NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION AND TRANSPLANTATION

MINUTES OF THE ELEVENTH MEETING OF THE LIVER PATIENT GROUPS AND OTDT HELD ON WEDNESDAY, 8TH JULY 2020 AT 11.00 AM VIA MS TEAMS VIDEO CONFERENCING

Present

John Crookenden	Co-Chair - Liver Patients' Transplant Consortium & Addenbrooke's Liver Transplant Association
Doug Thorburn	Chair LAG
John Forsythe	Medical Director, ODT, for NHSBT
Joan Bedlington	LIVErNORTH
Martin Boughen	Living Liver Donor
Ann Brownlee	AIH Support Group
Christopher Bryon-Edmond	iLIVEiGIVE
Rachel Halford	CEO Hepatitis C Trust
Tess Harris	Chair – Polycystic Kidney Disease Charity
Pam Healy	CE British Liver Trust
Sarah Matthew	Lay Member
Neil McClements	Haemochromatosis UK
Maxine Tapp	PSC Support
Robert Mitchell-Thain	PBC Foundation
Linda Turnbull	LIVErNORTH
Helen Morement	CEO Cholangiocarcinoma Charity
Martine Walmsley	PSC Support
Valerie Wheater	Wilson's Disease Support Group UK
Rhiannon Taylor	Statistician, NHSBT
Bruce Willan	NHSBT Corporate Communications

In Attendance: Kamann Huang ODT

ACTION

1 Apologies

Alison Taylor – Children's Liver Disease Foundation
Janet Atherton – St James's Liver Transplant Support Group
Brian Dean – Chairman of Addenbrooke's Liver Transplant Association
Fiona Hale - LIVErNORTH
Ian McCannah – Royal Free Hospital Liver Transplant
Richard Pitman – The Transplant Games

2 Minutes from the last meeting – 11 July 2019 – LPG(19)1

The minutes of the last meeting held on 11th July 2019 were agreed as an accurate record.

J Crookenden expressed his thanks on behalf of the charities, to NHSBT and the liver transplant centres, for their speed and hard work in overcoming problems to maintain a liver transplant service during the COVID-19 pandemic.

3 COVID-19 impact on organ donation, shielding, recovery programme and second wave planning

https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19002/pol296.pdf

Work has started two weeks ago to plan for managing a second wave for all solid organ donation. It is impossible to predict how the second wave will affect us but it is anticipated the virus will appear more as a cluster and will be district based. Statistical modelling has already started to understand what the next wave would look like. Sub-groups have been set up to help with the planning document in draft form. Key sections of the documents will include e.g. an early warning system, changes to donor criteria, donor and recipient testing, PPE, waiting list management and how to avoid the closure of units. Patient and lay member representation will be included in these discussions, for both the organ and donation side, and will provide an opportunity for specific items to be patient focused. It is hoped that the final document final will be received by next week, Tuesday 14th July and further consultation will be sought.

D Thorburn will work with J Crookenden and A Taylor and consult as quickly as possible to deal with rapidly changing situations.

Two key questions were discussed around a second wave. (1) Patients to be given the choice of whether to stay with their existing centre or move their care to another transplant centre. Initial plans have looked at e.g. if Kings were to shut down to allow the patient to be transported to Leeds. Cases of recipients from N Ireland undergoing transplant have already taken place in London. (2) How long should a transplant centre be closed before a patient is transferred for treatment to another centre? These two questions will require a huge amount of work and safety issues to be looked at. Patient and Lay Member representation will be sought in these discussions and the emphasis will be on rapid turn-around of communications. This could be via the weekly COVID-19 meeting and emails requiring a response asap could be entitled with a heading 'Rapid Answer Required'.

PSC Support stated that treatment at another centre was a good idea provided all the required patient information was given to the new centre. D Thorburn reported that a passport would be created holding all the relevant patient information. The two issues and the inclusion of a Patient Representative and Lay Member will be raised at the weekly COVID-19 transplant meeting on Thursdays. **D Thorburn**

The question was asked what the difference between a Patient Representative and a Lay Member was. The position of a Lay Member is advertised and should hold an unbiased viewpoint. A Patient Representative is usually someone who has been a patient or is closely attached to a patient journey.

In response to the concern raised about some immuno-suppression drugs being in short supply following Brexit and what can the government do to deal with this, J Forsythe stated that there is no formal process for this. At the beginning of the pandemic there were two or three drugs in short supply and in one case, NHSBT were fortunately able to provide dialysis fluid for kidney patients. Should patients face any problems with a shortage of drugs NHSBT are happy to step in and assist if possible.

Shielding

Advice on shielding which is scientifically based from the government was reported to be generic and did not address specific vulnerable patient groups. J Crookenden reported that receiving a letter from the DoH and

asking the patient to call the GP if there were any doubts was not at all helpful as a GP would not have the expertise knowledge regarding transplantation. J Forsythe stated that NHSBT were not always part of the government decision making around COVID-19 and acknowledged that at times the communication has been confusing. The three main vulnerable liver patient groups remain as patients with immuno-suppression, patients with cirrhosis and patients actively waiting for a liver transplant. Guidance will be broad as it is difficult to narrow this down to take into consideration every individual family's home environment and work status.

J Forsythe informed patient groups that it is hoped that there will be a risk analysis tool available to enable individuals to enter their own data to predict the likelihood of which vulnerable group you would fall into and the risk factor, but he had not heard any further information

P Healy, British Liver Trust, stated that as an organisation they had written many letters to all the chief medical officers and has had some success in being able to get conformity of information for the decompensated liver and to influence the Scottish Government to allow the BLT to advise their patients on shielding.

There are plans for the development of a badge regarding shielding i.e. a badge with a symbol asking the public to respect social distancing but this will not be available until the Autumn. P Healy will share this with the Liver Transplant Consortium. **P Healy**

D Thorburn stated that there is a problem that the true extent of the virus will not be known owing to the true risk being altered from people shielding from the start, those who have had symptoms and stayed at home but not reported it and on a national level, different recording methods for COVID-19 deaths between countries.

As a result of a conversation with the Chief Medical Officer, individual clinicians can now advise individuals and to weigh up their own risk. However, this has not been happened within England but it is anticipated that approval will have been given by the second wave.

J Crookenden will draft a letter next week to provide patient support for the convalescent serum. **J Crookenden**

PSC reported that they had written, on behalf of the Liver Transplant Consortium, in support of research for the use of machine perfusion looking into whether it would be best operated centrally or through individual hospitals. D Thorburn stated that currently machine perfusion is available in six out of the seven liver centres; the liver centre in Scotland have yet to get their programme up and running. Implementation has been through local business cases via the individual centre and most centres are now using it to assess livers that are marginal.

Cambridge and Edinburgh are championing the use of NRP (circulation maintained in the body to perfuse organs while being retrieved) in DCD. This technology will increase the supply of organs for transplant and NHSBT will work on a programme to maximise the utilisation of these organs. It is anticipated that consent will be higher. Any contributions of support from patient groups would be welcome on this. It was stated that we are still on a learning curve regarding machine perfusion with limited information and understanding, and in what circumstances you should use it e.g. which donor would most benefit and which donor could you have transplanted without machine perfusion. England is at the forefront of this technology compared to other countries.

Backlog

Transplant activity and registrations fell off during the pandemic. At its peak, transplants went down to 3 compared to 19 transplants being undertaken normally. The number of patients registered were very low for March and April whilst centres were not keen to bring in patients owing to the fear of the transmission of COVID-19. A weekly COVID-19 meeting was set up during the pandemic and donor criteria changed to restrict transplants to high urgency patients. A spike has not been seen in the waiting list and the backlog of patients are now being worked up.

Assessment

The trigger points would be to undertake the assessment from referral within 6 weeks maximum. If the transplant cannot be undertaken at the existing centre, to offer transplantation at another centre within a period of 6 weeks and for a final decision to be made within 4 weeks as per the existing quality indicators. The patient groups were in support of this process.

4 Transplant Activity – LPG(20)

This data has not yet been published as the report is not published until the end of the month.

Summary points are:

- Transplant activity for the last ten years (2019-2020) for deceased donors on the active transplant waiting list showed there has been a 21% decrease in the waiting list, a 56% increase in donors and a 39% increase in transplantation. The number of donors and transplantation has slightly decreased compared to the same time last year.

- The number of deceased and living donors over the last ten years show a 49% increase in DBDs, 70% increase in DCDs and a 4% increase in living donors.

- Over the last ten years there has been a 9% decrease in the waiting list but a slight increase over the last three years since the NLOS.

- The number of patients active on the waiting list by centre (7 adult centres and 3 paediatric centres) ranged between 22 at Newcastle, 128 at Birmingham and for paediatrics the numbers ranged from 7 at Leeds and 21 at King's College. Median waiting time was 65 days for adults and 77 days of paediatrics.

- Post registration outcome for new registrations between 2017 and 2018 showed 66% were transplanted within 6 months and this increased to 82% two years post-transplant. The percentage for patients who had died or were removed was 7% within the same period?

- For 2018 to 2019, under NLOS, the percentage was 65% transplanted within 6 months, 74% within one year and the mortality rate was 5% at 6 months and 7% at one year.

- For the 6 months registration outcome for patients registered in 2018/19, transplant activity ranged from 53% within 6 months at Newcastle and 74% at Cambridge. The percentage died or removed ranged from 2% within 6 months at Edinburgh and 8% at Newcastle.

- Over the last 10 years there has been a 31% increase in DBD liver transplantation and a 70% increase in DCD liver transplantation and a slight decrease in living donors. There were 18 living donor transplants last year.

- There has been variation in the number of liver transplants by centre. Royal Free has increased from 47 in 2010/11 to 141 2019/20. Newcastle undertook 35 in 2010/11 to 48 in 2013/14 and performed 36 transplants in

the last financial year. Leeds decreased from177 in 2017/18 to ?? (door creaking in background).

- A similar pattern has been seen for first deceased liver transplants for adults. There has been an increase in the Royal Free, a slight increase in King's and over time for Birmingham, though there has been a decrease in the last year. There has also been a fall in Edinburgh which is currently being investigated.

- For paediatric deceased liver transplantation in the last financial year, King's performed 23, Birmingham 26 and Leeds 12.

- The mean donor age was 50 years of age, the mean transplant recipient age was 49 years and the mean age for patients active on the waiting list was 45 years.

- Of the number of transplants undertaken for 2019/20, 90% were first grafts; 87% on the waiting list are active for first grafts and 13% are active for re-grafts.

- Patient survival rates from first elective liver transplant by centre (risk adjusted). The majority showed no significant difference between centres, though Cambridge's one-year survival rate is slightly higher than the national average. Survival rate data is currently being looked at.

- Primary disease from point of transplant. The national one-year unadjusted survival rate was 94% and ranged between 89.6% for other diseases to 96.1% for alcoholic liver disease.

- Patient survival from point of registration at NHSBT, for 2008/2019. Three centres were within competency intervals?, two below and one above. The one centre above the competency interval indicated it had a slightly higher survival rate from listing.

- Survival from point of transplant for SU patients. All centres were within the 95% competency interval level apart from Birmingham.

<u>Impact from COVID-19 on liver transplantation</u>

NHSBT made changes to donor ages to alleviate pressure on NHSBT resources.

Timeline of the steps taken during the pandemic:

11 March – pandemic declared by the WHO
27 March – centres could consider a named elective offer for any patient rather than a named patient only. Patients with a high UKELD or an HCC indication close to their limit were prioritised and deemed as clinically urgent patients. Patients requiring a liver and cardiothoracic transplant were also reviewed.
3 April – weekly COVID-19 transplant teleconference calls were held with all the seven liver transplant centres to review offering data for all livers offered within the UK.
7 May – centres formally notified NHSBT their clinically urgent patients.
9 July – named elective patient offering to restart i.e. going back to NLOS. All patients deemed non clinically urgent will come back onto the active waiting list.

- For March 2020, 124 livers were offered for transplant, 70 retrieved and 67 transplanted. For April, the numbers had decreased to 47 livers offered, 34 retrieved and 26 transplanted.

- For June, 105 livers were offered, 78 were retrieved and 73 transplanted. Our figures have now returned back to 2019 transplantation data before COVID-19.

- For DBD and DCD transplantation. Over the last three months, DBD have sharply increased to 74 retrieved (10 retrieved and not transplanted) compared to 20 not retrieved and transplanted for the same period last year. DCD transplant numbers have not returned to the numbers prior to COVID-19 with 31 livers offered last month, 12 retrieved and 9 transplanted. However, the number of transplants for June 2020 show that we have returned to our previous numbers prior to COVID-19.

- COVID-19 did not really affect paediatric patients but did for adults.

- All liver centres remained open during the COVID-19 period.

PSC thanked NHSBT for the good communication shared with the patient groups. This was supported by all the patient groups in attendance.

J Forsythe stated that it had been a huge effort from the whole team in the whole chain from the organ donation to the transplantation pathway to keep this going during COVID-19. The slides demonstrate that we have not had a U shape recovery but a V shape recovery which is very impressive. This has been due to the clinical group (a wide group of multi-disciplinary groups) meeting on a regular basis and reviewing decisions that needed to be taken. This enabled us to move things much faster e.g. making a change to the allocation process on a Friday afternoon to be in place by Monday. At the same time there were Clinical Team Meetings with Commissioners all around the country at the height of the pandemic informing them of the clinical team decisions made by NHSBT. This enabled a good collaborative approach and communication between all the relevant parties. We were also able to limit negative media reports regarding the sharp decrease in transplantation numbers by reporting on steps implemented to prioritise clinically urgent patients and highlight that all the liver transplant centres were able to stay open and maintain a transplant service. The next stage now is to plan for how we deal with a second wave.

5 Max and Keira's Law – the Organ Donation (Deemed Consent) Act

J Forsythe reported that there was concern expressed by clinicians and patients for the government to pass Max and Keira's Law in England during the height of the pandemic, as it was felt by some that the legislation would cause a distraction in dealing with COVID-19. J Forsythe met with many politicians to discuss this at length beforehand and the legislation was passed through parliament on 20th May. It was recognised that we may not be able to make best use of this legislation until the virus is under control. However, overall it was felt that the legislation is a positive move forward for organ donation.

For Scotland, enactment of the legislation will be a date in early 2021 and discussions are still ongoing in N Ireland though they are showing to be more in favour.

PSC reported that communication regarding the legislation had been done very well, though Haemochromatosis UK stated that whilst the communication was clear in England and Wales it was not clear for Scotland and N Ireland. J Forsythe commented that NHSBT were not in charge of the publicity and acknowledged that the legislation had progressed at different speeds in the United Kingdom.

6 National Liver Offering Scheme (NLOS)

The NLOS has not been operating in the last three months owing to the pandemic but the plan is to re-active it on 9th July. During the pandemic, we were able to maintain national liver offering with all centres open, with some restrictions at the peak, with great success. Whenever a donor was available, the organ was utilised for a HU or SU patient.

The two years report reviewed at LAG in May showed that over the first two years of the scheme there was a reduction in mortality on the waiting list from 10% pre scheme to 7% post scheme with no impact on patients after transplantation.

The 24 months report was reviewed at the Monitoring Committee in April and to LAG in May. The 30 months report will be reviewed at the Monitoring Group's next meeting in October. The Monitoring Group had been meeting on a quarterly basis to review the data but as there has been no key changes seen over the last year with the same issues arising, it has been agreed to hold future meetings every six months.

The main issues were the reduction in transplants in HCC patients with less access to DBD offers. It was believed that this was due to NLOS over estimating HCC patients' survival without a transplant. The second issue was patients on the waiting list at the start of NLOS seemed less likely to have a transplant, than those added on the list after, and there was an increase in the offering of livers being fast tracked across the country. The number of livers being converted to transplants is in part due to less DCDs being retrieved. The other was the reduction in transplants for HCC patients which is being addressed by a Fixed Term Working Unit looking at reworking the TBS parameters. It was found that the longer waiting time for patients added to the waiting list after NLOS was not solely as a result of the scheme itself but in part down to centres requiring a specific organ for certain types of patients.

It was reported that a review of the 30 patients active on the waiting list since March 2018, deemed clinically urgent by centres, 6 were deemed to be urgent and 28 not clinically urgent.

An area of work looking at the retrieval of DCDs by P Gibbs was halted owing to the pandemic, but it is hoped that a report will be presented at the next LAG meeting in November.

Although recommendations have been approved, a lot of the changes cannot be operational until it has been implemented by an IT change and this in turn cannot happen until the NLOS parameter issues have been addressed.

J Crookenden re-raised the question why a patient listed in 2009 and another in 2014 for end stage liver disease are still waiting for a transplant. It was not possible to comment on individual cases but there are a range of reasons e.g. patients with previous scarring or a patient requiring two or three surgeons to undertake the transplant will extend the waiting time.

Post meeting note:
As many of you will know, we have had a change to liver offering since the start of April this year and we have now agreed with the liver centre directors to return to the NLOS. We are hoping to progress this on Thursday 9th July 2020. The plan is that any patient that you wish to consider for transplantation should be re-activated on the 9th July after 10:00. During the re-activation NO matching runs will be undertaken to prevent some patients being either advantaged or disadvantaged during the switching period. We will need to make a decision on the day regarding

donor activity – therefore no patients should be re-activated until there is formal notification on the day of change. We will work closely with all recipient centres to support the teams during this change over period.

7 Fixed Term Working Units Update

D Thorburn thanked those members of the Transplant Consortium for agreeing to assist in the work of these groups.

Three new indications have been approved at LAG for liver transplantation.

Acute and chronic liver failure (decompensated cirrhosis). Led by W Bernal. This looked at prioritising these patients to ensure they get offers as the window for transplanting is within three months if they deteriorate. The work has been completed and is awaiting an IT change.

(1) Neuroendocrine Tumours Led by N Heaton. The Milan programme has indicated an 88% survival for those patients undergoing the transplant. As this is a new indication, the proposal is to run the programme with national oversight, protocol and follow up. Terms of Reference will also be drawn up. It is proposed that all centres will undertake the new indication for transplantation provided they meet the protocol and specification to do so.

(2) HCC (Hepatic Cholangioarcinoma)
Work on this has progressed to looking at the minimal listing criteria for patients with HCC, as the upper limits for registering patients are known, but not the minimal. This is being led by A Suddle and A Marshall. It was not possible to give a time frame to the Cholangiocarcinoma Charity of when patients will be eligible to be transplanted under this indication. A letter of proposal has been submitted to each centre requesting how they will register patients. A proposal for this indication has been requested for discussion at LAG in November. H Morement will communicate with N Heaton directly. **H Morement**

(3) HPS (Hepatic Pulmonary Syndrome) - Led by J Leithead
Work will look at prioritising patients with HPS whereby the condition of the lung determines their prognosis on the waiting list rather than the condition of the diseased liver to ensure they get a timely transplant.

Fast Track
This has been signed off at LAG and remains as an IT change yet to be undertaken.

Liver splitting
This has been signed off at LAG and remains as an IT change to be implemented.

HCV positive transplants into HCV negative recipients
As at February 2020 there have been 45 donors. Only King's remain as an unapproved centre. Approval for a centre to undertake this type of transplant needs to go through David Mutimer.

Protocol and dataset for machine perfusion - Led by C Watson.
All centres were keen to take part in the trial period for machine perfusion for six months. The data collection will require an IT change to change the dataset on the form and will record what happens once the organ is transferred to the implanting centre. The transplant record form will need to be reviewed to establish what additional information will be required for livers that are machine perfused.

8 Liver splitting and Paediatric Transplantation

Nationally, ninety paediatric transplants are undertaken per annum. Approximately one third or less are from paediatric donors and the rest are from split livers.

From the weekly COVID-19 meetings during the pandemic, we have seen fantastic collaboration and sharing of livers between the three paediatric centres. For HU recipients, where livers have been split at a centre, the lobe that could be retained has been offered to another paediatric centre to enable their HU paediatric patient to be transplanted who would not have survived for more than a few days. The three paediatric centres could not agree on prioritisation of criteria within a specific tier of the offering system for transplanting HU paediatric patients during COVID-19 but did agree on ways of assuring HU patients could be prioritised amongst the paediatric centres.

The new splitting criteria that had been defined before had resulted in one quarter of the livers being split i.e. a very low level of splitting that met the criteria and approximately 20% of livers split nationally fell outside the national criteria. With the new criteria, we hope to be more specific in identifying livers that can be split to enable more left lobes to be offered to paediatrics and less disruption of offering to adults. The final criteria have been produced and signed off in May and now requires IT to support the changes. However, the IT changes cannot be undertaken until we have refined the NLOS issues.

One of the concerns for paediatric transplantation from the new offering criteria for split livers is that the process will extend the CIT in transporting the livers up and down the country. We created three paediatric zones so that livers would be offered to those centres, within their zone first, to minimise travel and CIT. This will enable improved transplantation for paediatrics and for the right lobe to adults.

9 Organ Utilisation

This area of work has been implemented with kidney transplantation first. There has been a delay looking at livers due to COVID-19 and C Callaghan leading this work has been redeployed during the pandemic.

Criteria was drawn up to assess what was an excellent organ. This provided a benchmark so that if centres turned down organs, the centre director would be required to explain whether it was due to a clinical issue or a resource issue e.g. a centre declining an organ due to a lack of resource e.g. unavailability of an ITU bed. In future, more detailed information is required for the reason the organ is turned down.

10 AOB

One of the two British Liver Trust Group patient representative positions is due for renewal. The position is currently held by Vanessa Hebditch. It was confirmed that a current representative can be re-elected. M Walmsley will circulate information on how to vote and details of the role. **M Walmsley**

Results of the PSC survey on liver patients' rehabilitation pre after transplant can be viewed on their website.

The transplantation guidelines meeting was cancelled. A request for volunteers was made, some representatives came forward but have not responded. LIVErNORTH are now assisting in this work. The cost in writing transplant guidelines is around £5000K. It was stated that it was not appropriate to go to pharmaceutical companies, which are commercial

organisations, and the question was put to patient groups to support the cost. The consensus was that charities' funds are already depleted and charities should not be asked to bear the cost. It was suggested to explore the NHS charities' funds. N McClements will liaise on this issue with M Walmsley.

N McClements/ M Walmsley

T Harris requested if polycystic liver disease patients, who are part of PKD, could have their conditions added to the waiting list. This would be around 25-30 patients as we are getting more of these patients being registered now. R Taylor will look at the data in the Annual Report to see where they are included.

R Taylor

11 Date of next meeting: To be confirmed

July 2020