

**NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION AND TRANSPLANTATION**

**THE FORTIETH MEETING OF THE PANCREAS ADVISORY GROUP
AT 10:00AM ON THURSDAY 11th NOVEMBER 2021
VIA MICROSOFT TEAMS MEETING**

PRESENT:**Prof. Steven White**

Dr Arthi Anand
 Dr Richard Baker
 Mr Chris Callaghan
 Mr John Casey
 Mrs Claire Counter
 Mr Ian Currie
 Mr Martin Drage
 Mrs Kirsty Duncan
 Mr Doruk Elker
 Mr Sanjay Sinha
 Ms Anushka Govias-Smith
 Ms Susan Hannah
 Mr Simon Harper
 Mrs Julia Mackisack
 Dr Adam McLean
 Mr Anand Muthusamy
 Mr Simon Northover
 Mr Joseph Parsons
 Mr Andrew Sutherland
 Mr David Van Dellen
 Ms Sarah Watson
 Mrs Julie Whitney
 Mr Colin Wilson

Chair

BSHI Representative
 Joint National Clinical Governance Lead, NHSBT
 National Clinical Lead for Organ Utilisation (Abdominal)
 PAG Islet Steering Group Chair
 Statistics and Clinical Research, NHSBT
 National Clinical Lead for Organ Retrieval
 Guys Transplant Unit
 Recipient Coordinator Representative
 Cardiff Transplant
 Oxford Transplant Centre
 NSD
 Regional Manager & SNOD Representative – Organ Donation
 Cambridge Transplant Centre
 Lay Member Representative
 WLRTC & Hammersmith Hospital Representative
 WLRTC & Hammersmith Hospital Representative
 Recipient Coordinator Representative
 Statistics and Clinical Research, NHSBT
 Edinburgh Transplant Centre
 Manchester Transplant Centre & National CLU Lead
 NHS England
 Head of Service Delivery, OTDT Hub
 Newcastle Transplant Centre

IN ATTENDANCE:

Dr Ahmed Elsharkawy	Consultant Transplant Hepatologist Honorary Senior Clinical Lecturer (to present item 3.2)
Ms Lisa Mumford	Head of OTDT Studies (to present items 5.2 and 6.1)
Miss Sam Tomkings	Clinical & Support Services (minutes)
Dr Ines Ushiro-Lumb	Lead Clinical Microbiologist, OTDT (to present item 5.4.1)

Apologies

Dr Ayesha Ali, Mr John Asher, Mr Frank Dor, Ms Aileen Feeney, Dr David Hopkins, Mr Ben Hume, Prof. Paul Johnson, Dr Tracey Rees, Prof. Jim Shaw, Ms Sadie Von Joel

ACTION**1. Declarations of interest in relation to the agenda**

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

ACTION

2. Minutes of the meeting held on 28th April 2021 – PAG(M)(21)1**2.1 Accuracy**

The minutes of the meeting held on 28th April were confirmed to be a true and accurate record.

2.2 Action Points PAG(AP)(21)2

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

AP2 – Raised at the last meeting was funding issues in terms of patients transferred to other units and how centres would be reimbursed. S Watson advised funding is in the system and the intention is there is sufficient funding within the contracts for transplant services. If there are particular issues within the system of moving patients S Watson would like to be made aware of these issues. The CoxNet programme is funded slightly differently as there is an agreed funding flow.

S Sinha advised that management understand that we are under block contract and if more transplants take place, the unit will not be reimbursed. S Sinha asked if block contracts will remain. S Watson advised the arrangements agreed so far are for the second half of this year and the direction of travel is to remain the same for the remainder of this year. S White raised that if a transplant unit surpasses what they are funded for it could end up being a lot more work and cost. S Watson feels in that case the hospitals will need to look at the funding. S Watson reiterated that she would like to be made aware if there are any issues or barriers units are experiencing with this as the Trust board and Director of Finance have received these instructions from NHS England. J Casey suggested it may worthwhile having some communication from S Watson to the units to clarify this. S Watson to write a letter to clarify financial arrangements for Trust if they offer mutual aid to neighbouring centres.

S Watson

2.3 Matters arising, not separately identified

There were no matters arising.

3 Associate Medical Director's Report

C Callaghan presented an update from NHSBT highlighting that recent data shows that figures are almost back to normal in terms of donation and transplantation activity and the recent living donor kidney sharing scheme matching run noting there are significant challenges expected over wintertime and referred to the winter pressures document. C Callaghan emphasized the fantastic work done by clinical colleagues and donation and transplantation teams around the country.

C Callaghan highlighted a piece of work that is ongoing from Lisa Mumford and colleagues within the stats team, and Rommel Ravanan who are looking at the efficacy of two doses of COVID vaccines in patients on the transplant waiting list and transplant recipients. Those results are not yet ready to be released, but hopefully will have those analysis ready for discussion by the NHSBT team in the coming weeks.

NHSBT is very keen to have Clinical Leads in Organ Utilisation (CLUs) becoming business as usual from 2022 and therefore an application for funding has been submitted.

ACTION

The Organ Utilisation Group (OUG) which is led by Professor Steve Powis which is a group focusing on organ utilization issues in general within England. There have been several site visits, three of which have been pancreas units and the sub groups of the OUG are up and running and a stakeholder engagement forum has taken place. C Callaghan highlighted the difference between the OUG which is external to NHSBT, although NHSBT is the Secretariat and the Organ Utilisation Program (OUP) which is an overarching umbrella term to describe all the issues within NHSBT and all the projects within NHSBT regarding organ utilisation.

The risk and consent tools are up and running for lung and kidney and will be discussed further during today's meeting.

C Callaghan noted that this would be Julia Mackisack's last meeting as Lay Member of PAG and thanked Julia for her wisdom and sense of perspective which has been invaluable and that she will be missed very much. Also noted, is that Prof. John Forsythe is stepping down as Medical Director of NHSBT and Prof. Derek Manas has been appointed as Medical Director. C Callaghan and colleagues noted Prof. Forsythe's leadership which has been outstanding, especially over the very difficult period in the last couple of years and that he has been instrumental in many significant changes within this organization. Members wished him well for his retirement and also congratulated Derek Manas on his appointment.

3.1 OTDT Hub update

J Whitney advised that the Hub are slightly short of staff in Information Services and Hub Operations and are therefore are having to juggle priorities.

3.1.1 HTA B return rates – PAG(21)19

Identified back in April there is a significant backlog of HTA B forms. The majority of those forms sat in four or five units and have been working closely with units to address the backlog.

The chase report process has now been changed and a reminder will now be sent to each HTA B user. The document circulated to the group shows the last 5 years of outstanding forms for pancreas.

S White raised that moving to an electronic form have caused some problems and C Wilson advised that a colleague at Newcastle has been tasked with addressing the backlog.

J Whitney has received some feedback regarding the use of the HTA B forms and logging system and a piece of work will be taking place to obtain user feedback.

3.2 HCV positive donors – PAG(21)20, PAG(21)20a, PAG(21)20b, PAG(21)20c

Dr A Elsharkawy joined the meeting to discuss and answer any questions from the group regarding the use of HCV positive donors in transplantation stating that we now have a mechanism by which organs from hepatitis C positive donors can be transplanted into hepatitis C negative recipients. There is a committee chaired by A Elsharkawy to govern this.

Since opening in February 2019 there have been 90 donors offered, mainly kidneys

utilized which have all been treated and cured.

ACTION

J Casey highlighted that it is likely we will not be able to use these organs for islet isolation due to laboratory governance and this would apply to whole organ only. C Callaghan asked if we are referring to those donors who were HCV, IGG positive or HCV IGG plus NAT positive. A Elsharkawy confirmed if someone is infected with hepatitis C and it is either cleared spontaneously or they are cured, they will for the rest of their life remain IGG positive, therefore having a positive IGG does not tell you whether the donor has got the active virus or not, this can only be confirmed by testing the donors blood and when an offer is being made in the middle of the night this will not be known until further down the line. This program has therefore been set up to enable colleagues to make the assumption and to consent recipients accordingly.

S White asked if the first round of drugs does not work how effective are the second round of drugs and are there any other options after the second round. A Elsharkawy is confident this would not happen as patients are treated early on and have not caused any damage to the liver.

A Sutherland advised that Edinburgh have adjusted their kidney/ pancreas consent forms to include potential consent for Hep C but could not find much data on whether Hep C infects exocrine or endocrine pancreas cells directly. A Elsharkawy is not aware that the virus directly infects the pancreas, the only place outside the liver that it has been reported to infect is possibly some neurons in the brain, however A Elsharkawy is happy to look into this and come back to the group.

A Sutherland is happy to share the patient consent form used in Edinburgh with the group.

A Sutherland

M Drage asked if the risk of hepatocellular carcinoma is going to be a problem with organ recipients. A Elsharkawy advised the risk of hepatocellular carcinoma in Hep C is people with cirrhosis. The current protocol recommends testing your recipient within the first week and again at week two and to test again at week six. D Elker advised that Cardiff have been following these guidelines successfully and the patients are happy medically.

It was acknowledged that four centres have signed up for HCV positive donors for SPK - Cardiff, Edinburgh, Oxford and Cambridge.

4 Governance

4.1 Incidents for review: PAG Clinical Governance Report – PAG(21)21

R Baker advised there has been a number of incidents regarding pancreas damage but there are no particular cases to bring to the attention of PAG.

4.2 Summary of CUSUM monitoring following pancreas transplantation – PAG(21)22

C Counter reported there have not been any pancreas CUSUM signals in the last 6 months and we will be introducing kidney outcome following an SPK using the CUSUM method which will begin in December.

S White asked if it is possible to monitor graft failure for islets in terms of a trigger

using CUSUM or an alternative trigger. C Counter advised that we do not do a CUSUM for islet transplantation mainly due to small numbers at each centre but do report transplant outcomes at the ISG meeting which is generally shown as UK data overall rather than by centre.

ACTION

J Casey feels we are getting to the stage where we should be looking at individual centre islet outcomes. S White would like a mechanism of where this can be looked at in a bit more detail maybe over a period of years. C Counter to discuss mechanisms further.

C Counter

S White highlighted a large variation in outcomes and feels this should be monitored. M Drage raised that access to islet transplantation is very different across the units. For example, Kings place a huge importance on CGM monitoring and pumps and only patients that have got incredibly difficult diabetes only those who fail get transplanted, which is therefore very few and these are the worst patients which might reflect why Kings have got a slightly higher failure rate. S White has requested data on referral patterns and access to transplantation across the country. S Sinha raised it is likely the data will show inequity of access to islet transplantation and would recommend looking into this and addressing this.

C Counter

The question was asked if there are international standards for islet or benchmarks for isolation success rate etc. J Casey has previously tried to look at this but found slight resistance from centres to do so but there may be some justifiable reasons for this. This will be discussed further within the governance structure.

4.3 Pancreas damage

Discussed at previous PAG meetings was the high level of injury to pancreases and a paper showing data in the UK and a published paper by the Netherlands suggests that 15% decline rate on the back table immediately prior to transplantation for surgical injury, meaning this is not a UK specific problem.

I Currie advised pancreas damage will be discussed at the Masterclass which is taking place in December and there will be a session where patterns of injury are discussed in organ retrieval and explaining to people exactly what the patterns of injury are.

There is a desire to set up a pancreas specific Masterclass however setting up any multi cadaver training session in the UK this year and in 2022 is significantly compromised by the lack of body donation during the COVID pandemic. I Currie remains keen to do this and will be upgrading the amount of attention paid to pancreas retrieval at the Masterclass.

Post meeting note: I Currie and S White have scheduled a further meeting outside of PAG to discuss educational aspects.

The organ damage source grading scale has been changed and that will hopefully allow us to see more clinically relevant patterns in the data rather than coarse damage grading that was previously available and the results of that will be disseminated as it comes in.

S White pointed out that the last data presented showed that injury rates for

pancreas is going down.

ACTION

C Callaghan raised that organ imaging has experienced some governance issues, however there is a strong feeling from this group that organ imaging is important but that there is some resistance with Trust policy which has been raised particularly in Edinburgh for the use of personal devices taking images. C Wilson highlighted that the GMC guidance states a clear difference between patient imaging and postmortem imaging and suggested colleagues review that document. C Callaghan shared with the group the link for the NHSBT policy for organ imaging. <https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/24500/mpd1100.pdf>

I Currie encouraged images of the pancreas to be taken particularly if a pancreas is received damaged and for surgeons to ensure a checklist is completed before the pancreas is bagged such as checking the bile ducts and checking the portal vein etc.

4.4 Solid Organ Pancreas Clinical Leads in Utilisation

D Van Dellen provided an update on the Clinical Leads in Utilisation (CLU) scheme.

An initial meeting has taken place which focused on imaging of organs, particularly around trying to assess organs appropriately and to make sure that there is more objective assessment of organs to make sure they are going to the right places. The CLUs are also looking at making sure that organs are utilized in the right area, and that we are able to identify what is appropriate for islets and what is appropriate for solid organ transplantation. Another area of focus is the potential of making an early decision at the time of retrieval particularly on retrieval injuries and trying to improve the quality of retrieval.

The utilisation work group will be looking at trying to reintroduce the decline letters which were suspended over the period of COVID, and the intention is hopefully to be able to get those back into process early next year.

The group has also put together a submission to the organ utilisation group and looked at some of the other areas such as workforce planning and commissioning and have put together thoughts on behalf of the pancreas CLUs.

A Sutherland raised that the monthly centre organ offer report has been received and highlighted only one pancreas that was declined and transplanted as a solid organ elsewhere, but there were around seven declines that Edinburgh had that went for islet transplantation and asked how NHSBT records that data. C Counter clarified that the information is that the organ was offered for whole pancreas transplantation so therefore it was suitable for whole pancreas transplantation but subsequently declined and used for islets and the final outcome of the organ is specified there. C Callaghan asked A Sutherland what he feels is most relevant. A Sutherland noted that if this becomes part of the metric it would appear Edinburgh are declining a lot of pancreases but then with subsequent use for islets which is largely due to a higher BMI.

C Counter highlighted that in terms of the funnel plots, the data is provided separately and looks at those that were transplanted as a whole pancreas when looking at offers declined for whole pancreas.

5 COVID-19
5.1 Overview of COVID

L Mumford presented an overview of COVID which is also presented at the Clinical Team Meetings highlighting an average of 75-80 transplants per week from around 30 donors but at the end of March 2019 those numbers reduced dramatically at the beginning of COVID.

In August 2019 numbers were almost back to pre-pandemic levels however since that time have seen a steady decline leading up to the second and third wave of COVID and by February 2021 were back to fairly low numbers. Since then, we have seen a steady increase in transplants numbers and in the second week of October have seen the highest number ever of transplants performed since COVID started. Last week there were 26 donors, 14 were DBD and 12 were DCD which resulted in 54 transplants.

Monthly transplants at the beginning of May 2019 up to October 2021 showed pancreas numbers were around 20 transplants in month and raised from 12 up to 25. In March this year there were around 18 pancreas transplants performed within month and in July there were 16 pancreas transplants performed but are still around 10 to 12 pancreas transplants performed each month.

The activity broken down by centre for SPK/pancreas and islet transplants shows that Cambridge performed a large number of transplants at the end of 2020, beginning of 2021. Oxford showed slightly lower numbers and Edinburgh showed a dip in activity as well as in Manchester.

New registrations onto the waiting list shows approximately 420 new registrations each month prior to COVID and that more than halved at the beginning of COVID. We are seeing now more registrations within month prior to COVID and are trying to catch up with those referrals but because of COVID cases still rising we are not seeing as much of that build up as predicted and therefore it is likely this will be a delayed response and we will see more delayed registrations in the coming months. In terms of pancreas numbers, we can see slightly more in July and August 2021, around 30 within month.

There have not been any major spikes in deaths and removals but did see in March 2020 higher numbers, around 125 deaths or removals on the list compared to around 100 seen pre COVID. An extra number of deaths were noted in January, April, May and June of this year but deaths have now reduced again to lower numbers, but we are not sure if that is due to a delay in reporting and therefore will continue to monitor this.

The waiting lists shows prior to COVID around 6000 patients active on the waiting list and around 3500 patients suspended and in June and July 2020 where the majority of patients were suspended and since then have seen an increase on those returning to active.

Incidents of SARS-CoV-2 show a high number of transplant patients that have tested positive for COVID but is beginning to level off.

The readily available data published by NHS England shows the number of patients admitted to hospital is starting to reduce. A slight delay in the reporting of deaths was noted therefore at the moment are still seeing increases but expect that to follow the reduction in the number of patients admitted.

The estimated R number for England is above 1 and is particularly high in the South East of England, whereas in Scotland we were seeing a slightly reduced spread. Also monitored is the age distribution of COVID cases where most are happening in the younger age groups or aged 5 to 19, indicating that this is school aged children, and more recently seeing that spread up to the 30 to 50 age group, so this indicates that school age children are then passing that on to their parents. We are still not seeing many cases in the over 70 category, which indicates that the vaccine is still having a protectiveness on those people.

The SPI-M-O median term projections for patients admitted to hospital predict in England that cases will level off and then decrease, in Wales, Edinburgh and Northern Ireland see a decreasing trend.

The number of occupied COVID beds across the transplant units in England shows for example The Royal Free that there are very few empty beds available and are slightly higher number of occupied COVID beds (10%).

S Harper asked if there is any information on how the current peak in cases in transplanted patients is converting into hospital admissions or deaths. L Mumford advised a COVID information paper is available on the website looking at data by organ showing around 15% of patients go on to die. Unfortunately, hospitalization numbers are not available and therefore do not know how many end up in hospital. S Harper asked if that is different from the other peaks, which L Mumford confirmed it is slightly better than other peaks but not much but that a study is taking place and analysis on this will be available soon.

S White asked if those that have died on the waiting list includes islet patients? L Mumford confirmed that data is captured but is reliant on centres reporting that information.

A Sutherland raised a situation of a patient Edinburgh have suspended temporarily as the patient is refusing to be vaccinated and as COVID prevalence is high in Scotland, the team felt that was the best and safest decision for the patient, this has since created a storm on social media. J Casey added at that point, the patient had refused to be tested for COVID on admission. S Sinha feels if a patient is refusing to be tested for COVID, that the patient should not be allowed on the ward due to putting other patients at risk. M Drage has taken the stance that if the patient is aware of all risks, it is their choice to be listed. Oxford has taken the same approach.

5.2 Summary COVID data and pancreas offering – PAG(21)23

The paper was circulated, no comments were received.

5.3 Individual centre report

No specific concerns were raised.

5.4 COVID-19 donors ACTION

Discussion has taken place regarding the use of COVID positive donors for transplantation, the Clinical Team group within NHSBT have discussed this and have come up with 4 different categories;

1. Current (within 72 hrs of donation date) SARS-CoV-2 RNA +ve donor with COVID as main or contributing cause of death YES/NO
2. Current (within 72 hrs of donation date) SARS-CoV-2 RNA +ve donor but dying due to unrelated cause. Not +ve in previous 90 days YES/NO
3. Current (within 72 hrs of donation date) SARS-CoV-2 RNA +ve donor but dying due to unrelated cause. Has been previously +ve YES/NO
- 4a. Current SARS-CoV-2 RNA negative x 2 and dying due to non-COVID causes. Historic +ve <90 days ago YES/NO
- 4b. Current SARS-CoV-2 RNA negative x 2 and dying due to non-COVID causes. Historic +ve >90days ago

Further information on this was presented under item 5.4.1.

5.4.1 SARS-CoV-2 RNA positivity in donors and recipients of solid organ transplantation

I Ushiro-Lumb gave a presentation on SARS-CoV-2 RNA positivity in donors and recipients of solid organ transplantation.

S White had a particular donor that was used for a liver transplant who had a previous historical infection with COVID who tested negative but then within 72 hours of the donation had a weak positive and it was turned down by all other units. The team felt it was unlikely to be due to recurrent infection and proceeded to use one kidney and the liver. S White confirmed the recipients were consented appropriately. S White asked if colleagues have any comments about the use of SARS-CoV-2 RNA positive donors. I Currie made colleagues aware that this is happening already, and any time a donor has any type of suspicion, virologists are activated.

6 Transplant Risk Communication Tool – PAG(21)24

NHSBT have designed with the aid of the Winton Centre an online risk and communication tool which will be organ specific. The lung and kidney risk communication tools have recently gone live and are on the website. The pancreas risk communication tool will be available early in 2022.

C Counter presented the different models to the group and asked members to review the factors found to be significant and approve the final model to be used in the pancreas risk communication tool.

S White asked what donor factors are going to be considered for pancreas. The pancreas model used in the annual report for patient and graft survival includes donor factors: donor age, donor type and donor BMI as well as recipient's waiting time. These will be the factors used for the post-transplant outcome model in the risk communication tool. S White asked for these to be documented in the paper.

C Counter

6.1 Demonstration of kidney tool

L Mumford presented a demonstration of the kidney risk communication tool which

can be found using the link below:

ACTION

<https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/risk-communication-tools/>

7 National Pancreas Offering Scheme – 24 month review – PAG(21)25

The paper presented looks at the first 24 months of the pancreas offering scheme. Over the two years of the new scheme there has been 274 transplants in total, 17 transplants of patients in Tier A of either the kidney or pancreas offering schemes.

There are 278 patients on the waiting list as at 1 September this year: 249 whole and 29 islet patients. An increase from 216 whole and 43 islet patients as at 1 September 2019.

The utilization rates overall in the second year of the scheme saw 50% of DBD pancreases retrieved and transplanted and 40% of DCD pancreases retrieved and transplanted. The outcome of 118 islet isolations overall shows 35% of those were transplanted.

C Counter will look at the number of donors which were referred for islet isolation that were not used for islet transplantation and subsequently discarded for the age group of under 25 yrs and a lower BMI of under 26.

C Counter

S White highlighted the transplant numbers have gone down for the higher matchability scores which could be due to lack of numbers and those difficult to match may not have been on the list.

S Sinha asked if the BMI criteria gets trumped by the priority islet transplant? C Counter clarified if the donor has a BMI of 31 or more then the organ is offered to islet patients preferentially and they are the patients who are on the matching run but if it is declined by all islet centres then it could be offered to whole organ transplantation. Those that have a BMI of under 25 and are aged under 25 are not offered to islet patients but if they only have one of those criteria, they could be offered to islet patients then the other point scores would come into play to where patients are ranked on the matching run. S Sinha asked J Casey if he would be keen to have donors with a BMI of under 26 being offered for islets. J Casey confirmed that presented at the last PAG ISG meeting were donors aged under 25, so 18 to 25 but BMI over 25 showing very good results from isolation and transplantation from those donors. If the age is under 25 and BMI under 25, we practically never get a transplantable isolation, and it has been agreed that combination should pretty much never go to islets. C Counter pointed out that there are also the points in the scheme that push higher BMI donors towards islet patients and lower BMI donors to whole pancreas patients.

S Sinha asked if it was time to consider tweaking the offering scheme. J Casey highlighted that this was raised a few years ago where a group looked at this specifically from the BMI side of things and agreed things would remain as they currently are but that we should keep them under review.

- 8 Pancreas Transplant Activity ACTION**
- 8.1 Pancreas Fast Track Scheme – PAG(21)26**
 C Counter highlighted the last 6 months of the Pancreas Fast Track Scheme which showed 37% of pancreases were offered through the scheme which is lower than the previous two financial years and the year before the introduction of the 8 hour cold ischemic time cut off. There were 18 organs accepted and 11 of those were transplanted.
- A full review of organs offered and transplanted through the fast track scheme since its initial introduction in 2010 will be taking place.
- S White highlighted the number of DCDs (39%) offered through the fast track scheme and of those, three were accepted and none transplanted which may be due to COVID.
- 8.2 Transplant list and transplant activity – PAG(21)27**
 The number of transplants were lower in the last financial year and the waiting list at the end of March 2021 was 172 patients which has increased recently.
- S White highlighted the pancreas population per million and made a request to have something similar for the islet registrations and transplants.
- 8.2.1 Group 2 patients report**
 There have not been any group 2 patients.
- 8.3 Transplant outcome – PAG(21)28**
 C Counter highlighted that there has been a slight improvement in one year pancreas graft survival in the latest cohort compared to the previous cohort, statistically significant for DCD donors but not significant for DBD donors. There are very small numbers of pancreas alone transplants performed so only DBD data is presented this time.
- 9 Pancreas Islet Transplantation**
- 9.1 Report from the PAG Islet Steering Group: 30 September 2021 – PAG(21)29**
 J Casey presented a report from the last PAG Islet Steering Group Meeting (PAG ISG).
- All centres and labs are up and running and not substantially impacted by COVID at the moment.
- Discussed lab governance and the process that is happening and ensuring it is robust and consistent throughout the labs.
- The group looked at donor BMI particularly young donors with higher BMI which some centres have turned down young donors without considering their BMI.
- Members discussed utilization of islet preps where around 40-50% of islet preps which meet release criteria are not transplanted for various reasons and the group discussed ways of increasing the utilization rate and one of the ways is to reduce the minimum release criteria for purity from 50% to 30% and that should allow us to release and use more preps. S White supported this.

ACTION

ISG discussed emerging SIK data and from the small numbers that we have outcome data for which seems good so far, that will continue to be monitored.

Members of ISG felt the pancreas forum held annually moving forward should be made into a pancreas and islet forum.

S White requested clarification about third transplants and highlighted some issues around funding. J Casey recalled that centres would check and confirm their funding status for that as services in England are commissioned to provide up to two islet transplants per patient and if centres wish to give a patient a third graft as part of their primary treatment that may become a funding issue. J Casey also raised that members of ISG are largely commissioned to reverse hypoglycemic unawareness however there are substantial benefits to patients coming off insulin all together. A Govias-Smith asked if there is a projection for the number of patients requiring third transplants. It is difficult to know how many patients would require this, but it would be an increase in the number of patients requiring three grafts. S White suggested looking at this to provide accurate figures. J Casey added that the aim of this is to use the islets that the labs are already preparing and this will not require more isolations.

**J Casey &
S White**

S White is hoping to do a national review of both pancreas and islet transplantation during his tenure as PAG chair.

S Sinha would like defined criteria which will then be used on a select group of patients that require a third graft but would like some reassurance that having a third transplant would not impact a patient having a first or priority transplant.

9.2 Islet transplant activity and outcome – PAG(21)30

C Counter presented one year graft survival for first routine islet transplant alone which is 87% and five year graft survival is 51% and there is a significant difference for five year graft survival in those patients receiving a routine and priority top up graft compared with those receiving a routine only graft, 60% compared to 34%, respectively.

At one, three and five years improved rates are seen in the annual rate of severe hypos, median HbA1C and insulin dose required compared with at transplant.

9.3 Islet isolation outcomes – PAG(21)31

The paper was circulated, and S White asked the reasons why in the Appendix section used for isolations there were 30 isolations (94%) and 7 where the isolations were not completed. S White feels if you start an isolation that should still be recorded as a failed isolation.

C Counter

C Counter highlighted those are organs that were offered to an islet patient first and all the organs that are used for isolations are shown in the tables by isolation facility. For example, in table 1 in 2020/21 there were 42 pancreases arrived at the isolation facility and 40 of those show isolations started and at the end of the table shows the number transplanted overall and the percentage of isolations started. S Sinha requested further clarification on this information. C Counter advised the data in Figure 1 is split into those who met release criteria and those that did not

and whether or not they were subsequently transplanted. The release criteria referred to is those that met 200,000 islet yield, over 50% purity and 70% viability. There are cases where preps are transplanted even if they did not meet those criteria however they were suitable for that patient particularly an SIK where the patient has already had a kidney and they can have the islets even if it is not the ideal yield. The final column in Table 1 shows all transplants from the isolations that started. Therefore, this is the overall utilization rate, but as pointed out, for Oxford two met the release criteria, but neither of those were transplanted which is why the next column is missing, but one transplant did happen from isolations that were started.

ACTION

J Casey suggested there is an aspect of lab policy that perhaps needs addressing in this as it does not make sense to start an isolation and then not finish as that rarely happens in Edinburgh. S White feels it would be useful to know how centres know when to stop an isolation. This will be discussed further at the next PAG ISG meeting.

J Casey

Stephen Hughes has retired, and a new Islet Lab Representative will need appointing to attend the PAG meetings.

J Casey /
S White

10 Standard Listing Criteria

10.1 Summary data – PAG(21)32

The form return rates have been good and of those with forms returned all patients have met the criteria or were approved by the exemption process.

C Counter drew centres attention to point 6 which states if any patients are transferred between centres or between transplant lists it is essential, to ensure the accrued waiting time is transferred correctly to the new registration, that OTDT Information Services are contacted by telephone and that conversation is followed up by confirmation in writing to ODTRegistrationTeamManagers@nhsbt.nhs.uk.

All centres

10.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(21)33

The exemption request and outcome of previous applications to the appeals panel was circulated to the group.

11 Any Other Business

The next Pancreas Forum will be hosted face to face by Edinburgh in January 2022.

A Sutherland asked what transplant units are doing when a health care worker is exposed to COVID. Edinburgh still have a 10 day isolation policy even if double vaccinated. A McLean advised staff at Hammersmith would not be given any exemption because of the contact with immunosuppressed patients. S Sinha advised Oxford's process is if you have a household COVID contact you must self isolate but if you are pinged on the APP a PCR test is required.

Members were notified that there is no IPITA meeting taking place in January but will be held in June or July in Norway which will include an islet isolation workshop.

- | 12 | FOR INFORMATION ONLY | ACTION |
|------|---|---------------|
| 12.1 | Summary from Statistics & Clinical Studies – PAG(21)34
The summary from statistics & clinical studies was circulated and no comments were received. | |
| 12.2 | Transplant activity report: September 2021 – PAG(21)35
The transplant activity was circulated, and no comments were received. | |
| 12.3 | Current and Proposed Clinical Research Items – PAG(21)36
The current and proposed clinical research items paper was circulated and no comments were received. | |
| 12.4 | QUOD – PAG(21)37
The QUOD report was circulated, and no comments were received. | |
| 12.5 | Winter Pressures – PAG(21)38
The winter pressures document was circulated, and no comments were received. | |
| 13 | Date of Next Meeting: TBA | |

November 2021