# ORGAN DONATION AND TRANSPLANTATION DIRECTORATE – NHS BLOOD & TRANSPLANT NATIONAL ORGAN DONATION COMMITTEE (NODC) MEETING MEETING DATE: Tuesday 10 November 2020

### **MINUTES**

		MINUTES
Attendees		
Dr Alex R Manara (Chair)	AM	National Quality CLOD
Miss Jo Allen	JA	Performance and Business Manager, ODT, NHSBT
Ms Cliona Berman	CB	Regional Manager, Eastern
Dr Jeremy Bewley	JBe	Intensive Care Society Representative
Dr Tom Billyard	TB	Regional CLOD, Midlands
Prof Stephen Bonner	SB	Royal College of Anaesthesia Representative
Dr Chris Booth	СВо	Regional CLOD, North West
Ms Jackie Brander	JBr	Lead Nurse, Service Delivery, NHSBT
Ms Chloe Brown	CBr	Statistics & Clinical Studies, NHSBT
Dr Helen Buglass	НВ	Regional CLOD, Yorkshire
Ms Becky Clarke	BCI	Regional Manager, South Central
Mr Andrew Davidson	AD	Regional CLOD, Yorkshire
Ms Clare Denison	CD	Afternoon session
Ms Sue Duncalf	SDu	Head of Operations, NHSBT
Ms Laura Ellis-Morgan	LEM	Lead Nurse, Donor Transformation, NHSBT
Dr Katja Empson	KE	Regional CLOD, South East
Ms Jill Featherstone	JFe	
		Medical Education SNOD Lead, NHSBT
Prof John Forsythe Ms Amanda Gibbon	JFo	Associate Medical Director, ODT, NHSBT
	AG	Organ Donation Committee Chair Representative
Dr Pardeep Gill	PG	Regional CLOD, South East
Ms Monica Hackett	MHac	Regional Manager, Northern
Ms Susan Hannah	SH	Regional Manager, Scotland
Miss Gillian Hardman	GH	NHSBT Clinical Research and Clinical Audit Fellow in
		Cardiothoracic Transplantation
Margaret Harrison	MHar	Lay Member
Dr Dan Harvey	DH	National Innovation and Research CLOD, NHSBT
Dr Alison Ingham	Al	Regional CLOD, North West
Dr Ben Ivory	BI	National Education CLOD, NHSBT
Mr Roderick Jaques	RJ	Statistics & Clinical Studies, NHSBT
Mr Craig Jones	CJ	Lay Member
Dr Iain MacLeod	IML	Regional CLOD, Scotland
Ms Patricia McCready	PMC	Critical Care Sister, St Thomas Hospital
Ms Katy Portell	KP	Organ Donation Ambassador Coordinator, NHSBT
Ms Olive McGowan	OM	Assistant Director of Education & Excellence, NHSBT
Ms Susan Richards	SR	Operations, NHSBT
Mr John Richardson	JR	Acting Assistant Director, OTDT
Ms Rachel Rowson	RR	Regional Manager, London
Mr Antonio Rubino	AR	Regional CLOD, Eastern
Ms Angie Scales	AS	National Lead Nurse for Paediatrics, NHSBT
Ms Margaret Stevens	MS	Afternoon session
Ms Rachel Stoddard-Murden	RSM	Acting Regional Manager, South West & South Wales
Mr Ian Thomas	IT	Regional CLOD, South West
Dr Dominic Trainor	DT	Regional CLOD, Northern Ireland
Dr Andre Vercueil	AV	Regional CLOD, London
Mr Phil Walton	PW	Opt-Out Legislation Implementation, Organ Donation & Nursing
Dr Argyro Zoumprouli	ΑZ	Regional CLOD, South East
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Apo	logies

Ms Liz Armstrong	LA	Head of Transplant Development, NHSBT
Ms Helen Bentley	НВ	Head of Education and Professional Development, NHSBT
Dr Paul Carroll	PC	Regional CLOD, Eastern
Dr Maria Cartmill	MC	British Society of Neurological Surgeons Representative
Ms Joanna Chalker	JC	Regional Manager, South Wales
Mr Ben Cole	BCo	Lead Nurse, Family After Care, NHSBT
Dr Dale Gardner	DG	National Clinical Lead for Organ Donation
Mr Ben Hume	ВН	Assistant Director, Transplantation Support Services
Dr Tariq Husain	TH	Regional CLOD, London
Mr Tim Leary	TL	Regional CLOD, Eastern
Mrs Sue Madden	SM	Statistics & Clinical Studies, NHSBT
Mr John Stirling	JS	Interim Head of Operations, Organ Donation and Nursing
Dr Angus Vincent	AV	Regional CLOD, Northern
Dr Charles Wallis	CWa	Regional CLOD, Scotland
Ms Julie Whitney	JW	Head of Referral and Offering/Hub, NHSBT
Ms Claire Williment	CWi	Head of Transplant Development, NHSBT

### In attendance

Heather Crocombe (Minutes) HC Clinical Support Services, NHSBT

No.		Action
1.	Welcome	
	AM welcomed everyone to the meeting and advised that the meeting was being recorded to assist with Minuting. There were no objections to recording the meeting.	
	AM advised that he has spoken to DG after his recent elective surgery, and he is recovering well. DG hopes to be back at work at NHSBT in around a week, and back to clinical work in three or four weeks.	
	Apologies received	
	Please see above	
	Declarations of Interest (NODC)(20)14	
	There were no Declarations of Interest in relation to today's Agenda.	
2.	Reviews	
2.1	Review of previous Minutes and Decisions Made NODC(M)(20)2	
	The Minutes of the NODC Meeting from 22 June 2020 were deemed to be a true and	
	accurate reflection of the content of that meeting.	
2.2	Review NODC Membership	
	A NODC Membership list was circulated ahead of today's meeting. Please can attendees let	
	AM or HC know if they require any amendments to be made to this.	
3.	Standing Items	
3.1	Performance	

#### **COVID Update**

- We have been keeping a very close eye on what is happening from the impact of COVID and will continue to do so
- We are doing our best to protect the SNOD workforce from having to go back to the frontline during this second wave. Teams are under significant pressure.
- JF shared a graph showing deceased donation statistics as at 10 Nov 2020. We are monitoring data twice per week, and each time the figures come in, they are showing a downturn in donor offers. This is not a surprise given the current situation. We managed to stage a great recovery in July and August and hopefully the same will happen again.
- Only one transplant centre is currently closed this time around, and that unit is looking for alternative premises in order that transplants can continue.
- Our aim is not to redeploy transplant nurses to other areas however they are free to do so if they are available to support different teams during their prescribed working hours.
- Potential donations will very much be looked at on a case by case basis.

#### Performance Report NODC(20)17

#### Key Points – Deceased donors

- Statistics & Clinical Studies predict that we could achieve 134 deceased donors per month (401 per quarter), ie. 1,399 by the end of 2020/21
- During September there were 131 deceased donors, equating to 395 deceased donors in Q2, which approximately matches the Statistical predictions
- Year to date there have been 589 deceased donors. In the rolling 12-month period from Oct 2019 to Sept 2020 there were 1391 deceased donors, resulting in a rate of 20.9 deceased donors pmp.
- In Q1, the ratio of DBD to DCD was 77:23. In Q2, this settled back to more normal levels of 63:37
- Of the Sept patients who were not referred, there were 9 occasions where it was felt there was missed donation potential. This brings year to date total to 27
- The consent rate in September was a respectable 68%

#### Key points – Deceased donor transplants

- Statistics & Clinical Studies predict that we could achieve 334 deceased donation transplants per month in the remaining 9 months of 2020/21
- During September there were 300 deceased donor transplants, equating to 966 deceased donor transplants in Q2
- Year to date there have been 1499 deceased donor transplants. In the rolling 12-month period from Oct 2019 to Sept 2020 there were 3390 deceased donor transplants, resulting in a rate of 50.9 deceased donor transplants pmp.

#### Key points – Living donors

- Statistics & Clinical Studies predict that we could achieve 616 living donors by the end of 2020/21
- During August there were 35 living donors, equating to 70 living donors so far in Q2
- Year to date there have been 97 living donors reported. In the rolling 12-month period from Sept 2019 to Aug 2020 there were 695 living donors, resulting in a rate of 10.4 living donors pmp.

ODR opt-in overrides seem to be rising, and JE is unsure why this is (9 in Sept, 12 in Oct)

#### **Deemed Consent England Update**

#### Key Points:

- PW wanted to acknowledge all SNOD and SR colleagues who have given their time and gone out to provide training to others. Deemed consent is being used in practice exactly as training was given, so that is very reassuring
- Debriefs have been taking place with SNOD and SR colleagues, and they have asked
  whether the same training would be given to intensivists in the future, as that would
  be very useful? Debriefs also show that where the process is followed, families are
  receiving the very best in end of life care
- It is great to have the SNOD in the room during donation conversations, but the
  point was made that the whole process is very much a team approach. SNODs are
  being taken into breaking bad news conversations more and more which is also very
  helpful
- We will be taking this to Congress, which is an exciting opportunity

#### <u>Campaign – Sharing Your Decision</u>

This campaign has been deferred since April/May time so we are really happy to get it launched. 16-34 year olds, Londoners and the BAME community are the target audiences. This campaign is going to be launched in February 2021. The question was raised as to why awareness in London is lower? This is probably because the London population tends to be younger and more ethnically diverse.

#### Pass It On

We have pulled *Pass It On* from specifically being part of the campaign. The area we are heading in is the feeling of regret, where families were unaware of their loved ones' wishes and wish they had known

#### **Deemed Legislation Summary Report NODC(20)18**

This report presents information relating to the introduction of opt-out legislation across the UK and includes data from the NHS Organ Donor Register (ODR) and the UK Potential Donor Audit (PDA). ODR data includes all registrations as at the month end and data are recalculated each month.

The report tracks trends in ODR registrations and deceased donor consent/authorisation rates across the four UK nations following changes in legislation relating to organ donation in the UK. ODR registration data are provided for the Crown Dependencies (Jersey, Guernsey, Isle of Man) but data relating to PDA activity are too small to be published (<5)

#### **Key Messages**

- Opt-out legislation has been implemented in Wales (2015), Jersey (2019), and England (2020). Implementation of new legislation is planned for Scotland, Guernsey and the Isle of Man in 2021
- Scotland has the highest proportion of opt-in registrations on the ODR, 50.2%
- Wales has the highest proportion of opt-out registrations on the ODR, 6.1%. Opt-out registrations remain low in nations without opt-out legislation
- There has been a significant fall in the number of donation decision conversations (family approaches) across all nations in 2020/21 due to the COVID pandemic, although consent/authorisation rates remain consistent
- Northern Ireland and Scotland have the highest deceased donor consent/authorisation rates during 2020/21, 78.9% and 73.1% respectively
- Funnel plots for 2020/21 indicate that deceased donor consent/authorisation rates are not significantly different across the UK nations

•	Separate DBD and DCD funnel plots demonstrate that DBD and DCD consent/authorisation rates are consistent across the UK	
Update	e new PDA	
LEM is	in the process of gathering feedback following the PDA go-live in September 2020,	LE
and wi	ll report back.	
Update	es by Region	
Easter		
<u>Succes</u> :		
•	Organ donation activity didn't stop, even in the peak of COVID phase one. This was	
	down to communication and team working. Bonding between teams has been very	
	important	
•	SNOD involvement in end of life support (bereavement service). SNOD presence	
	over the last 6 months stands at 90%	
Challer	New ways of working (electronic communications)	
<u>Challer</u>		
•	Geography Responding to referrals	
•	Responding to referrals  Shielding colleagues. This has been as much a success as much as it has been a	
•	challenge and worked very well.	
Londo	1	
Succes	<u>ses</u>	
•	Donations continued even if numbers were reduced	
•	The centre had a speedy and successful recovery following the first COVID wave	
•	New ways of working	
•	Maintained Operational Team	
•	ELSE Cluster collaboration	
•	Staff Health + Wellbeing Team Initiatives	
•	Support to Eastern OC rota	
•	Support to wider NHS	
<u>Challer</u>		
•	Health & Wellbeing/resilience/uncertainty/mental health	
•	Travel to Work	
•	Lack of social interaction	
•	Team unable to travel to Home Counties	
•	Maintaining engagement with RC	
•	Hospital offices not compliant with social distancing	
South	Central	
Succes	<u>ses</u>	
•	Performance: Achieved same number of DBD YTD than last year. SNOD presence is	
	highest in UK and historically have struggled with DCD presence	
•	Regional Chair: Bi-monthly calls with collaborative members to support media and	
	comms strategy. Integral part of leadership team to support ODCs	
•	Role of deputy RCLODs to support RCLOD. CLOD reviews complete & successful 1st	
	digital collaborative meeting	

#### Challenges

- Supporting cross cover. Surrounded by 6 teams and provide significantly more cross cover than rest of cluster
- COVID on ICU
- Recent fire on ICU at Level 2 Trust. Evacuation caused broken circuits and ICU staff exposure. Impact for potential donors
- Reduced nursing staff outside of NHSBT may reduce engagement
- New ways of working ie. covering Isle of Wight, staff working from home etc.

The message that South Central is putting out is please keep offers and donations coming

#### Northern/N. Ireland

#### Successes

- Maintaining BAU despite COVID impact
- 30.9 DPM to end Sep, 26 Proceeding donors, matching 2019/20 performance, overall consent rate 78.9%(significant increase on 2019/20), no missed ops for donation
- 1<sup>st</sup> DCD Heart donor
- Moving forward with Legislation change

#### **Challenges**

- COVID Impact: stakeholders' engagement
- Recommencing SR service
- Developing staff/strengthening the team/motivation and resilience

#### **North West**

#### Successes

- High donor numbers during COVID first wave recovery
- September highest donor numbers despite COVID/staff shortages
- Maintained referral rates (40 last week)

#### Challenges

- High COVID testing rate resulting in more staff isolating
- High infection rates in hospitals, making it more difficult to do the PDA
- Ongoing COVID challenges and keeping the team including TMs motivated when social distancing

#### Yorkshire

### Successes

- Continued to facilitate donors through the first wave
- Shortlisted for NT Award

#### Challenges

- COVID
- ND Testing

#### **South East**

#### <u>Successes</u>

- 3rd highest donors pmp in UK at 26
- Improved NDT rate at 85% (lowest region at 78% in 2018/19)
- Large decrease in Coroner declines. One decline in this 6-month period, 14 declines in year 2016/17)
- Effective yearly CLOD reviews which now include Regional ODC Chair

	<ul> <li>Good use of virtual working (CLOD reviews, Team meetings, teaching, Donation Week)</li> </ul>	
	<u>Challenges</u>	
	DCD referral rate 57%, lowest in UK	
	Low BAME consent 36%	
	Improve NDT rate	
	Promote law change	
	• Promote law change	
	NODC Stakeholder Representative Update	
	BACCN	
	<ul> <li>BACCN fully supports (and is very happy to continue such support) organ donation and the education of critical care nurses. This was demonstrated by the NHSBT Workshops at the BACCN Annual Conference in 2019 and the express teaching</li> </ul>	
	sessions recently for OD on the critical care nurse's role	
	If attendees think of anything which they feel BACCN can promote to their members	
	or messages they would like BACCN to put out, please can they contact PMC	
	British Society of Neurosurgeons	
	No update at today's meeting	
	British Transplant Society	
	No update at today's meeting	
	Faculty of Intensive Care Medicine	
	No update at today's meeting	
	Intensive Care Society	
	<ul> <li>Congratulations to NHSBT on winning the ICS Education award</li> </ul>	
	<ul> <li>It was proposed that the State-of-the-Art Meeting take place in October 2021,</li> </ul>	
	however it now seems likely that this will be shifted to June 2022	
	<ul> <li>In December 2020 there is a joint meeting with the Physiological Society focusing on COVID - Lessons Learned</li> </ul>	
	<ul> <li>ICS units across the country are struggling, particularly nurses supporting ICU who</li> </ul>	
	have no transplant experience, so any support that can be given would be greatly appreciated	
	<ul> <li>Pressure on beds with ventilated patients having to wait in A&amp;E</li> </ul>	
	<ul> <li>Issues around visiting and being unable to develop a rapport with relatives</li> </ul>	
	Royal College of Anaesthesia	
	S. Bonner asked if it would be helpful if College and other professional bodies had a joint	
	meeting to look for any solutions to try to help over the next 6 months? SB and AM to	SB/AM
	discuss outside of today's meeting.	
	Royal College of Emergency Medicine	
	KE reported that the pressures in emergency medicine are different to those in other	
	specialties, due to the volume of patients, getting patients onto wards and ICU capacity.	
	Busy hospitals have quite an impact on EM. EM is more focused on managing patient flow and cohorting safely	
3.2	Policy	
	Deemed Authorisation Scotland Update	

	Type A Regulations complete
	Type B Regulations work ongoing
	Public consultation is live, ends November
	Accepting body parts is live
	Masterclass 1 Training online and completed
	Masterclass 2 & 3 Training in progress – online
	Door Drop leaflets with Ministers for approval
	Preview of campaign advert will be shared at November Collaborative
	Length of the Process/Retrieval Time
	Pathway Implementation Group is continuing
	<ul> <li>Length of Process paper was circulated ahead of today's meeting</li> </ul>
	More to report at the next NODC Meeting
	6-Monthly Length of Process Report (for information)
	Paper was circulated for information only, no major points to pick up from it
	Next Strategy
	<ul> <li>Strategy was delayed by COVID but that gave us time to finalise it</li> </ul>
	<ul> <li>Going to Board on 26 November – no issues anticipated</li> </ul>
	Soft launch planned for January
	Perimortem Interventions
	Process continuing, impacted quite badly by COVID
	Draft in progress, update further at next NODC Meeting
	NODC Recommended Terminology – DNC, DND/DBD (choice), DCD
	Death using neurological criteria (DNC) is one option, as is the neurological
	determination of death (NDD). DNC . It was noted that DNC was used by the World
	Brain Death Project and may be the preferable terminology.
	DBD – should this change to DND (donation after neurological death)? We need to
	think about the correct terminology.
	DCD – noted that many countries using DCDD terminology (Donation after
	circulatory determination n of death. In Europe this is also being used by the council
	of Europe although the acronym DCD will continue to be used.
	DG has concerns about increasing the number of letters in an acronym from three to
	four
	For further discussion at next meeting
-	Uncontrolled Lung DCD – Protocol Development NODC(20)21
	Small working group looking at what a potential Uncontrolled Lung DCD project
	might look like
	Ethical and practical concerns to be addressed
	Be brought back at next NODC for discussion
	Unexpected Discovery of Pregnancy during Organ Retrieval – RAG Guidance
	NODC(20)22
	Background  AM shared MRD /8014, setting out what should happen in the event of prognancy being
	AM shared MPD/8914, setting out what should happen in the event of pregnancy being unexpectedly discovered during Organ Retrieval.
	unexpectedly discovered duffing Organ Nethleval.

#### **Recommended Actions**

- 1. Stop retrieval surgery. Retrieval Team stand down
- 2. **Seek immediate support** from the intensive care team and ensure senior clinician involvement, usually an ITU Consultant
- 3. **The donor should continue** to receive the physiological support that was being received at the time the pregnancy was noted. Therefore, DBD donors will continue to receive ventilatory and circulatory support if foetus is viable.
- 4. **A senior obstetric opinion** should be secured immediately, usually the on-call consultant. The objectives should be to establish gestational age, determine viability, and optimise obstetric management of the foetus
- 5. Seek senior outside support SNOD to discuss with Regional Manager NHSBT
- 6. **The SNOD should inform the NHSBT Hub** of events, and the Hub should inform recipient centres urgently
- 7. If the foetus is considered to be viable, the ITU team should inform the Senior Obstetrician
- a. Obstetric intervention must be carried out immediately in case of donor instability
- b. Whether or not the donor and foetus are fully heparinised
- 8. **If NRP is in use,** the ITU team should consult a clinician qualified and experienced in ECMO/cardiopulmonary bypass by phone or in person regarding suitable parameters for the NRP system and appropriate management
- 9. The Obstetric team will now manage the viable foetus as appropriate. Once the foetus is delivered, retrieval could be reinstated
- 10. **If the foetus is not viable,** the Senior Obstetrician must inform the ITU Consultant, who will direct the NRP to stop, or to stop respiratory and circulatory support in a DBD donor.
- 11. Once the foetal heart has ceased beating, and foetal circulatory death has been determined by the senior obstetrician, the retrieval may proceed if the lead NORS surgeon deems it appropriate to retrieve organs and the team are able to retrieve. This may not be possible given the warm ischaemia time. Additionally, team members may no longer be able to participate in the retrieval process. The opinion of the NORS surgeon, supported by the on-call Consultant at the NORS base, as to organ viability and suitability for retrieval will be final
- 12. Speak to the family after the event, Duty of Candour.
- 13. Lodge a clinical incident with local hospital and NHSBT.
- 14. Lodge a clinical incident with the NORS base hospital
- 15. Debrief in theatre at the conclusion of the case (SNOD, NORS team, local staff, ICU)
- 16. Staff in all groups should arrange to meet line managers as soon as possible to discuss and de-brief.
- 17. A group to examine confidentially the details of any such cases should be established.

#### Points made:

- 1. This shouldn't happen in the first place if all screening and characterisation is right
- 2. Decisions about what happens next ultimately will be made by family

Please can attendees read the paper and revert to AM with any comments.

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#### 3.3 Education

#### Medical Education Update NODC(20)23

 Medical Education Team NHSBT became winners in the ICS Award 2020 for Education last month. The award recognised an individual/team who has developed a sustainable education programme to improve patient care. This is great recognition for not just the Medical Education Team but the wider group of

contributors to NHSBT Courses. Anthony Clarkson's letter of congratulations will be circulated to those contributors The National Deceased Donation Course (NDDC) is usually delivered 6 times per year, with 18 delegates attending each session. This course is currently suspended and hasn't run since the last course in February 2020. A new set of courses is planned, commencing in London on February 1/2 2021. Others planned so far are Saltford (March 2/3) Stirling (April 15/16) and Cardiff (June 29/30) CLOD Inductions have been developed online to ensure continued education and networking with new CLODs. The aim is to return to face-to-face inductions in Spring 2021 **Chair Inductions** This course will remain face-to-face unless it is deemed more suitable to be delivered online within Government Regulations at the time Paediatrics The "Child and Infant Deceased Donation Leaders Course" was delivered successfully online in September. The course will be delivered online again in March 2021 AAGBI collaboration evening webinars One has been delivered with more planned for delivery once a month for around 10 months TRODs Current trainee representative for organ donation (TROD), Dr Nicky Crowley, has been supporting paediatric developments Website and e-learning Digital is currently updating the website pages ad hoc with us. No further progress yet on an e-learning platform, and other opportunities are continuing to be explored ACCPs Ben Ivory has been working to seek further opportunities to support ACCPs in their learning NHSBT & BTS Congress 2021 Work continues to develop sessions of education and the keynote presentation. **Specialist Nurse Training Update** No update at today's meeting **Promotion** No update at today's meeting **Community Ambassador Programme** KP reported that the ambassador programme is slowly returning to its previous levels of support and is increasingly using teleconferencing to communicate with recipients and their families. Ambassadors can still be requested as virtual speakers by emailing Ambassadors.ODT@nhsbt.nhs.uk . Ambassador recruitment is sadly paused for the time being, but prospective volunteers could still be referred to Ambassadors.ODT@nhsbt.nhs.uk and their details will be held to inform them the next time we're recruiting in their region (please do help us manage expectations that this might be a while) Joint BTS/NHSBT Congress 2021 See Medical Education update above Commonwealth "Tribute to Life" MOU (for information) https://www.odt.nhs.uk/odt-structures-and-standards/clinical-leadership/commonwealthtribute-to-life-project/ **Working Group/Subgroup Updates** 

4.

4.1

**NODC Statistics Working Group** 

## PDA 2019/20 Report (For information) NODC(20)24

Key points:

- In the year 1 April 2019 31 March 2020, there were 34,235 deaths audited for the PDA. Of these deaths, 1,994 and 6,288 patients met the referral criteria for DBD and/or DCD respectively, and 99% and 91% were referred to NHSBT. Of the 1,994 patients for whom neurological death was suspected, 87% were tested
- Of the families approached, 72% and 65% consented to/authorised DBD and DCD donation. Of these, 89% and 53% respectively became actual solid organ donors. 110 families overruled their loved one's known decision to be an organ donor
- There was no statistically significant difference in the consent/authorisation rates for male and female patients for DBD. There was a statistically significant difference in the consent/authorisation rate between male and female patients for DCD
- There was a statistically significant difference in both DBD and DCD consent/authorisation rates between white and BAME patients and this effect remains after adjusting for patient age, sex and month of patient death
- Since 2015/16, the testing rate for neurological death as well as referral, SNOD present and consent/authorisation rates have all improved. Notably, DBD and DCD referral rates are very high, 99% and 91% respectively. In addition, the DBD consent/authorisation rate has increased to 72% over the five-year period, and the DCD consent/authorisation rate has also increased to a record high of 65%.

#### **NODC Statistics Working Group Update**

Nothing extra to add from the NODC Statistics Working Group, as most points have been discussed at today's meeting.

#### **Conclusion of morning Minutes**

#### 5. Research

#### SIGNET Trial Update

Members viewed a presentation by J Dark about the SIGNET Study. This study was prompted following a study which was published by Karl Lemstrom from Helsinki in 2019. The SIGNET Study received RINTAG approval in October 2020. The Helsinki Study involved 84 recipients, of whom half received organs from donors given Simvastatin, and analysed the outcomes on the heart and the effect on all other organs. It was noted that there was no harm to lung recipients, and Simvastatin may have helped improve outcome, with a halving of PGD rate.

The SIGNET Study is envisaged to start in April 2021 using 2600 adult DBD donors, for a period of 4 years, to be randomised after consent for donation and research to receive Simvastatin 80mg as a single dose. All potential recipients will receive information about the study, with a description of the potential benefits - there is unlikely to be any risk to recipients and the intervention will occur before the potential recipients have been identified so no consent, additional data or samples will be required from the recipients. This will be the largest donation intervention study in the world.

The SIGNET Protocol is under preparation and is in an advanced form.

#### Trial Practicalities

After the diagnosis of death After obtaining consent

	<u>Trial Delivery</u>
	How are we going to get this Study open and recruiting?
	The Study is remarkably simple, and will consist of the following teams/people:
	Study team with REMAP CAP expertise
	PI-ICU Consultants with research experience
	• CLOD
	Research Nurse
	• SNOD
	Trainee Associate PI
	Regional Clinical Research Network Portfolio support
	Regional NHSBT Team support
	Wide ranging discussion with suggestions to study team on how to maximise
	recruitment
	Specific questions on trial protocols were put to the team and will be incorporated
	into the current regulatory review
6.	Any Other Business
	None
	Dates of next Meetings
	Post-meeting amendment to dates:
	- Tuesday 9 <sup>th</sup> March 2021, virtual;
	- June – Face to Face: Tuesday 22 <sup>nd</sup> and Wednesday 23 <sup>rd</sup> June, Birmingham:
	(Day 1 RMs/R-CLODs meeting; Day 2 NODC)
	- Tuesday 9 <sup>th</sup> November 2021, virtual.