

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

**THE THIRTY FIFTH MEETING OF THE PANCREAS ADVISORY GROUP
AT 11:00AM ON TUESDAY 5th NOVEMBER 2019
AT ODT, FOX DEN ROAD, STOKE GIFFORD, BRISTOL BS34 8RR**

PRESENT:

Mr John Casey

Dr Ayesha Ali
Dr Arthi Anand
Mr Argiris Asderakis
Mrs Hazel Bentall
Mrs Claire Counter
Mr Ian Currie
Mrs Kirsty Duncan
Ms Susan Hannah
Mr Simon Harper
Dr Stephen Hughes
Prof. Paul Johnson
Mrs Julia Mackisack
Ms Katie Morley
Mr Anand Muthusamy
Mr Simon Northover
Dr Tracey Rees
Mr Sanjay Sinha
Mr Andrew Sutherland
Ms Sarah Watson
Prof. Steven White
Mrs Julie Whitney

Chair

NHS England
BSHI Representative
Cardiff Transplant Centre
Lay Member Representative
Statistics & Clinical Studies, NHSBT
UK Clinical Lead Organ Retrieval
Recipient Coordinator Representative
Regional Manager (deputy)
Cambridge Transplant Centre
Islet Laboratory Representative
Pancreas Islet Steering Group Chair
Lay Member Representative
Lead Nurse Recipient Co-ordination
WLRTC & Hammersmith
Recipient Coordinator Representative
Scientific Advisor – ODT
Oxford Transplant Centre
Edinburgh Transplant Centre
NHS England
Newcastle Transplant Centre
Head of Service Delivery – ODT

IN ATTENDANCE:

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

Apologies

Mr John Asher, Mr Titus Augustine, Dr Richard Baker, Mr Chris Callaghan, Dr Pratik Choudhary, Mr Martin Drage, Prof. John Forsythe, Mr Nicholas Inston, Prof. Nizam Mamode, Dr Rommel Ramanan, Prof. James Shaw

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 1 May 2019– PAG(M)(19)1

- 2.1 Accuracy**
The minutes of the meeting held on 1 May 2019 were confirmed to be a true and accurate record of that meeting.

2.2 Action Points PAG(AP)(19)2

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

AP1 – Transplant Centre Profiles – It has been decided that a national version of a transplant centre profile as a summary infographic will be developed for each organ which will be published in the near future. A survey will be available for feedback regarding the profiles.

[Post meeting note: The summary infographics and survey are now available on the ODT website [here](#).]

AP 2 – Lessons learned document – A Asderakis shared the lessons learned from the CUSUM trigger which was raised at the previous meeting. From this review, a recommendation was made to implement joint MDT meetings between Manchester and Cardiff which Cardiff have found useful, however these have been difficult to organise due to the centres schedules, therefore it may not be possible for the joint MDTs to continue. J Casey stated the recommendation made was as a long-term solution. A Asderakis and J Casey will discuss this further outside of the meeting.

The suggestion was made that collaborative working should be made a priority, to discuss and improve issues such as sustainability, access to transplantation and equity of access to transplantation. J Casey felt this should be discussed as part of the sustainability working group.

S White

West London Renal Transplant Centre (WLRTC) and Hammersmith Hospital have experienced issues with the level of anesthetist support for pancreas transplantation. Members discussed whether a minimal level of anesthetic cover should be proposed although it was acknowledged the majority of centres do not experience this problem.

J Casey requested A Muthusamy formalise the issue and include whether there have been specific adverse events that relate to pancreas for PAG to provide recommendations.

A Muthusamy

AP3 – Pancreas Offer Review Schemes – A concern was raised at the last PAG meeting regarding the outcome of kidneys, accepted with the pancreas for an SPK transplant, but subsequently offered on after the pancreas was declined on inspection. C Counter presented a paper, submitted to the Kidney Advisory Group (KAG) in June, which showed data on deceased donors from the UK Transplant Registry over 5 years. The outcome of the kidneys initially offered as an SPK and subsequently transplanted as a kidney alone were compared to the outcome of the other kidney transplanted. A proportion of these data could not be analysed due to not knowing which kidney was offered with the pancreas. In summary, the median cold ischemic time (CIT) time for kidneys offered with the pancreas was statistically significantly longer ($p < 0.0001$) than for the kidney not offered with the pancreas, 19.3 hours and 12.8 hours, respectively. There was no evidence that three-year kidney graft survival outcomes were any different between the two kidneys. PAG members agreed to continue assessing the pancreas as soon as it

arrives to avoid delay for SPK offers to help reduce the CIT for the kidney. J Casey added that the introduction of the images of the pancreas may assist with making a decision earlier. It was asked why it was not known which kidney was offered with the pancreas. C Counter advised it is because the specific kidney isn't recorded until an outcome of the kidney is available.

Members of PAG discussed ways to reduce the CIT time for the kidneys offered with the pancreas and suggested centres consider a provisional offer to a kidney patient. The concern was raised that this would increase the number of offers made, therefore members proposed identifying a kidney recipient who is in the closest proximity of a pancreas centre. J Casey will take the suggestion of simultaneous national and regional offering for these kidneys to KAG.

J Casey

AP 5 – J Casey encouraged members to feedback their comments on the use of the organ quality eForm to J Asher's nhs.net email address.

All Members

AP 10 – A Sutherland has received the DUK information sheet and informed members that he and M Rutter are working together on a SIK information sheet.

2.3 Matters arising, not separately identified

3 ASSOCIATE MEDICAL DIRECTOR'S REPORT

3.1 Developments in NHSBT

J Casey provided an update below on behalf of J Forsythe on the current developments within NHSBT.

3.1.1 Hepatitis C positive donors to Hepatitis C negative recipients

The funding for the antiviral treatment to enable Hepatitis C positive organs to be transplanted into Hepatitis C negative recipients has been secured across England, Scotland and Wales. J Forsythe has written to centres informing them that if they wish to receive such organ offers, centres must complete the paperwork which must be returned to Prof David Mutimer and NHSBT. J Casey reiterated centres will only receive the organ offers if they opt-in to the positive virology fast track scheme. S Watson advised the funding for the antivirals will be available through standard commissioners.

All Centres

3.1.2 Opt Out update – PAG(19)24

The Opt out legislation in England is progressing with an aim of implementation in Spring 2020.

3.1.3 ODT Strategy update – PAG(19)25

J Whitney presented and update on the ODT strategy.

There have been 9 open events across the UK to engage with stakeholders. The outcomes from the events will go towards producing a draft strategy which will be circulated in January.

3.1.4 Sustainability

J Forsythe has contacted units across all organs regarding sustainability issues which NHSBT are investigating.

3.1.5 Lack of resources

Highlighted at the recent Pancreas Forum was the process in place for kidney transplantation regarding reporting declines due to lack of resources which J Casey is keen to replicate for pancreas transplantation as this is a significant issue. J Casey advised S White is chairing a group which are looking into lack of resources for pancreas transplantation.

A lung summit took place last week which was very successful where multiple recommendations were made.

3.2 Governance issues**3.2.1 Non-compliance with allocation**

There has been no non-compliance with allocation.

3.2.2 Incidents for review: PAG Clinical Governance Report – PAG(19)26

The Clinical Governance Report was received which reports that all three incidents were regarding the failure of the gastric staple line.

I Currie advised that Jeanette Foley investigated previous incidents with a similar trend. This highlighted that it is standard practice to use a blue staple cartridge during retrieval as this is designed for small bowel and colon, however it has been raised that during retrieval, the tissue becomes thicker and this can lead to failure of the staple line when a blue staple is utilised as it is not designed to staple thick tissue. It has since been agreed to use a green staple for thick tissue.

Members of the group felt to avoid confusion it would be more appropriate to use the green staple which is ideal for thicker tissue for both ends of the staple line. I Currie will feed this back to the NORS teams.

I Currie**3.2.3 Summary of CUSUM monitoring following pancreas transplantation****– PAG(19)27**

There were no CUSUM signals in the last 6 months.

3.2.4 Organ Damage – PAG(19)28

This paper looks at the level of damage reported for organs intended for whole pancreas transplantation from the information provided on HTA B form.

Between 1 April 2018 and 31 March 2019, 325 donor pancreases were accepted and overall 50 had any grade of surgical damage reported, 28 of which were reported as severe damage.

C Counter reminded centres who receive pancreases with surgical damage to raise an incident through the ODT clinical website for further investigation.

All Centres

It was suggested that the level of damage could be as a result of lack of training in pancreas retrieval. I Currie advised that there are a number of initiatives taking place to address this such as the NORS report which highlights when a retrieval team's damage rate is higher than the national distribution, and one centre has flagged up within that report for pancreas damage. I Currie proposed developing a pancreas retrieval workshop.

**I Currie /
J Casey**

S Sinha added that it is also the responsibility of the implanting surgeon to ensure they are not disregarding organs for reasons such as no flush through the vein. Members agreed and would like this discussed at the next Pancreas Forum.

J Casey

3.2.5 Offer review scheme for higher quality pancreas donors – PAG(19)45

J Casey provided a summary of the letters which have been sent to centres including reasons of declining and unit responses on behalf of C Callaghan.

Peter Friend from Oxford has discussed the number of organs declined due to lack of access to ICU beds with J Forsythe and J Casey to help address this issue.

S White asked who receives the letters for Newcastle and was advised that the information is sent to the Clinical Director of the centre.

3.2.6 Pancreas Imaging Pilot

The pancreas imaging pilot started in July 2019 where retrieval teams have a protocol to take six images of the pancreas on retrieval which are available for the recipient surgeon who has accepted the organ. Of the 109 pancreas donors between 23 July and 23 October 2019 only 16 images have been recorded which is lower than expected.

S Hannah advised that the Regional Managers have circulated a reminder to SNODs to encourage this. I Currie suggested circulating a joint letter reminding units to photograph the organ on retrieval and send the images to ODT Hub Operations. It is anticipated the number of images will increase by the next meeting.

I Currie /
J Casey

The feedback from the units who have received images have found them useful.

J Casey encouraged PAG to view the images if available before the organ leaves the retrieval centre.

3.2.7 Retrieving vessels for pancreas

J Casey raised this item to clarify the retrieval of vessels for pancreas transplantation.

There have been circumstances where a liver team who have accepted a liver to split have requested both sets of iliac vessels which has raised concern.

This was discussed at RAG where there was input from liver surgeons who stated an extra set of iliac vessels do not routinely have to go with a split liver. The routine is the iliac vessels should go with the pancreas, even if the liver is being split.

I Currie suggested including a paragraph stating this within the NORS guidelines and anything different, will require a discussion between surgeons. S White proposed adding to the NORS guidelines that the vessels are not to arrive separately from the pancreas.

I Currie

3.2.8 Age limits of pancreas donors – PAG(19)29

C Counter presented a paper arising from an action at the previous PAG meeting and a comment from the National Clinical Lead for Organ Donation regarding efficiency gains that could be made with regards to older donors.

Data over a five year time period showed of the 393 deceased solid organ donors aged 61-65 years, the pancreas was offered in 293 (75%) cases but only resulted in nine transplants, 3% of those offered. It was asked what the exact ages were of these transplanted donors.

[Post meeting note: five were 63 years, one was 62 years and three were 61 years]

Members were asked to consider whether there is sufficient evidence to reduce the pancreas age limit. The consensus is that most centres would not want to accept pancreas offers for whole pancreas transplantation from DBD donors over the age of 60. S Sinha will speak to the team at Oxford to gain consensus from his colleagues before the age limit is reduced from <66 years to <61 years. Members agreed that the age limit of <56 years should remain from DCD donors for whole pancreas transplantation.

**S Sinha/
C Counter**

4 Pancreas Offering Scheme

4.1 New Scheme update – PAG(19)30

The Revised National Pancreas Offering scheme went live on 11th September 2019 and C Counter provided a brief summary of donation and activity in the one month since the introduction of the new scheme.

The National Pancreas Offering Scheme will be monitored and a 6 month report will be produced at the next meeting.

A Asderakis stated it would be interesting to know the reasons why the 4 pancreases were declined in Tier A and not subsequently transplanted. J Casey advised that more information will be available within the next report.

[Post meeting note: Two declines for islet patients, one due to donor unsuitable size and poor function and one due to donor past history; one decline for whole pancreas patient as they were unfit; one organ was accepted and not used due to organ damage.]

5 Pancreas Transplant Activity

5.1 Transplant list and transplant activity – PAG(19)31

C Counter presented a paper reporting activity and transplant listing until 31 March 2019.

Over the last few years, the waiting list has declined, however there was a 15% increase from March 2018 to March 2019. There has been a 3% reduction in transplants between the two years.

Of the 250 patients on the active transplant list at 31 March 2019, 42 were Islet or SIK patients which is an increase on last year's data and the remaining 208 were SPK or pancreas alone patients.

There were 467 deceased pancreas donors which equates to 7.1 per million population.

There has been a 6% decrease in DBD pancreas transplants, however there has

been a 4% increase in DCD transplants.

5.1.1 **Group 2 patients report**

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

5.2 **Transplant outcome – PAG(19)32**

C Counter presented the pancreas transplant outcome report which shows patient graft survival over one, two and three years.

There was no significant difference in one year graft survival following first SPK transplant from a DBD donor between the time periods presented and three year graft survival was 87%. There was a significant difference in kidney graft survival between the two time periods from 100% in the early time period to 97% in the most recent time period. There was a significant improvement in one year patient survival between the two time periods from 96% to 99%.

There was no significant difference in one year graft survival following first SPK transplant from a DCD donor between the two time periods.

The one year graft survival following a DBD pancreas alone transplant was 91%.

5.3 **Fast Track Scheme – PAG(19)33**

The pancreas fast track paper was received which audits activity of the pancreas fast track scheme.

An in-depth analysis was presented at the November 2018 meeting looking at the number of offers made via fast track, it was then agreed to not fast track a pancreas if the cold ischemia time (CIT) was greater than 8 hours at the time of potential fast track.

Since the implementation of the CIT cut-off rule in April 2019, there were 187 pancreas donors. 41% were offered through the scheme in 2019 compared with 42% in 2018. The intention of introducing the 8 hour CIT cut-off was to reduce the number of fast track offers but this hasn't been shown in the data.

After a detailed discussion a request was made consider an analysis using 2 years' worth of data and consider the reason for fast track and at what time point the pancreas was fast tracked.

C Counter

The group supported the proposal to implement a 4 hour CIT cut-off for whole pancreas and 8 hours for islet offers and monitor this. J Whitney advised this would require an 8 week training period following formal agreement.

**J Whitney /
C Counter**

5.4 **Contact and Offering – PAG(19)34**

A paper submitted to the Advisory Group Chairs and was circulated which apply to all organs where recommendations were made.

J Casey highlighted the following sections for PAG members to consider:

Fast track/group offers

J Casey sought opinions of the group regarding repeat fast track offers that were

previously declined for named patients. J Whitney clarified that if an offer is made to a centre who refuses an offer due to logistics, Hub Operations would repeat the offering of the organ as the logistics for that centre may change. The proposal is if a centre declines an offer for all recipients due to donor related reasons, that centre would not receive a repeat offer.

Donor suitability

Members agreed that after a conversation including the retrieval surgeon and the initial offering surgeon who decide that an organ is untransplantable the organ would not be offered out. It was acknowledged that the next patient on the list could be an islet patient which would require a discussion. Members agreed that images of the organ should be considered.

Trigger to stop offering following multiple declines

J Whitney suggested looking at the data to identify what the triggers are for pancreas offers. The request was made to complete a retrospective analysis of the number of offers where the organs have been turned down by 3 centres for the same donor related reason and how often this has resulted in a transplant.

C Counter

Key information missing from fast track offers

Transplant centres reported that some key information required is not included in the fast track offer message. J Whitney requested that a list of the key information required for centres is developed.

Recipient Coordinators

6 Working Groups

6.1 SIK (Working Group)

J Casey advised part of the working groups remit will be looking at the monitoring of SIK and outcomes of SIK transplants.

6.2 Declines for Logistical Reasons (Working Group)

S White is collating data and information from C Counter. S White requested volunteers and the group agreed is A Sutherland, A Muthusamy, S Northover/ S Sinha and S Harper. An update will be provided at the next meeting.

6.3 Graft Outcome (Working Group) – PAG(19)46a & PAG(19)46b

P Choudhary is leading this working group and is in the process of getting a group together to look at how pancreas and islet outcomes are measured and the data that are required for this.

6.4 Quality of Life (Working Group)

J Shaw is leading on a group of quality of life outcomes in islet transplantation and will provide an update at the next meeting. J Casey requested that any volunteers who would like to be involved in this work to email J Shaw.

All Members

7. Pancreas Islet Transplantation

7.1 Report from PAG Islet Steering Group: 24th September – PAG(19)35

P Johnson highlighted the main points discussed at the last PAG ISG meeting.

It was agreed that routine images of islet preps will be taken before and after culture and as they are released to the transplanting centre. This will take place routinely for every islet isolation.

A formal piece of work will take place looking at islet capacity which will include simulations of islet activity and will look at SIK which has added additional activity.

Agreed at the meeting was for Islet Facilities to inform Hub Operations when they are unavailable and will contact the Hub as soon as they are able to accept pancreases to avoid unnecessary phone calls whilst in the process of isolating.

Identified at the recent HTA inspections at King's and Oxford was the requirement for all isolation centres involved in the Islet Autotransplantation to have a procurement license which centres are purchasing.

J Casey attended the CITR meeting in Washington where international units presented data.

7.2 Islet transplant activity and outcome – PAG(19)36

C Counter provided summaries of transplant activity and transplant outcome in the last 3 financial years.

A Sutherland recommended including the islet patient survival outcome.

C Counter

7.3 Islet Isolation Outcomes – PAG(19)37

C Counter presented the islet isolation outcome data.

In the latest financial year there were 104 donors where the pancreas was accepted for islet transplantation. All 104 arrived at the islet isolation facility and 100 were used for isolation. 86 had isolation completed and 25% of those were transplanted, 6 as SIK patients. 39 did not meet release criteria which also included those where information may be missing and 3 of those were transplanted, 2 as SIK.

Overall of the 100 which were indicated to have isolation started, 28 were transplanted which gives a conversion rate of 28% and the main reason for not transplanting was due to insufficient islet yield.

In the latest financial year, 9% of donors were categorised as grade A and 91% were non grade A.

S White queried why Oxford have a smaller number of isolations completed than the other islet facilities. P Johnson advised this is because several isolations were started and then abandoned, therefore the policy has been changed to state that if the isolation is a nonstarter this will be declined by the facility.

8 Standard Listing Criteria

8.1 Summary data – PAG(19)38

There were 261 registrations between April 2018 and March 2019 and nationally the return rate for the supplementary forms reached 95% for whole pancreas registrations and 92% for islet registrations. Of the 67 new supplementary forms received between February and May 2019 only 1 patient did not meet standard listing criteria.

An action from the last meeting was to remove the criteria specified in Appendix 1 in the pancreas transplant alone section regarding patients listed with type 2 diabetes, however C Counter informed that the Patient Selection Policy has recently been reviewed where this has remained. It was subsequently agreed for these criteria to remain within the Appendix for pancreas alone transplantation.

8.2 Pancreas transplant listing exemption requests and outcome of previous applications to appeals panel – PAG(19)39

Since the last meeting there were 4 appeal requests which were all approved.

9. Any Other Business

9.1 9.1 New findings made at transplant centres requiring histopathology – PAG(19)40a & PAG(19)40b

The two papers were discussed at the Advisory Group Chairs meeting and the request was made to circulate the papers to each advisory group. J Casey drew attention to the top of algorithm and advised members to inform Hub Operations if a lesion is detected and request that a biopsy is taken.

9.2 P Johnson recommended members consider attending the European Pancreas Islet Transplant which was historically islet focused but is now incorporating whole pancreas transplantation and is an excellent forum for discussion.

10. FOR INFORMATION ONLY

10.1 Summary from Statistics & Clinical Studies – PAG(19)41

Noted for information.

10.2 Transplant activity report: September 2019 – PAG(19)42

Noted for information.

10.3 Current and Proposed Clinical Research Items – PAG(19)43

Noted for information.

10.4 QUOD Statistical report – PAG(19)44

Noted for information.

11. Date of Next Meeting:

Tuesday 28th April 2020, 10:30am, Lancaster Gate Hotel, London W2 3NA

November 2019