits 11 months of the scheme since the introduction of the 8 hour cold ischemic time (CIT) cut off was introduced. There has been very little reduction of pancreas donors fast tracked.

The action from the last PAG was to investigate over a 2 year period how many fast tracked organs with a CIT of more than 4 hours were transplanted which was circulated to members earlier in the year.

The data shows just 3 (1.5%) of 198 organs fast tracked with CIT more than 4 hours were transplanted. The document asked members to provide comments and those received indicated approval to have a 4 hour CIT cut off for offering to whole centres but continue offering to islet centres up to the current 8 hour CIT cut off. C Counter requested agreement from the group today to introduce the proposal. All members supported this proposal.

7.2 Transplant list and transplant activity – PAG(20)6

The transplant list and activity paper was circulated, and no comments were received.

7.2.1 Group 2 patients report

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

7.3 Transplant outcome – PAG(20)7

The transplant outcome paper was circulated, and no comments were received.

8 Working Groups

8.1 SIK (Working Group) – PAG(20)16

S White suggested holding a teleconference to discuss this further as not all representatives were available at the initial meeting. **D Van Dellen**

8.2 Declines for Logistical Reasons (Working Group)

S White provided an update on the working group which has looked at data in the last 12 months showing that approximately 45 donors were declined for logistical reasons. Most of the patients were usually transplanted around 3 or 4 weeks later from the point system, therefore the way to explore this is to identify if the recipient received a worse graft on the second offer. This would mean gaining more detail and more accuracy on the logistics. Out of 40 patients only 1 graft was lost. C Callaghan volunteered a lot of this information if required.

9 Pancreas Islet Transplantation

9.1 Report from PAG Islet Steering Group: 25th March 2020

P Johnson highlighted there have not been any deaths on the islet waiting list in the last year possibly due to the introduction of the pumps and sensors which have kept patients safe.

The majority of the PAG ISG meeting was surrounding COVID-19.

Every isolation now has a picture taken pre and post culture which are sent to the

recipient centre and the photographs are stored at that centre. A virtual meeting will take place to share the images and check the assessments are similar across the 3 centres. **Action**

The islet autotransplant program has been commissioned for English and Welsh centres and parallel funding is being introduced in Scotland. The reporting of that will be to PAG ISG and then feed into PAG.

The UK islet transplant consortium meeting taking place on 11th and 12th May will discuss different adjuvant therapies. S White added the autotransplant groups are happy to engage with the PAG ISG meeting.

9.2 Islet transplant activity and outcome – PAG(20)8
The islet transplant activity and outcome paper was circulated, and no comments were received.

9.3 Islet Isolation Outcomes – PAG(20)9
The islet isolation outcome paper was circulated, and no comments were received.

10 Standard Listing Criteria

10.1 Summary data – PAG(20)10
The summary data paper was circulated, and no comments were received.

10.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(20)11
The exemption requests and outcome of previous application to appeals panel was circulated, and no comments were received.

11 Any Other Business
J Casey proposed holding another full PAG meeting in August/September. Members agreed.

12 FOR INFORMATION ONLY

12.1 Summary from Statistics & Clinical Studies – PAG(20)12
Noted for information.

12.2 Transplant activity report: February 2020 – PAG(20)13
Noted for information.

12.3 Current and Proposed Clinical Research Items – PAG(20)14
Noted for information.

12.4 QUOD Statistical report – PAG(20)15
Noted for information.

13 Date of Next Meeting:
August/September tbc
Thursday 5th November 2020, ODT Stoke Gifford, Bristol BS34 8RR

April 2020