

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

**MINUTES OF THE THIRTY-EIGHTH MEETING
OF THE KIDNEY ADVISORY GROUP
ON WEDNESDAY 25th NOVEMBER 2020
VIA MICROSOFT TEAMS MEETING**

PRESENT:**Dr Rommel Ravanan**

Mr John Asher
Mr Atul Bagul
Dr Richard Baker
Mr Adam Barlow
Mr Stephen Bond
Mr Tim Brown
Ms Lisa Burnapp
Mr John Casey
Mr Chris Callaghan
Ms Rebecca Curtis
Mr Frank Dor
Dr Sarah Cross
Dr Jan Dudley
Ms Anusha Edwards
Prof John Forsythe
Ms Anushka Govias Smith
Mr George Greenhall
Mr Abbas Ghazanfar
Dr Gareth Jones
Dr Phillip Mason
Ms Julia Mackisack
Mr Sanjay Mehra
Mr Pramod Nagaraja
Dr Paul Phelan
Ms Sadie Von Joel
Mr Ravi Pararajasingham
Mr Gavin Pettigrew
Dr Tracey Rees
Dr Matthew Robb
Mr Debarata Roy
Mr Imran Saif
Ms Angie Scales
Dr Oliva Shaw
Ms Clare Snelgrove
Ms Rachel Stoddard-Murden
Mrs Julie Whitney
Mr Ian Wren

Chair

Medical Health Informatics Lead
Representative for Leicester & Nottingham
National Clinical Lead Governance, ODT
Leeds & Newcastle Representative
Recipient Co-ordinator Representative
Northern Ireland Representative
Clinical Lead Living Donation, NHSBT
Pancreas Advisory Group Chair
National Clinical Lead for Organ Utilisation (Abdominal)
Statistic & Clinical Studies
Deputy Chair and Imperial & Oxford Representative
QUOD Representative
KAG Paediatric Sub-Group Chair
Cardiff & Bristol Representative
Medical Director, ODT
Commissioner for Kidney Transplant NHS Scotland
Clinical Research Fellow NHSBT
Guy's & St George's Representative
Lead London Collaborative
Renal Association Representative
Lay Member Representative
Liverpool & Manchester Representative
Cardiff & Bristol Representative
Glasgow & Edinburgh Representative
Lead Nurse Recipient Coordinator
Sheffield & Cambridge Representative
PITHIA
Chief Scientific Officer – ODT
Statistics & Clinical Studies, NHSBT
Birmingham & Coventry Representative
Plymouth & Portsmouth Representative
Lead Nurse Paediatric and Neonatal Donation
BSHI Representative (deputy)
Recipient Co-ordinator Representative
SNOD Representative and Regional Manager
Head of Service Delivery – Hub Operations
NHS England (Specialist Commissioning)

IN ATTENDANCE:

Prof. John Dark
Miss Sam Tomkings

Simvastatin Study (To present item 15)
Clinical & Support Services, NHSBT

APOLOGIES:

Mr Ian Currie, Dr Sian Griffin, Ms Cinzia Sammartino, Ms Susan Spence

1 Declarations of interest in relation to the agenda – KAG(20)18

There were no declarations of interest.

2 Minutes of the meeting held on 17th June 2020– KAG(M)(20)1

The minutes of the previous meeting were approved.

2.1 Accuracy

The previous minutes were agreed as a correct record.

2.2 Action points – KAG(AP)(20)1

All action points were either completed, included on the agenda and those with a verbal update were listed below.

AP1 – Provisional offering of pancreas from MVT blocs

In cases where Cambridge accept a multi visceral bloc, sometimes not all organs are needed and therefore an offering process to make use of a SPK transplant has been developed to facilitate that. M Robb and C Callaghan have met with Hub Operations and have a proposal for a process for MVT bloc cases. A risk assessment has been submitted and following that the intention is to bring a paper to the next KAG.

**M Robb &
C Callaghan**

AP3 – Sustainability – delayed audit data

The GAP analysis took place around the introduction of Max and Keira's law where individual renal transplant centres were contracted to prepare for the introduction and to identify any key constraints regarding being able to increase activity in line with the projections provided by NHSBT around additional organs. COVID has delayed this and therefore responses from Coventry, Oxford, Newcastle, Liverpool and Leeds have not been obtained. I Wren plans to contact those centres again. Initial reporting suggests significant issues around staffing and theatre capacity. I Wren has been advised there may be a rerun of those numbers but are currently going by the numbers provided back in 2019. Manchester and Portsmouth were the only units who were not reporting staffing issues. All units apart from the paediatric units were reporting constraints with theatre capacity. Going forward, we need to be aware of the new financial arrangements from the NHS as all funding has gone out to providers to manage acute pressures they are under. It is anticipated that the financial framework will be in place from April 2021. This will provide more detail and discussions can begin with individual centres regarding legacy issues. I Wren advised continued negotiations will take place with NHSBT around whether the numbers have changed since the last run and whether there are any lessons to be learned from Wales who have been in the Opt Out legislation for a longer period of time and can feed into this piece of work. R Ravanan would like to have this as a bigger agenda item at the next meeting. I Wren will check if the information collated includes the devolved nations.

I Wren

AP5 – Sequential liver and kidney for oxalosis

R Baker spoke with Graham Lipkin and discussed the standard of care if simultaneous transplantation or sequential with a liver first and then a kidney. Graham feels at the moment it should be sequential but acknowledged there is a lot of technology coming along which will mean a kidney alone will be given without a liver. R Baker has asked a colleague if there is any outcome data that can be analysed from sequential transplantation in oxalosis vs simultaneous. J Dudley feels there is equipoise in terms of sequential vs simultaneous and that paediatrics are doing both. Birmingham have opted to do sequential whereas London are often doing the combined. R Ravanan summarised that KAG is not going to recommend one or the other as there

may be case dependent discussions but if exceptional allocation is required that will come through to KAG as an exceptional request.

AP6 – Update on A2 donors for B recipients

This was a paper lead by Nizam Mamode looking into facilitating transplants from A2 donors to blood group B recipients. M Robb has worked with Nizam and the first part of this piece of work is to identify whether the donor hospital laboratories are able to sub type for A within 4 hours. A survey was put together in mid-March and are currently waiting until things settle in terms of activity with COVID and then will send this to all donor hospitals. Until that information is obtained, it is not known whether this can be taken forward. L Burnapp highlighted that when this was first discussed it was noted that we could potentially direct those kidneys that fall out of exchanges to B recipients on the waiting list. R Ravanan asked unit leads for this work to progress, we need to know whether the laboratories within units can routinely return information on the sub type of the A blood group. T Rees asked if there will be any consideration given to the titres of the blood group recipients. G Jones agreed that when this took place in London a few years ago the biggest issues was keeping the recipient titres up to date and making sure recipients were suitable to receive an A2 kidney. It was acknowledged some of the inequity issues have been addressed within the new allocation scheme however members felt if there are any ways to identify additional matches for hard to match patients it may be worth exploring. KAG agreed further discussion is required and R Ravanan suggested a small working group discuss this offline and bring it back to the next meeting.

**R Ravanan /
T Rees /
M Robb /
G Jones**

AP7 – CIT and XM Practices

R Stoddard-Murden advised the policy will be updated and will be trained out to begin in January.

AP13 – Report from KAG Paediatric Sub-Group

A request was made from the KAG Paediatric Sub-Group to add some additional virology fields to the follow up forms to capture EBV, BK and CMB. This has been discussed with IT who advised that the changes would not be implemented for about a year. M Robb is happy to put this change forward but asked whether this information is worth capturing for adult transplantation. J Dudley added this piece of work has identified that there is a tenfold variation between centres and therefore it is critical to assess outcomes and until this is included on the national reporting forms it is down to individual clinicians to record this which is not a good way of assessing outcomes. J Dudley requested that if this is something that will be open to adults, J Dudley would like this implemented which is mandated for children and perhaps optional for adults. No objections were received from the group to record this information for adults. R Ravanan requested if members have any other data request let R Ravanan and M Robb know by 4th December. As soon as feedback is received the form will be submitted. As it is unlikely this will not be picked up for about a year, R Ravanan, M Robb and J Dudley will pick this up offline.

**All Centres
R Ravanan
M Robb
J Dudley**

2.3 Matters arising, not separately identified

R Ravanan welcomed Frank Dor who has been appointed as Deputy Chair of KAG.

The KAG representative which attends the Pancreas Advisory Group (PAG) has stepped down and R Ravanan sought expressions of interest from members of KAG to be the next representative. F Dor has volunteered and will be invited to attend future PAG meetings.

3 Medical Director's Report and COVID update

J Forsythe thanked colleagues for the communication within the transplant units across the UK. If a centre runs into difficulties in providing a service or staff difficulties in terms of resilience, we are rapidly in communication which gives early warnings of any issues. In many cases NHSBT have intervened on a unit's behalf to ensure donation and transplantation is maintained.

Regular bulletins are circulated from NHSBT and J Forsythe encouraged clinical leaders to cascade as much as possible.

During the second surge a huge amount of work has taken place within units to maintain donation and transplantation which has largely been successful. The activity data demonstrates that whilst the data was dampened over the last couple of weeks there has been a small rise in donor and transplant numbers in the last week or so.

The vaccine was discussed at the Clinical Team Meeting and J Forsythe and R Ravanan have opened discussions with the Joint Committee for Vaccination and Immunisation (JCVI) and hopefully with the registry data available and the work with other data colleagues can demonstrate how vulnerable our patient population is. The outcome of those discussions will be shared at the Clinical Team Meeting and at the KAG Clinical Representative meeting.

4. Living Kidney Donor update – KAG(20)18

L Burnapp presented the Living Kidney Donor paper which noted no activity for 2 months during the first wave of the pandemic. All centres came back online between end of May and end of September. The impact on activity is that it has reduced to approximately 50% of normal activity but is variable between centres and from week to week. The graph presented provides data up until the end of October due to late reporting; living donation is always recorded in arrears because the data is not available in real time. This is not ideal and there is a recommendation within the paper to ask centres to focus on returning data as promptly as possible and to feed this request back to living donor coordinator teams and H&I laboratories.

An agreement was made and implemented at the last KAG meeting to request that centres submit restoration and contingency plans for living donor kidney transplantation in the event of a second wave. 22/23 restoration plans were received which have been very helpful in maintaining activity during the second wave. All centres have remained open during the second wave but we are aware of particular constraints in Northern Ireland which is having an impact on the kidney sharing scheme.

The centre specific living kidney transplant report will be published soon.

The Kidney Sharing Scheme was suspended in April and July but, with the support of all centres, was reinstated in October. The outcome statistics from this matching run show that the run was equivalent in size to October 2019. 92 transplants are now pending and thought needs to be given to how those transplants are managed. We are coming to the end of outstanding transplants pre COVID and anticipate that 50% of these transplants will have been achieved overall.

L Burnapp highlighted that it may be helpful to consider low risk non simultaneous surgery, provided that the non-directed donor initiates any chain (where applicable) and collaboration with other centres, to reduce delays in scheduling transplants.

There were two incidents in the Kidney Sharing Scheme one from October 2019 and one from January 2020 and as a result of these, significant work has been done to manage manual processes and to ensure safeguards within the scheme. Provision of a digital solution for the Kidney Sharing Scheme has now been prioritised and work is currently underway to look at the critical functions that need to be replaced in the first phase.

In the interim, L Burnapp asked members for their support to manage safety within the scheme and to be vigilant about late requests, use of the correct forms and completeness of registration data for donors and recipients they wish to be included. A list of actions was provided in the paper. L Burnapp requested members pass on the list within the paper to coordinator teams as they are responsible for submitting the paperwork.

Clinical Leads

Some request for prioritisation for transplantation have been received as a result of the earlier incidents in the scheme and all of those recipients have now been transplanted from the deceased donor list. One further request was submitted for an individual donor who donated in 2010, L Burnapp is in the process of establishing further details about this.

NHSBT represent the UK on the Council of Europe national focal point network around transplant related crimes. The focus of the network is to understand why people travel for a transplant as a donor or recipient and where illicit activity is happening across the world. This is informed by an annual data collection process in each participating country. A letter was sent out in 2018 asking for members support with this. Data continues to be collected on a two-year cycle and the anonymised data is in the process of being verified by each country pending publication. The numbers in the UK are very low and limited to living kidney donation numbers but there are some cases that merit follow up. When individuals return from abroad with a transplant, centres are asked to report this through ODT online incident reporting so that they can be followed up by L Burnapp.

In summary, L Burnapp reiterated the recommendations related to the topics covered in the update, including asking members to address the timely reporting of living donor activity data and to consider ways to manage scheduling of transplants from the October run.

KAG endorsed the recommendations as listed within the paper.

5. Governance Issues

5.1 Non-compliance with allocation

There was no non-compliance with allocation.

5.2 Incidents for review: KAG Clinical Governance Report – KAG(20)19

R Baker presented the Clinical Governance Report.

An incident was raised regarding likely donor derived malignancy where both kidney recipients and islet recipient died. This incident is ongoing. NHSBT have taken the action to prohibit any transplant from patients with melanoma no matter what grade. NHSBT have referred the matter to SaBTO but that does leave a discrepancy between SaBTO recommendation and European recommendation and are awaiting more clearer guidance from SaBTO.

J Forsythe advised that a recent agreement from SaBTO and DORA has been made that melanoma at a very early stage is acceptable for donation. Concerns are that trying to find the different histological grading of melanoma is quite challenging especially at early hours of the morning and in those

circumstances could argue for a degree of caution. This agreement has very recently been decided and it is currently still set up that malignant melanoma is a contra indication. It was acknowledged that recipient melanoma is a different matter and can be dealt with using local immunology advice. R Baker drew attention to a paper produced by Dave Collett back in 2010 regarding risk to recipient melanoma.

There have been two incidents regarding QUOD biopsies where bleeding has occurred which largely relates to incorrect techniques. R Baker is in discussions with Ian Currie and a letter has been sent to the NORS teams about the technique for biopsing. Every retrieval surgeon will have been signed off by taking a module for taking biopsies. Ian Currie is keen to introduce formal learning procedures. S Cross added that taking the biopsy from the lower pole not the upper pole should not itself result in the adverse outcome and under further investigation it was revealed that it was a failure to adequately suture the biopsy that led to the bleeding and there was some discrepancy in the training documentation because it should be the implanting surgeon who sutures rather than the retrieving surgeon which is what happened in both of these incidents. The online training has since been updated for the NORS teams.

A recommendation made within the document is a to ensure photographs are taken if organ damage has occurred.

6. Transplant MDT workforce survey

This item was raised by a member of KAG who asked if KAG could give bench marking of the number of transplant surgeons to the number of transplants in a particular unit to help with the understanding of the workforce. NHSBT does not routinely collect this data. L Burnapp and R Ravanan are discussing how a surgical data collection could be updated. L Burnapp has worked with the BTS and the Renal Association about the wider MDT but did not have access to surgeons and specifically whole time equal and dedicated transplantation. F Dor has been asked as the Chair of the Chapter of Surgeons in the BTS to assist with the surgical data for the workforce planning. This group represents all of the abdominal organs. G Jones added that some data from the London units is available and may be a good place to start.

The overall feeling from the group was that this piece of work would be useful and would support the MDT approach and perhaps a collaboration between BTS, NHSBT and BRS would be good. A suggestion was made that it would be useful to find out the number of juniors to bench mark that and the number of theatres required to provide the bulk of access work in transplant and keeping vascular access is very labour intensive across the UK and this is an opportunity to increase the workforce. Members agreed to not omit none transplanting hospitals and providing some guidance for none transplanting centres would be very helpful as part of this.

A Govias-Smith is doing a Commissioning plan for Scotland and is looking for information with bench marking regarding staff and skill mix levels and would welcome this piece of work. I Wren agreed and supported this.

L Burnapp will circulate the BRS findings. R Ravanan requested G Jones circulate the information from the London centres and then members of KAG feed their thoughts to R Ravanan and L Burnapp. R Ravanan would like a small group to develop a draft questionnaire.

**L Burnapp
G Jones
R Ravanan
S Bond
F Dor**

7. **KAG participation from non-transplanting renal units – KAG(20)20** **ACTION**
KAG were asked to consider expanding the membership of the group to the following recommendations:

- (1) by inclusion of two non-transplant unit Nephrologists
- (2) by inclusion of trainee representatives
- (3) by inclusion of patient representatives

No objections were raised to expanding the group to all three proposals.

8. **Developments in IT**
8.1 **Organ Quality eForms update**

J Asher informed members that the funding for the electronic HTAA form is not yet cleared. The HTAB form is working well, a change to the form will be made for the recording of damage. ODT are keen to more accurately record retrieval damage. The definition of the categories on form B have changed.

The SaBTO aide memoir is an easily accessible tool which can be used on a mobile device that will provide a rapid reminder of SaBTO guidance on donor transmitted diseases. Resource is now in place to get this built. J Asher is looking for representatives to get this sense checked and provide feedback. There is not a lot of scope to change what is proposed therefore this will need to be reviewed quickly. J Dudley and G Pettigrew would like to be involved.

9. **Organ Utilisation**
9.1 **Unit Clinical Leads in Utilisation**

Funding has been obtained for Clinical Leads in Utilisation (CLU) for every transplant unit in the UK for 4 months. CLU's will be filling in information about local organ utilisation schemes and giving feedback on NHSBT led schemes and working collaboratively to improve organ utilisation schemes in the future. R Ravanan asked in terms of the output following the CLU's in post how will we know the impact from how organ utilisation is improved. C Callaghan advised output will be available from the surveys and will share the output with KAG and is looking into drawing up a national strategy document. All unit's bar one unit has a nominated CLU. C Callaghan has contacted that centre but has not received a response. R Ravanan offered his support regarding contacting the remaining centre.

9.2 **Kidney Images at Organ Retrieval**

The plan initially was a pilot scheme to be introduced to image selected deceased donor kidneys at retrieval. That pilot scheme has been in place for SNODs to take 3 images and send those images to Hub Operations who will send them to nhs.net addresses of the implanting centres. The uptake of the scheme has been reasonable at around 50-70%.

C Callaghan has recently updated the Pancreas Advisory Group on the equivalent scheme for pancreases and the strong feeling from the advisory group was that they wanted to move the pilot photography scheme into a business as usual approach and to formally move this to within NHSBT remit. C Callaghan asked if KAG would like to consider this for the kidney photography scheme.

The Clinical Team Meeting agreed a number of images and views and the next point will be to take this to the Retrieval Advisory Group (RAG) who will have to action this. A SOP is in place for kidney where it states 3 images is required.

C Callaghan has had discussions with Ian Currie (Chair of RAG) who is very supportive of this as there are repeated issues with Clinical Governance for organ damage and whether the damage occurred at retrieval or at benching.

Members supported this to be a part of the routine. J Whitney confirmed the Hub Operations are supportive of implementing this using the same criteria as before and if this is being considered for every kidney retrieval this can be supported if that is KAG's preference. J Forsythe highlighted that John Richardson has requested that the protocols that are in place match exactly what is taking place. C Callaghan will circulate another letter emphasising the appropriate use of the images but suggested for now to not introduce the requirement to take pictures of all kidneys as most kidneys will not need it and would suggest sticking to current criteria and consider this in the future. C Callaghan will liaise with John Richardson about this.

C Callaghan

9.3 PITHIA update

The PITHIA trial was suspended in March due to the pandemic. G Pettigrew anticipates that the trial will restart in March 2021. G Pettigrew welcomed thoughts from the group if members think it is an appropriate time to restart and what would need to be done to provide centres with access to the PITHIA service. R Ramanan added that if the vaccine rollout goes to plan in England then most over 65-year olds will be vaccinated early next year and agreed that restarting the trial in March should be a reasonable thing to do. Members supported the restarting of the trial in March.

Funding for the PITHIA trial is a slight issue as the trial was funded for 3 years and this will now roll into 4 years. There are additional issues with the NORS team to restart the PITHIA process and will need to ensure they are on board. The trial requires a lot of work from Hub Operations regarding transporting of the biopsy.

10 KAG Paediatric Sub-Group

10.1 Report from KAG Paediatric Sub-Group: 12th October 2020 – KAG(20)21

J Dudley provided an update from the KAG Paediatric Sub-Group who are moving forward with a number of projects and themes.

There is a national RTC called the PLUTO trial which is looking at intraoperative and post-operative plasmalight compared with standard therapies.

A surgical techniques questionnaire has been circulated to the KAG Paediatric Sub-Group that A Edwards has put together and would like colleagues to respond to that survey.

An annual services challenges meeting took place last week which was very enjoyable and provides the opportunity to learn and sharing of practices.

The group are keen to look at declines due to the high number of organ decline rate which is around 50% with a variation between 20% and 60%.

One of the focal points of the meeting was a change to the donor age criteria. One centre felt restrained by the upper age limit of 50 for a young person that was running out of time and therefore it was agreed to make some changes to the offering system for that recipient. This created a big debate about whether restricting the donor age to 50 was the right thing for paediatric patients. It was therefore agreed to extend that criteria for Tier A patients to 60. It was since advised it would be difficult to achieve this from

the IT side for Tier A alone therefore a proposal was made to extend the donor age to 60 across both Tier A and Tier B. Hopefully a conclusion on this will be reached at the end of the year to accept one of the 4 options proposed.

No objections were received from KAG to extend the donor age for paediatric patients.

11 Pancreas Advisory Group**11.1 Report from Pancreas Advisory Group: 5th November 2020**

J Casey advised all pancreas services are open after being significantly affected by the pandemic and have managed to stay open and active during the second wave. The number of patients listed for pancreas transplantation are close to numbers pre COVID.

As mentioned by C Callaghan the Pancreas Advisory Group unanimously felt the pancreas imaging pilot should be business as usual and would be of significant advantage to pancreas transplantation particularly in making early decisions about whether a pancreas is utilised and therefore minimising the cold ischemia time on the kidney that would otherwise be offered with the pancreas.

J Casey's term as pancreas Chair will come to an end at the end of November and Prof. Steven White has been appointed as the new Chair of the Pancreas Advisory Group and will attend future meetings. R Ramanan thanked J Casey for his contributions to the Kidney Advisory Group over the years.

12. Monitoring of Deceased Donor Crossmatching – KAG(20)23

T Rees presented an update on the initiative to reduce cold ischemic time (CIT) by encouraging and having guidelines for H&I laboratories to wherever possible do a virtual cross match or to do peripheral blood match requesting peripheral blood is sent ahead of any organs. The suggestion was made to capture that information therefore T Rees put a small subgroup together to progress this.

The suggestion has been to manually collect the data as a pilot for 3 months. The proposals are that we add a question to the kidney transplant record paper form that will return the time of the cross match reported through the ODT hub transport contract recognising that not all centres are participating within the pilot. There are two centres that the transport data will not be obtained therefore it is anticipated to gather 75% of the data. KAG are happy to support this project.

C Callaghan asked who will be documenting those times on the form and how are individual centres aware of this change. T Rees and the team have been working with recipient co-ordinator colleagues who are working on the practicalities of the collection of that data. S Bond feels recording the time of the arrival of the organ is useful and suggested that recording the time of arrival until perfusion is a better indicator of the internal processes of the unit rather than just looking at CIT which includes issues with transport which would be useful information to collate. M Robb advised this pilot is to record the time of the arrival of the organ which will be obtained from the transport data. S Bond feels an issue may arise as every centre may do this differently and it may be that the H&I laboratories are recording the time, they phone this through.

In order for our audit to improve access to theatre to reduce CIT, Sheffield looked at the contract between NHS England and it is clear in the contract that as soon as you have a cross match and the patient is ready it states that

induction of anaesthesia should start within 2 hours and any exception should be reported. R Pararajasingham reported this has helped the unit and since the improvement of the cross match in over 70% of instances in the last two years, the cross match is available to the unit before the kidney has arrived in Sheffield.

T Rees will look at how we engage further with the collection of timing of the cross match data. T Rees asked if there any renal recipient co-ordinators on the call that can help. S Bond and C Snelgrove are happy to be involved.

13. Outcomes of en-bloc renal transplants in Leeds/Guy's – KAG(20)24

A Barlow raised this item on behalf of a request received to consider whether the number of donors nominated to preform en-bloc renal transplants from donors less than 2 years of age should be reviewed and potentially increased.

In 2017 an in dept review of renal transplantation from small donors was conducted by two Lay Members and the recommendation from that report is that donation and transplantation of these small en-bloc transplants should be centralised to two units. The units chosen because of interest and experience was Leeds and Guy's. The paper circulated is an abstract submitted which looked at the results from the two years of that programme from November 2017 to November 2019.

There have been 16 offers over the two year period from donors less than 2 years of age of which half were accepted for transplant either by Guy's or Leeds and the rest declined predominantly because of co-existing medical reasons or genetic abnormalities. Of those 8 two did not proceed and 6 transplants went ahead. The results have been very good with all transplants having immediate function and graft and patient survival remains 100%.

Two offers were made recently but unfortunately could not accept as there was no suitable recipients on the waiting lists. The programme between the two units has worked very well and A Barlow's recommendation is that we should continue with the previously agreed arrangement for this to be centralised in two centres. J Mackisack added that it has been very successful and fully supports the two centres continuing with this. A Ghazanfar asked if there is any opportunity to expand this to more centres in the future, that St George's would like to be involved.

Discussed at previous meetings was that if Leeds and Guy's turned down an offer the option should be given to other centres via the fast track scheme, bearing in mind that if the two centres with experience have turned them down and the reason for why they have been turned down. A Ghazanfar proposed that if Leeds and Guy's do not have a suitable recipient but St George's do could one of the implanting centres provide a service to another centre. A Barlow agreed particularly because Leeds on occasions have struggled to find a well matched recipient as the matching of these kidneys tends to be poor.

R Ramanan suggested that the two centre model should continue for two more years and this is then reviewed in two years' time at the autumn meeting 2022 and the policy will remain that if Guy's and Leeds turn down a sub 2 year old donor purely for logistical reasons or not having a suitable recipient, such en-bloc kidneys will be fast tracked which any centre can accept.

R Pararajasingham raised concerns with this and feels that if Leeds and Guy's turn down a kidney that it should not be offered anywhere else because they are experts in this and the public need to have confidence in what we are doing and feels there are repercussions if this is not done well. J Mackisack

agreed with this and would be keen to restrict things to the two centres for another two years. It was noted that accepting a fast track offer after Leeds and Guy's have declined it would be a matter of size and weight of the donor that could be a major consideration also.

Members concluded that it would be good to share the knowledge and expertise on this in the future. R Ramanan requested A Barlow, F Dor, A Ghazanfar and C Callaghan to think about over the next couple of years how this could move forward and take into consideration the entire pathway.

14. Summary of CUSUM monitoring of outcomes following kidney transplantation – KAG(20)25

M Robb presented the CUSUM report from NHSBT which monitors short term patient outcomes following organ transplantation. This was traditionally done using within centre analysis but this time some results are being shown against the national rate as suggested at the June 2019 KAG meeting.

The last two runs of the CUSUM monitoring have identified 2 signals for graft failure, one at Plymouth and one at Edinburgh and the investigation for the signal at Plymouth showed no underlying issues identified and the second signal at Edinburgh is still outstanding. For 30 day patient mortality outcome a signal was raised at Plymouth and the investigation for this signal is still outstanding.

Table 2 shows the results from the CUSUM analysis for centre specific monitoring and the national monitoring. The signal for graft failure at Plymouth was seen against the national monitoring and an additional signal for Birmingham although it was noted that 3 of the transplants that contributed to that signal had led to a signal in December 2019 in the centre specific monitoring which took a bit longer for the national monitoring to pick up. The Edinburgh signal for graft failure in the centre specific monitoring was not picked up in the national monitoring.

The proposal was made to continue to run the national monitoring alongside the centre specific monitoring for another 12 months and present that data at KAG in autumn next year and decide whether to continue with the national monitoring and whether a formal process is required where CUSUM signals from national monitoring should also trigger a signal investigation. Members are happy to continue with the national monitoring alongside centre based monitoring.

Members were asked to consider what additional information might be useful for centres who receive the CUSUM information, one suggestion was to provide the information from the failure rates across the reference period which has been provided in the CUSUM paper. The survival rates for 1 and 5 year information is published and the CUSUM monitors the 30 day outcomes, M Robb asked members if more up to date information on that would be useful. A suggestion was made that the donor and recipient risk appendices outcomes would be useful. Publishing the D1-4 and R1-4 for each centre would help set a context which could be included in the annual report and the CUSUM report in the event of a signal.

M Robb

15. Simvastatin study – KAG(20)26a & KAG(20)26b

J Dark presented an outline of the findings from a study published by Karl Lemstrom from Helsinki in 2019. This led to the design of the SIGNET Study which received approval in October. The study is envisaged to begin on 1st April 2021 using adult DBD donors, for a period of 5 years, to be randomized

after consent for donation and research to receive as single dose of Simvastatin.

Data will be shared retrospectively to show there is no confounding effect. J Dark requested if anyone is planning a study to contact J Dark to discuss potential co-enrolment agreement to do an anonymous data exchange.

This is one of the largest randomised prospective study in the world. Members involved in this study are applying for a mechanistic study using QUOD specimen in the same cohort.

This has been endorsed by other advisory groups where this has been presented.

Any questions, please contact using the SIGNET website.

16. **Any Other Business**

A concern was raised when activity restarted after COVID whether any particular demographic of patients was less likely to get back on the transplant list or less likely to be transplanted. A concern regarding lack of equity was raised therefore some initial analysis took place a few months into the pandemic where it did not look as if any specific group had been disadvantaged. M Robb presented some more up to date data on this.

A heatmap was presented with a snapshot of the size of the waiting list of each centre in February compared to the size of the waiting list at successive month. In addition to that information, some centres closed early on in the pandemic and those centres patients were still listed as active which cannot give a full picture but the information in May and June showed patients that were suspended if they were closed.

In February, 62% of patients were in the white ethnic group and 35% were BAME. In June that had decreased to 24%. A lot of the centres that were closed back in June were centres in London who typically account for a high proportion of BAME patients. Since June many of the centres have opened up and by the end of October were up to 77% compared to February. The breakdown by ethnic group was the same as it was back in February.

Looking at the other characteristics in terms of median age who were activated decreased to 51 in June which has increased but not quite at the level as seen in February. Other characteristics noted not much change across the sex and blood group over the last few months and for primary disease for diabetes went down to 12% compared to 15% in February.

Exceptional allocation request – A Barlow

An exceptional allocation request regarding a patient in Leeds was presented to the group. The patient has had a pro longed ITU stay and has had their forearm on both sides amputated and full foot amputations. The patient has recovered a degree of renal function and GFR has been hovering between 15 and 20 over the course of the last year. The patient is highly sensitised with a CRF has run between 69% and 90% on antibody screening. The patient has a young family and the absence of hands has an impact on the quality of life and has therefore been listed for a bilateral hand transplant and has also been listed for a kidney transplant. The hands and kidney will need to be acquired from the same donor. A Barlow asked if the patient could have priority from a suitable kidney donor. No members objected to this patient being listed as a priority. The practicalities of listing this patient will be discussed offline.

M Robb asked as more patients are being transplanted in a different centre due to collaborative working, how would that patient be accounted for in terms of reporting. R Ramanan suggested that the 30 day outcome are badged with the centre that performed the transplant and anything beyond 30 days can be badged against the centre that cares for the patient. Members are happy with this suggestion.

I Saif has been representing Plymouth for over 3 years and will be handing over to Keith Gratez from Portsmouth in the New Year. R Ramanan thanked I Saif for his time and expertise given to KAG.

17. Date of next meeting:

Wednesday 9th June 2021

Tuesday 23rd November 2021

18 FOR INFORMATION ONLY

18.1 Update on KAG Offer Review Schemes – KAG(20)27

High quality deceased donor kidney's that have been discarded are flagged with C Callaghan and on occasion C Callaghan will write out to colleagues requesting further information for why the organ was declined. This scheme has been suspended due to the pandemic and will remain suspended until the New Year.

18.2 Statistics and Clinical Studies Update – KAG(20)28

Noted for information.

18.3 Infant Donors Update – KAG(20)29

Noted for information.

18.4 Liver and Kidney Registrations - KAG(20)30

Noted for information.

18.5 12 month review of Kidney Offering Scheme – KAG(20)31

It was acknowledged that the 12 month review paper was not a true review due to the change of activity and is a 12 month activity paper that has excluded the time period from 30 March 2020 to 16 June 2020 when the process deviation was in place. As this is not a true review another review will take place in autumn next year.

18.6 Transplant Activity report: October 2020 – KAG(20)32

Noted for information.

18.7 QUOD statistics 2020 report – KAG(20)33

S Cross advised that QUOD restarted at the end of July and is going well. The scheme is averaging around 50-70% of expected donors per week. There have been a couple of incidents as noted earlier within the Governance report. An audit of the biopsy size has started and is in the analysis stage and hopefully will have some analysis to report at the Masterclass and will report on this at the next KAG.