NHS
Blood and Transplant

PAG(M)(24)02
PAGISG(M)(24)02

NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

PANCREAS ADVISORY GROUP (PAG) & PAG-ISLET STEERING GROUP
THURSDAY 28th NOVEMBER 2024
1000-1600

THE WESLEY HOTEL AND CONFERENCE VENUE, LONDON, NW1 2EZ

Steven White	**PAG Chair**
John Casey	**PAG-ISG Chair**
Argiris Asderakis	Cardiff Transplant Centre Representative
Chris Callaghan	NHSBT Associate Medical Director, Organ Utilisation
Yee Cheah	KCH Transplant Centre Representative
Claire Counter	NHSBT Senior Statistician
Gail Defries	Cambridge Pancreas Transplant Coordinator
David van Dellen	Manchester Representative
Kirsty Duncan	Edinburgh Islet Cell Transplant Coordinator
Lora Irvine	SNBTS Islet Cell Production Manager
Paul Johnson	Oxford Director Islet Isolation and Transplant Programmes
Derek Manas	NHSBT Medical Director OTDT
Zia Moinuddin	Manchester Transplant Centre Representative
Anand Muthusamy	Imperial College Transplant Centre Representative
Edward Sharples	Oxford Transplant Centre Representative
James Shaw	UK Islet Transplant Consortium
Tahmid Siddique	KCH Laboratory Quality Manager
Lewis Simmonds	NHSBT Statistician, Statistics and Clinical Research
Sanjay Sinha	Oxford Transplant Centre Representative
Rebecca Spiers	Oxford Islet Isolation Laboratory and Facilities Manager
Andrew Sutherland	Edinburgh Transplant Centre Representative
Rhiannon Wallis	NHSBT Statistician, Statistics and Clinical Research
Julie Whitney	NHSBT Head of Service Delivery – ODT Hub Operations
Colin Wilson	Newcastle Transplant Centre Representative

In Attendance	
Chloe Bainbridge	NHSBT Advisory Group Administration Officer
Tanya MacHale	NHSBT Business Support Manager
Miranda Coles	KCH Pancreas Islets Recipient Transplant Coordinator
Sophie Cullen	NHSBT Assistant Quality Assurance Manager ODT

Apologies
Ian Currie, Doruk Elker, Aileen Feeney, Hussein Khambalia, Alistair Lumb, Rommel Ravanan, Sarah Jane Robinson, Miranda Rosenthal, Laura Stamp, Gareth Walker, Sarah Watson

1.	**Declarations of interest in relation to Agenda**
	Please note that it is the policy of NHSBT to publish all papers on the website unless the papers include patient identifiable information, preliminary or unconfirmed data, confidential and commercial information or will preclude publication in a peer-reviewed professional journal. Authors of such papers should indicate whether their paper falls into these categories. There were no declarations of interest in relation to today's Agenda.
2	**Minutes**
2.1	**Accuracy**
	The Minutes of the PAG Meeting held on 9 May 2024 and the PAGISG Meeting held on 18 April 2024 were accepted.
2.2	**Action Points**
	The following Action Points were discussed: S White updated PAG Action Points: - Islet Summit D Manas to discuss as part of his MD report. - HTK update from D Manas, more cases being added to the data will report back once complete (Abstract submitted to ESOT) - Small paediatric donors - consensus difficult to reconfigure, consideration to be offered for Pancreas, numbers low 1-2 per year, agreement not to pursue. - ERAS, proposed members of the group will be contacted to join a working group relating to pancreas transplantation, over the next few months. - SCORE, Pancreas damage, Organ Utilisation, DCD Working Group and NRP on agenda for today. J Casey updated PAG Islet Action Points: - All to be covered on agenda for today.
2.3	**Matters Arising, not separately identified**
	NRP Outcomes – S White updated our NRP data for Pancreas graft survival, new data suggests an improving trend for graft survival for Pancreas and Kidneys, but as yet the numbers do not reach statistical significance. Suggestion from S Sinha that obtaining the Liver data can help in making a decision to accept the Pancreas, especially if the data is showing poor results. The NRP Passport usually contains all the relevant information and J Whitney confirmed that the passport is available upon request, however it will be available on TransplantPath in the next release. **Action: S Sinha to contact Marius Berman (RAG chair) for it to be discussed through RAG, copying in Richard Baker (AMD Clinical Governance).**
3	**Medical Director of OTDT's Report**
	D Manas gave an update:

	- Rommel Ravanan has completed 2nd term as KAG chair. Gareth Jones has been appointed into the role and will commence as KAG chair 1st December 2024. Gareth Jones will continue in National Collaborative lead role. - Venkat Rajamiyer is leaving his CTAG Heart chair role due to him securing a position in the US. Aaron Ranasinghe has been appointed as the CTAG Heart chair and will commence in post 1st December 2024. - David Briggs who was covering when Tracey Rees left for H&I support is retiring, appointment will start in February/March 2025, all AG's will have H&I support. NHSBT will manage H&I. - Diana Garcia Saez has stood down from her National Clinical Lead in Cardiothoracic Organ Utilisation post. Vicky Gerovasili has agreed to undertake the role for an interim period. C Callaghan updated - with Vicky Gerovasili stepping up to the National Clinical Lead for Cardiothoracic Organ Utilisation, Nick Innston will be stepping up to the National Clinical Lead for Abdominal Organ Utilisation. - Environmental Sustainability Group has expanded with Matt Wellberry-Smith chairing the group ESiT (Environmental Sustainability in Transplantation). The group will interact with all the national groups. - R&D Steering Committee, formally RINTAG, has within it an Operational Feasibility Group that considers study applications. The R&D Steering Group looks at strategy in line with NHSBT's Strategy. - Finance - DCD Heart and CLU funding still not secure for 2025. They have been included in the baseline funding for the spending review, including funding for NRP. If agreed this will allow for funding for these areas for 5 years. - Histopathology interim solution in place with funding identified. Machines for Pithia are currently being updated, funding for Pathology has been agreed by NHS England. By April 2025 there will be a National Pathology Service. - OUG, ISOU are the subgroup formed within the implementation steering groups, there were 5 sub committees, Trust Engagement is almost ready with recommendations. ISOU groups coming to an end, recommendations due within next month. Some already out, H&I, ARC recommendation draft is out, Xeno group is out. If all recommendations are agreed the amount of money required is astronomical. - ARCS bid submitted to DHSC as part of the spending review, alongside the ISOU group recommendations, £39M over 5 years likely to receive notification of decision by April 2025. - Living Donor Liver Proctor Team model started in July, 12 referrals 2 transplants to date. - ERAS programme started in Renal Transplantation, now opened up to all other organs. - SCORE – J Whitney will update in today's meeting. - Consent rate down at 60%, summit next year to look at why the consent rate is so low and how to engage with the CLOD and donation community. With no changes donor numbers next year will be 600 less than this year. - Kings Islet lab service being down had a huge impact on transplantation, summit 10th December 2024 looking islet lab resources, what should it look like in next 5 years. - Diagnosis of death new guidance goes live Jan 2025. https://www.aomrc.org.uk/publication/2025-code-of-practice-for-the-diagnosis-and-confirmation-of-death/ - OUG recommendation to set up collaboratives across all organs, Renal have a meeting on the 9th December 2024, Liver working together, Pancreas not approached yet.
3.1	**SCORE**

	Paper shared - SCORE **PAG(24)18** J Whitney shared this paper – The programme has been running for approx. 12 months. Donation workstream looking at organ offering, organ screening and a predictability tool for DCD - work ongoing. Looked at daytime offering solutions, proposals within the paper have gone to the board for approval. Recommending daytime offering solutions, CT offers in 2 hours timeframe, all offers simultaneously, sent at 08:00 all responses by 10:00, admin time for hub to allocate organs, by 10:30 it will be known if a CT team is required, who will need planes etc. Next is Liver and Bowel offers between 10:30 – 12:30, same time scales as CT. TA's offered Pancreas and Kidneys in the morning, allows for cross matching and tissue typing to be done in the morning therefore processing in the day. Then Renal and Pancreas offering in 3 rounds. By lunchtime NORS will know if they are likely to go out. Logistics then arranged in the afternoon. NORS Workstream recommends a planned arrival window, 20:00 – 03:00, this provides reduced travel time, modelling 1 retrieval per team per night. Super Urgent Livers will continue to be offered and transplanted immediately. Offers will be received during the day, organs arriving during the day, implanting during the day. Hoping to move to a digital offering and decline system. Provides donor families with certainty for donation process. Timeline 18 months, currently undergoing high level engagement as funding not yet agreed; board has agreed some finding if full funding not agreed. Dan Harvey is working with Clinical Leads Organ Donation (CLOD) to consider level 4 hospitals; they are more willing to come in as donation infrequent. Clinical input into the hub will assist with decision making.
4.	**Governance (PAG & PAGISG)**
4.1	**Incidents for Review: PAG Clinical Governance Report**
	R Baker provided paper PAG Clinical Governance Report **PAG (24)16.** S Sinha informed all that the Governance team are now known as the Patient Safety Team. S Sinha thanked the group for putting in incident forms. CUSUM damage letters are being considered as a possible action. C Callaghan informed us that a recent Pancreas where the CBD was left untied was transplanted and all went well. A Sutherland enquired as to how this type of case was to be reported as the pancreas was not damaged, and some centres may not have used it. S Sinha confirm that the incident would be flagged as not classed as severe. The NORS team would be asked why there was damage, regardless of organ usage. It was noted that HTA communication was sparse, information was not going back to the clinical lead or HTA lead. Suggestion was to provide a group email for the information to be send to; D Manas reminded the group it's the clinical leads responsibility to ensure that the correct contact details have been provided. **Action: Centres to update their email lists.** J Shaw queried if S Sinha was aware of a pancreas being sacrificed for a liver vessel as it's not being captured, if the group notify the Patient Safety team a record should be kept which could be fed back to LAG. Retrieval teams to be reminded that there are updated documents at the Retrieval Master Class. **Action: S White requested that Sandra Campbell (Newcastle coordinator) submit an incident form. D Manas informed that the policy is clear, and S White agreed to send a reminder email to the retrieval teams.**

4.2	**Summary of CUSUM Monitoring following Pancreas Transplantation**
	Paper shared – Pancreas CUSUM report **PAG(24)19** No signals for transplant outcomes noted.
4.3	**Pancreas Damage**
	S White explained that a change to the current grading system would be difficult to implement, the HTA form is a standard form, there is a free text box that can be used, therefore the decision was to stick to the current grading system for all organs. J Whitney confirmed that there is a manual check for the free text box for CUSUM monitoring of retrieval and the grading was for utilisation reasons. S White informed that the required information would be available from free text box and grading could take place at a later stage.
4.4	**Solid Organ & Islet Utilisation**
	D Van Dellen highlighted that the high-quality review scheme started pre-covid, then paused361 cases since 2021, 12% down to 8% since then, themes to be reviewed at local level, letter has had some benefit. Other issues include funding uncertainty, local CLU meetings, more collaboratives and paediatric outcomes. For high quality decline letters there should be consideration to extend the scheme, some felt the letters had a benefit, to consider using for islet as well - No objections noted. Parameters are to be considered to trigger the letter. Letters are screened before sending. **Action: S White suggested a formal paper to be presented at PAG as lots of detail on this subject.** There have been 100 declines due to beds, questions raised if a letter required about this. S Sinha stated that bed space for this is not on the agenda of the senior teams in Trust. D Manas's letter about exec representation regarding utilisation has made improvements this year. S Sinha confirmed happy for letter to be sent. **Action: Girth measurements - those successful <100, female donors better, less fatty – paper suggested.**
4.5	**High Quality Organ Offer Declines**
	Covered in section 4.4.
4.6	**DCD Working Group**
	A Sutherland – Outcomes were excellent, but can we improve better equity of access, Pancreas offered to closest centre to reduce ischemic times, consider minor changes that don't affect ischemic times or sustainability, offering system would be greatly affected by IT, offer to 3 closest centres extra points, proposal to wider stakeholders - should extra points be given to closest 3 centres. NI donors no extra points offered. 10,000 points closest, 5000 to next 2 centres – options considered with less IT changes, CC will run some simulations to see what difference it makes, consider moving towards same system as DBD. This may impact on islets due to location to isolation lab (150 mins from) if points changed. **Action: A Sutherland will email members if they wish to join the working group.**

4.7	**Terms of Reference: CUSUM**
	D Manas letters have been written, outcomes from retrieval, some tweaks made, CUSUM on donors not the organs, face to face meeting if repeatedly triggering.
5.	**Pancreas Transplant Activity**
5.1	**Fast Track Scheme**
	Paper shared – Fast Track Scheme **PAG(24)20** L Simmonds shared paper – data from last 5 years, similar results between DBD & DCD, lots of declines due to age and size.
5.2 5.2.1	**Transplant List & Transplant Activity Group 2 Patients Report**
	Paper shared – Transplant List & Transplant Activity **PAG(24)21** C Counter shared paper – Figure 2 is new, waiting lists are increasing. There have been no Group 2 or non-UK Group 1 patients listed or transplanted.
5.3	**Transplant Outcomes**
	Paper shared – Transplant Outcomes **PAG(24)22** C Counter shared paper.
6.	**Islet Transplantation**
6.1	**Update from each Centre**
	Kings – islet isolation unit been closed for 1 year, reopened, received 1-2 patients a month, nothing yet transplanted, 5 patients discussed for listing, taking part in studies. Royal Free – no activity, no consultant lead, transfer patients to Kings, consider being removed by commissioners. Oxford – patients on waiting list being worked up, SIK patients on list, hypo awareness, getting referrals, taking part in studies. Manchester – steady referrals, 23 patients on waiting list 1/3 suspended, SIK waiting lists, 2 islets, 4 SIK's last year. Newcastle – 2 patients on waiting list, some suspended short-term reasons, 1 transplant, some education done with other centres. Regional online MDT set up to capture hypo glycaemia, taking part in studies. Edinburgh – 29 patients listed 14 for transplant only, 3 are priority, all long waiters, 6 SIK's in for assessment at the moment, 3 transplants completed in this financial year, 2 were 3rd transplants and 1 a 4th transplant.
6.2	**Islet Transplant Activity & Outcome**
	Paper shared – Islet Transplant Activity & Outcome **PAGISG(24)1**

	L Simmonds shared paper – Consideration to be given to how islet transplantation is reviewed. Discussion around high yield numbers and when to transplant. **Action: D Manas requested that Bristol be removed from paper and consider removing Royal Free.**
6.3	**Auto Transplant Update/Data Collection**
	S White updated that the programme is up and running and discussed if for Allo's and Auto's to be merged. Meetings have taken place with NHS England about how to record the data, a database has been created, clinical data to be held in clinical database led by Newcastle with each centre contributing to it. Islet isolation data to be held in the ISG group. A discussion regarding whether the data can be held by NHSBT. J Whitney suggested that Governance needs to be considered as it's data on a group of patients that NHSBT wouldn't normally keep. J Whitney also highlighted that IT would need to be involved in this change which may take some time. **Action: A meeting is to be arranged to discuss further with IT and CC and JW**
6.4	**Age Limit for NRP DCD Pancreases**
	Previously agreed cut off for DCD pancreas for islets is 50, question if it could be increased to 60, J Whitney wouldn't know at offer if NRP being used, all offers would need to increase, may have more declines, consent process would need to change, could raise to 55 as cut off for whole pancreas is <56 years, all agreed. **Action: J Whitney and C Counter to coordinate the implementation of increase in age criteria for DCD islet to 55 years (i.e. <56 years) as for whole pancreas.**
6.5	**Research Organs**
	R Wallis shared – Research Organs **PAGISG(24)2**
7.	**Islet Isolation**
7.1	**Isolation Statistics**
	L Simmonds shared **PAGISG(24)3a** R Spiers fed back that it would be useful for the data to display Islet transplants alone and SIK alone as currently looks like isolation preparations are being made from those that don't meet the release criteria. **Action: To create data separating the types of transplants for future meetings. (LS)**
7.1.1	**Impact of limited isolation laboratory availability**
	L Simmonds shared **PAGISG(24)3a** T Saddique gave a further update that KCH have performed 7 allogeneic and 3 autologous donations since the lab re-opened in July 2024. There are no further inspections planned because of the previous closure.

	HTA inspection was July 2024, they were happy with response made by the laboratory to the issues. Once validation and studies were complete, KCH submitted their findings to HTA which were satisfied with. **Action: Update graphs for Islet Transplant Summit to see the change in trend for laboratory availability (LS)** K Duncan fed back that if laboratories are not isolating that this is not always fed back to the Hub Operations department.
7.2	**Report of Islet Isolation Sub-Group Meeting**
	L Irvine fed back that the group met Monday 25th November 2024 Consumables • Most centres have experienced issues with the COBE bags, which have since been issued with a safety notification and the rotation seals of the bags. All centres are now aware of the checks required to ensure the bags are meeting the quality standard. The particular batch is no longer in use in the UK but there is a need to ensure the checks are performed. • The bags from BioRep are continually faulty, complaints have been raised due to the bags leaking, issues with probes not fitting among many other issues. The group are waiting on a report. Everyone has been good at raising complaints but unfortunately it has not been resolved. • Supplies are not reliable; it has not been an issue in Edinburgh as they can re-use but perhaps an issue elsewhere. Sent out communications to all that there was an issue for their assay. There is still no identifiable root cause. Edinburgh have purchased the new platform to support the service but there is a need to perform validation before the assay is used. • Prism replacement still ongoing. Edinburgh – the current system is excluding larger islets which has resulted in lower yields and clogging of the system. Edinburgh are looking to accept organs in January 2024 to perform a proof of principle following changes to the process to allow larger islets. SNBTS have approved of the non-GMP programme but there is work for a GMP approved programme in place. HTA – Oxford, Kings and Manchester have had their inspections. Edinburgh is due inspection on 10th December 2024. Keen to be more collaborative to learn from each other and visit each other's labs. For example, imports from different centres are dealt with differently between labs which is a concern with the regulator. The group could then discuss how to standardise based on what the clinician's requirements are. P Johnson reiterated that islet processing involves isolation then purification, purification is currently an under-threat process worldwide now. J Shaw gave assurance there has not been any issues with infection relating to transport at his centre. There were concerns of delays related to differences to viability practices. P Johnson offered that Gram stain viability in lab is favourable over a recount so that there's no need to delay transplantations.

	A Sutherland turned down islets recently due to delays that could have been related to delay related to viability testing at another lab when being sent from another lab before getting to the centre.
7.3	**UK Isolation Provision / Islet Summit**
	Discussed during Medical Director's report.
7.4	**SCORE & Isolation Laboratories**
	L Irvine provided an update. Recent meeting with Richard Battle. H&I testing – comes through the clinical side, islet labs are not impacted by this. If retrieval of organs overnight, pancreases are arriving in the day when there is more support. A more robust/knowledgeable team is a positive. In Edinburgh they are a shared facility where their processes involve more competition for clean rooms so this may be an issue if more organs are received in the daytime. J Casey offered the perspective that this is similar to the issues for access for theatres. P Johnson suggested that everything needs to be times well to enable time for radiology.
8.	**NPOS Annual Review**
	C Counter gave an overview of the paper. **Action: D Manas to investigate work required to look at referral patterns between centres due to there being apparent differences in practices between centres which can result in patient inequity for access to transplantation.**
9.	**Standard Listing Criteria**
9.1	**Summary Data**
	R Wallis presented **PAGISG(24)5** to the group. Potential for a change to the standard form to include details such as 'severe hypos'. Indications have been in place for the last 15 years and J Casey supports change of the policy. C Counter suggested that this may be taken through exemptions initially. J Casey suggested they document what the criteria ought to be as a workaround of the IT issues. Islet transplant policy changes should also align with pancreas policy (M Drage). **Action: P Johnson and J Shaw to bring any patients forward to exemption committee first and then go through PAG/PAGISG for next Spring.** **Action: to discuss policy change at next PAG/PAGISG in 2025**
9.2	**Pancreas Transplant Listing Exemption Requests & Outcome of previous applications to Appeals Panel.**
	There were no recent appeals.

10.	**ERAS Pancreas Transplantation**
11.	**Recipient Coordinator Update**
	V Prior stated that they need to check Rubella status, but it is not required for kidney which leads to delays especially if they are transferring from SPK list to SIK list. V Prior wished to check the reasoning behind the testing not applying to the kidney. **Action: Follow up with Ines Ushiro-Lumb to query why there is a requirement for Rubella testing and subsequent vaccination for islet donors. V Prior to email Ines and copy in S White.**
12.	**Report from UKITC and UKITC Research Steering Group**
	J Shaw suggested time to reconvene National plans for beta cell replacement and building a clinical network to ensure more of a future for allotransplants. J Shaw extended an invitation for anyone to join to formulate a proposal. QUOD- number of organs available is going well, good clinical information provided by NHSBT.
13.	**Any Other Business**
	No AOB declared. S White thanked everybody at the meeting for their attendance at the new combined meeting and thanked everyone for its success.