POTENTIAL DONOR AUDIT
SUMMARY REPORT FOR THE 12 MONTH PERIOD
1 APRIL 2016 - 31 MARCH 2017

1 INTRODUCTION

This report presents Potential Donor Audit (PDA) information on the financial year 1 April 2016 to 31 March 2017.

The dataset used to compile this report includes all audited patient deaths in UK Intensive Care Units (ICUs) and Emergency Departments as reported by 8 May 2017. Patients aged over 80 years and patients who died on a ward have not been audited. Paediatric ICU data are included however neonatal ICU data have been excluded from this report.

This report summarises the main findings of the PDA over the 12-month period, in particular the reasons why patients were lost along the pathway, and should be read in conjunction with the PDA section of the Organ Donation and Transplantation Activity Report, available at http://www.odt.nhs.uk/odt/potential-donor-audit/.

On 1 December 2015, The Human Transplantation (Wales) Act 2013 became operational in Wales, introducing new legislation for a soft opt-out system for organ donation (deemed consent). More information can be found here http://organdonationwales.org/

2 DEFINITIONS

Eligible donors after brain death (DBD) are defined as patients for whom death was confirmed following neurological tests and who had no absolute medical contraindications to solid organ donation.

Eligible donors after circulatory death (DCD) are defined as patients who had treatment withdrawn and death was anticipated within four hours, with no absolute medical contraindications to solid organ donation.

Absolute medical contraindications to organ donation are listed here:
http://www.odt.nhs.uk/pdf/contraindications_to_organ_donation.pdf

Deemed consent applies if a person has not registered an organ donation decision to either opt-in or opt-out or appoint a representative, is aged 18 or over, has lived for longer than 12 months and is ordinarily resident and also died in Wales, and had the capacity to understand the notion of deemed consent for a significant period before their death.

The consent/authorisation rate is the percentage of eligible donor families approached for organ donation discussion where consent/authorisation for donation was ascertained.
Further definitions to aid interpretation are given in **Appendix 1**.

3 BREAKDOWN OF AUDITED DEATHS IN ICUs AND EMERGENCY DEPARTMENTS

In the 12-month period from 1 April 2016 to 31 March 2017, there were a total of 34,369 audited patient deaths in the ICUs and EDs in the UK. A detailed breakdown for both the DBD and DCD data collection flows is given in **Figure 1 and 2**, and **Table 1** summarises the key percentages.

Figure 1 Donation after brain death

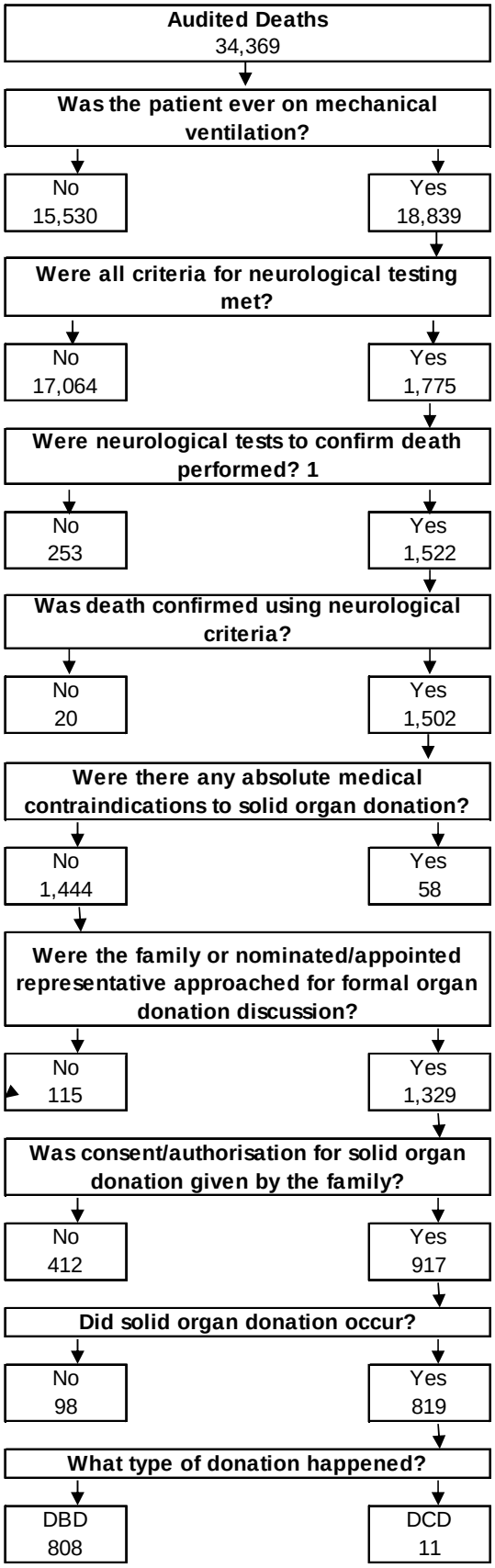
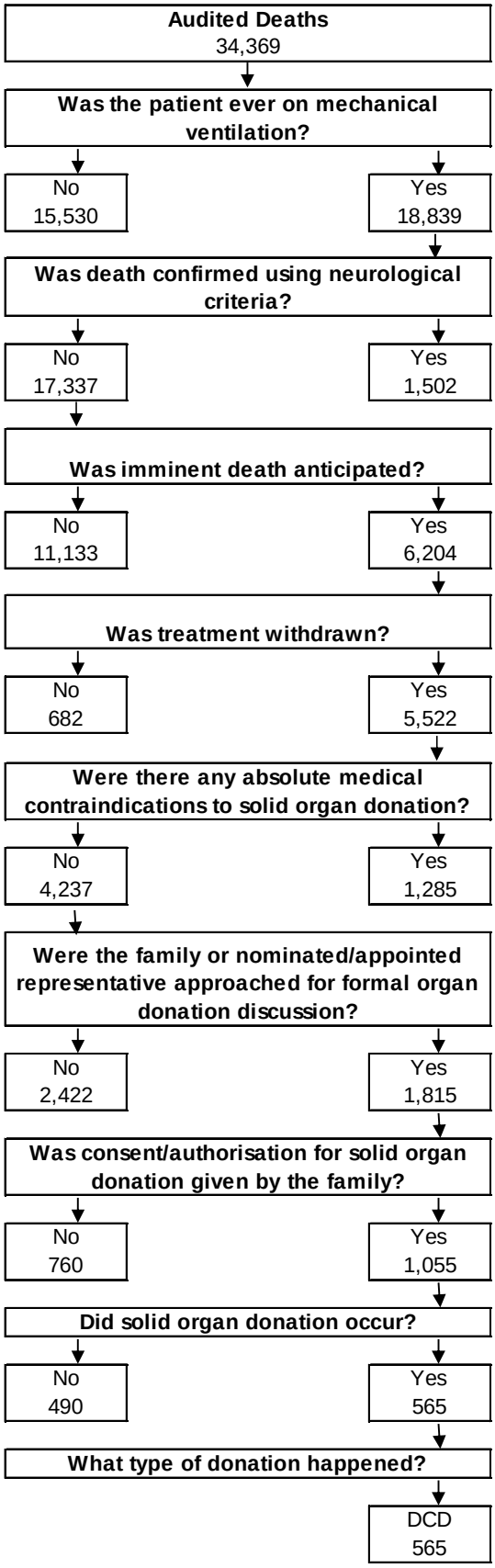


Figure 2 Donation after circulatory death



[1] Patients for whom tests were not performed due to: Cardiac arrest despite resuscitation occurred, brainstem reflexes returned, or neonates – less than 2 months post term are excluded from the calculation of the neurological death testing rate

Table 1 Key numbers and rates

	DBD	DCD
Patients meeting organ donation referral criteria[1]	1775	6204
Referred to SN-OD	1728	5308
Referral rate %	*97.4%*	*85.6%*
Neurological death tested	1522	-
Testing rate %	*85.7%*	-
Family approached	1329	1815
Family approached and SN-OD involved	1236	1460
% of approaches where SN-OD involved	*93.0%*	*80.4%*
Consent/authorisation given	917	1055
Consent/authorisation rate %	*69.0%*	*58.1%*
Actual donors from each pathway	819	565
% of consented/authorised donors that became actual donors	*89.3%*	*53.6%*

[1] DBD - A patient with suspected neurological death excluding those that were not tested due to reasons: cardiac arrest occurred despite resuscitation, brainstem reflexes returned, neonates - less than 2 months post term
DCD - A patient in whom imminent death is anticipated, ie a patient receiving assisted ventilation, a clinical decision to withdraw treatment has been made and death is anticipated within 4 hours

4 NEUROLOGICAL DEATH TESTING RATE

Table 2 Reasons given for neurological death tests not being performed

	N	%
Patient haemodynamically unstable	75	29.6
Clinical reason/Clinicians decision	37	14.6
Inability to test all reflexes	25	9.9
Family declined donation	21	8.3
Biochemical/endocrine abnormality	20	7.9
Continuing effects of sedatives	15	5.9
Other	14	5.5
Family pressure not to test	10	4.0
SN-OD advised that donor not suitable	10	4.0
Treatment withdrawn	8	3.2
Unknown	8	3.2
Medical contraindication to donation	4	1.6
Hypothermia	3	1.2
Patient had previously expressed a wish not to donate	3	1.2
Total	**253**	**100.0**

The neurological death testing rate was 86% and is the percentage of patients for whom neurological death was suspected that were tested. To be defined as neurological death suspected, the patients were indicated to have met the following four criteria - apnoea, coma from known aetiology and unresponsive, ventilated and fixed pupils. Patients whom tests were not performed due to; cardiac arrest occurred despite resuscitation, brainstem reflexes returned, neonates - less than 2 months post term were not possible to test meaning these reasons were excluded. Neurological death tests were not performed in 253 patients (14%) for whom neurological death was suspected. The primary reason given for not testing is shown in **Table 2**.

75 (30%) patients were haemodynamically unstable and were therefore not tested. Other reasons given for not performing neurological death tests were: 37 (15%) patients had a clinical reason or it was the clinician's decision, and for 25 (10%) patients was unable to test all reflexes.

5 REFERRAL RATE

A patient for whom neurological death is suspected or for whom imminent death is anticipated, i.e. receiving assisted ventilation, a clinical decision to withdraw treatment has been made and death is anticipated within four hours, should be referred to a Specialist Nurse - Organ Donation (SN-OD). The DBD referral rate was 97% and the DCD referral rate was 86%. **Table 3** shows the reasons given why such patients were not referred. One patient can meet the referral criteria for both DBD and DCD and therefore some patients may be counted in both columns. Please note that the referral criteria have now changed, see **Appendix I**.

Table 3 Reasons given why patient not referred

	DBD		DCD	
	N	**%**	**N**	**%**
Not identified as a potential donor/organ donation not considered	12	25.5	340	37.9
Medical contraindications	8	17.0	183	20.4
Other	8	17.0	155	17.3
Family declined donation prior to neurological testing	4	8.5	5	0.6
Reluctance to approach family	4	8.5	4	0.4
Thought to be medically unsuitable	4	8.5	156	17.4
Coroner/Procurator Fiscal Reason	3	6.4	2	0.2
Family declined donation after neurological testing	2	4.3	-	-
Family declined donation following decision to withdraw treatment	2	4.3	34	3.8
Thought to be outside age criteria	0	0.0	1	0.1
Pressure on ICU beds	0	0.0	5	0.6
Neurological death not confirmed	0	0.0	1	0.1
Clinician assessed that patient was unlikely to become asystolic within 4 hours	0	0.0	5	0.6
Patient had previously expressed a wish not to donate	0	0.0	5	0.6
Total	**47**	**100.0**	**896**	**100.0**

Of the patients who met the referral criteria and were not referred, the reason given for 26% of DBD and 38% of DCD was that the patients were not identified as potential donors and so organ donation was not considered. The reason given for 17% of DBD and 20% of DCD was medical contraindications.

6 APPROACH RATE

Families of eligible donors were approached in 92% and 43% of DBD and DCD cases, respectively. The DCD assessment process identifies a large number of eligible DCD donors which are unsuitable for organ donation prior to the approach. Consequently, the DCD approach rate is currently underestimated, as families of these patients are never approached for the formal organ donation discussion and the reason for not approaching is recorded as 'Patient's general medical condition', 'Other medical reason' or 'Other'. The information in **Table 4** shows the reasons given why the families were not approached.

For eligible DBD donors not approached, the reason stated in 29% of cases was that the Coroner/Procurator Fiscal refused permission. In a further 25% of DBD cases, the reason stated was the patient's general medical condition.

For eligible DCD donors not approached, the main reasons stated were the patient's general medical condition (39%) or other reason (27%), the majority of these cases are result of the DCD assessment process which identifies patients unsuitable for donation prior to the approach. In a further, 15% of cases, the patient was not identified as a potential donor.

Table 4 Reasons given why family not formally approached

	DBD		DCD	
	N	**%**	**N**	**%**
Coroner / Procurator Fiscal refused permission	33	28.7	45	1.9
Patient's general medical condition	29	25.2	953	39.3
Other medical reason	12	10.4	277	11.4
Family untraceable	9	7.8	33	1.4
Family considered too upset to approach	8	7.0	15	0.6
Family stated that they would not support donation before they were formally approached	7	6.1	66	2.7
Not identified as a potential donor / organ donation not considered	3	2.6	351	14.5
Patient had previously expressed a wish not to donate	2	1.7	19	0.8
Resource failure	0	0.0	2	0.1
Pressure on ICU beds	0	0.0	10	0.4
Patient outside age criteria	0	0.0	3	0.1
Other	12	10.4	648	26.8
Total	**115**	**100.0**	**2,422**	**100.0**

7 OVERALL CONSENT/AUTHORISATION RATE

The consent/authorisation rate is based on eligible donors whose families were formally approached for formal organ donation discussion. The consent/authorisation rate is the proportion of eligible donors for whom consent/authorisation for solid organ donation was ascertained.

During the financial year, the DBD consent/authorisation rate was 69% and the 95% confidence limits for this percentage are 67% - 71%. The DCD consent/authorisation rate was 58% and the 95% confidence limits for this percentage are 56% - 60%. The overall

consent/authorisation rate was 63% and the 95% confidence limits for this percentage are 60% - 65%.

When a patient was known to be registered on the Organ Donor Register (ODR) at the time of approach the DBD consent/authorisation rate was 93% compared to 59% when a patient's ODR status was not known at the time of approach. For DCD, the rates were 87% compared with 46%. Overall, these rates were 90% compared with 51%. In total during the financial year, 100 families overruled their loved one's known wish to be an organ donor.

When a SN-OD was involved in the approach to the family, the DBD consent/authorisation rate was 71% compared with 38% when the SN-OD was not involved. Similarly, for DCD the rate was 66% compared with 25% when the SN-OD was not involved. The overall rate was 69% compared with 27%.

Table 5 Reasons given why family did not give consent

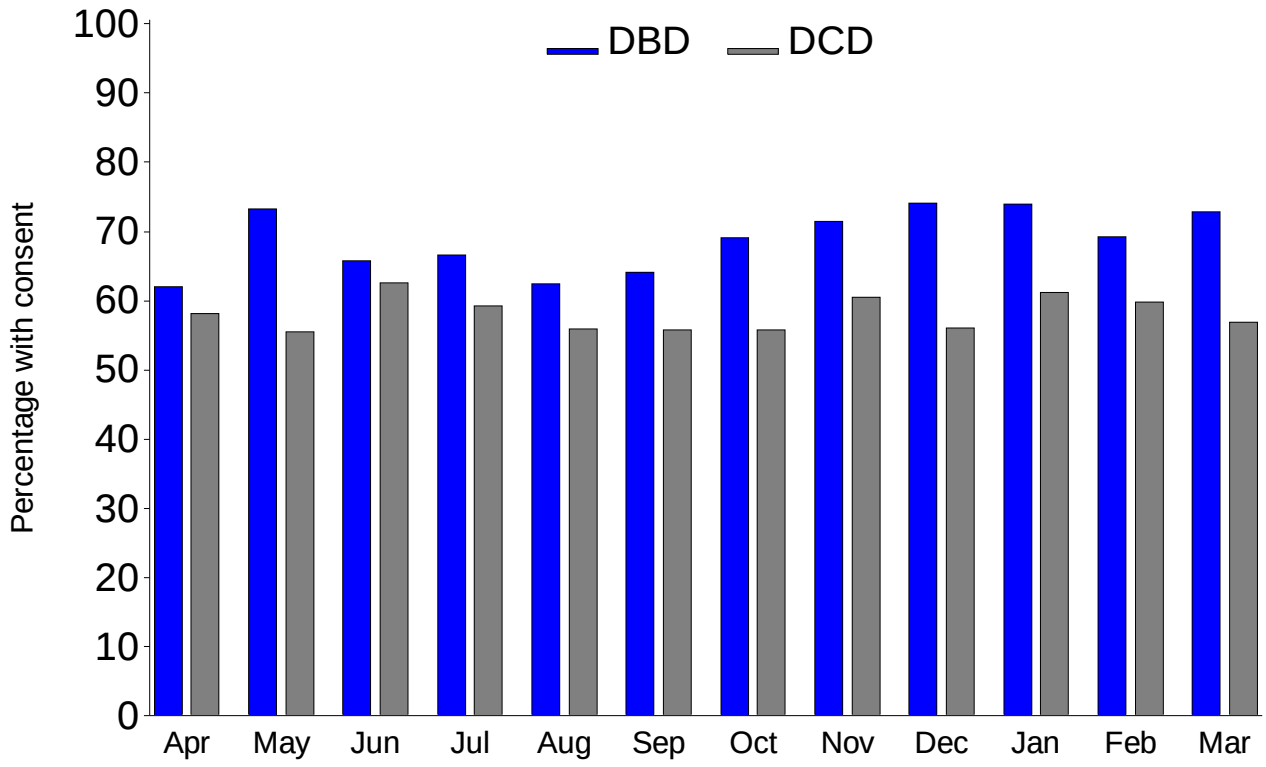
	DBD		DCD	
	N	**%**	**N**	**%**
Patient previously expressed a wish not to donate	83	20.1	162	21.3
Family were not sure whether the patient would have agreed to donation	63	15.3	114	15.0
Family did not want surgery to the body	53	12.9	65	8.6
Family felt the length of time for donation process was too long	19	4.6	125	16.4
Family felt the patient had suffered enough	21	5.1	59	7.8
Family felt it was against their religious/cultural beliefs	45	10.9	21	2.8
Strong refusal - probing not appropriate	27	6.6	39	5.1
Family were divided over the decision	25	6.1	32	4.2
Family felt the body needs to be buried whole (unrelated to religious or cultural reasons)	21	5.1	23	3.0
Family did not believe in donation	20	4.9	23	3.0
Family concerned that organs may not be transplanted	4	1.0	8	1.1
Family had difficulty understanding/accepting neurological testing	3	0.7	2	0.3
Family wanted to stay with the patient after death	2	0.5	11	1.4
Family concerned that other people may disapprove/be offended	1	0.2	0	0.0
Families concerned about organ allocation	0	0.0	2	0.3
Other	25	6.1	74	9.7
Total	**412**	**100.0**	**760**	**100.0**

The reasons why the family did not give consent/authorisation are shown in **Table 5**. The main reason that families of eligible DBD and DCD patients gave for no consent/authorisation was patient previously expressed a wish not to donate (20% and 21% respectively). Other common reasons why the family did not consent were that the families were not sure whether the patient would have agreed to organ donation or they didn't want the patient to go through surgery to the body. Amongst DCD patients, families felt that the length of time for donation was too long.

8 MONTHLY VARIATION IN THE CONSENT/AUTHORISATION RATE

Monthly consent/authorisation rates are shown in **Figure 3**. From this figure it is apparent that over the financial year there is no clear monthly pattern. The DBD consent/authorisation rate was highest in December 2016 (74%) and lowest in April 2016 (62%), whereas the DCD consent/authorisation rate was highest in June 2016 (63%) and lowest in May 2016 (56%). The differences in the monthly consent/authorisation rates from 1 April 2016 to 31 March 2017 are not statistically significant for either DBD or DCD, p=0.42 and p=0.97, respectively.

Figure 3 Month-to-month variation in consent/authorisation rate



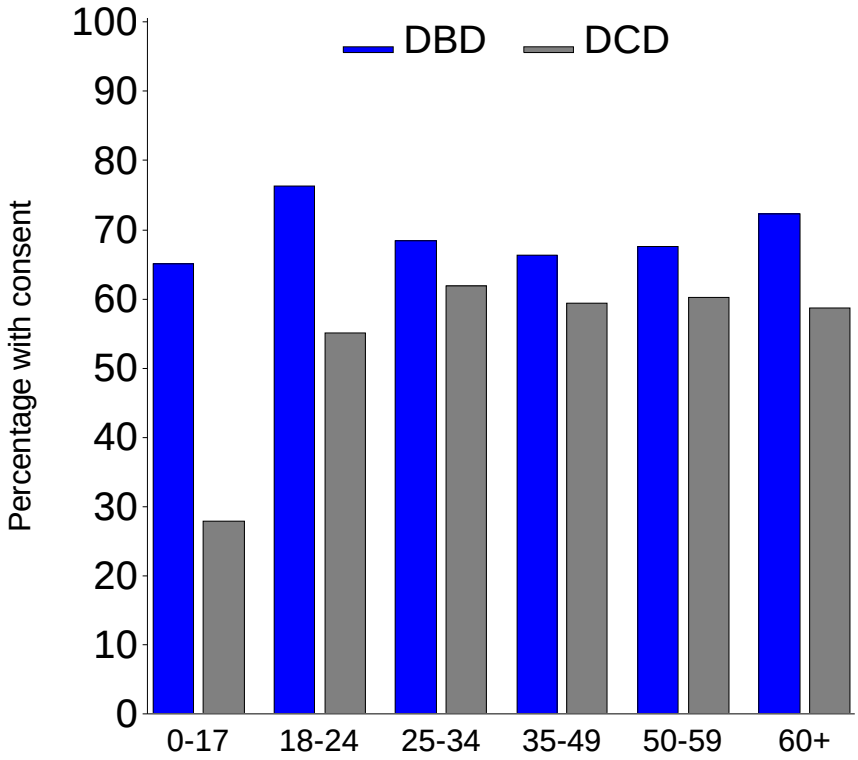
9 EFFECT OF DEMOGRAPHIC VARIABLES ON THE CONSENT/AUTHORISATION RATE

The consent/authorisation rate for the 718 male eligible DBD was 70% and the consent/authorisation rate for the 611 female eligible DBD was 68%. The difference is not statistically significant, p=0.5853. For the 1099 male eligible DCD the consent/authorisation rate was 59% and for the 715 female eligible DCD was 57%.This difference is not statistically significant, p=0.32.

Age is represented by a categorical variable with intervals 0-17, 18-24, 25-34, 35-49, 50-59 and 60+ years. The consent/authorisation rates for the six age groups (for the 1,329 eligible DBD and 1,815 eligible DCD whose families were approached) are illustrated in **Figure 4**. The highest consent/authorisation rate for eligible DBD occurred in the 18-24 age group (76%) and for eligible DCD in the 25-34 age group (62%). The lowest consent/authorisation rate for eligible DBD and DCD was in the 0-17 age group 65% and 28%, respectively. The differences in consent/authorisation rate across the six age groups for DBD are not statistically significant (p=0.38) and for DCD are statistically significant (p=<0.0001).

When comparing only between adult and paediatric (<18 years), the differences in consent/authorisation rate for DBD are not statistically significant (p=0.49) and for DCD are statistically significant (p=<0.0001).

Figure 4 Age variation in consent/authorisation rate



To conduct a meaningful analysis on ethnicity, patients have been categorised as white or in an ethnic minority group and the rates are shown in **Figure 5**. Note that there were an additional 35 DBD and 67 DCD families approached where the ethnicity was not known or not reported which have been excluded from the ethnicity figures below.

For eligible DBD, the consent/authorisation rates were 74% for white eligible donors and 34% for eligible donors from an ethnic minority group. The 95% confidence limits for DBD consent/authorisation rates are 72% - 77% for white eligible donors and 27% - 41% for eligible donors from an ethnic minority group.

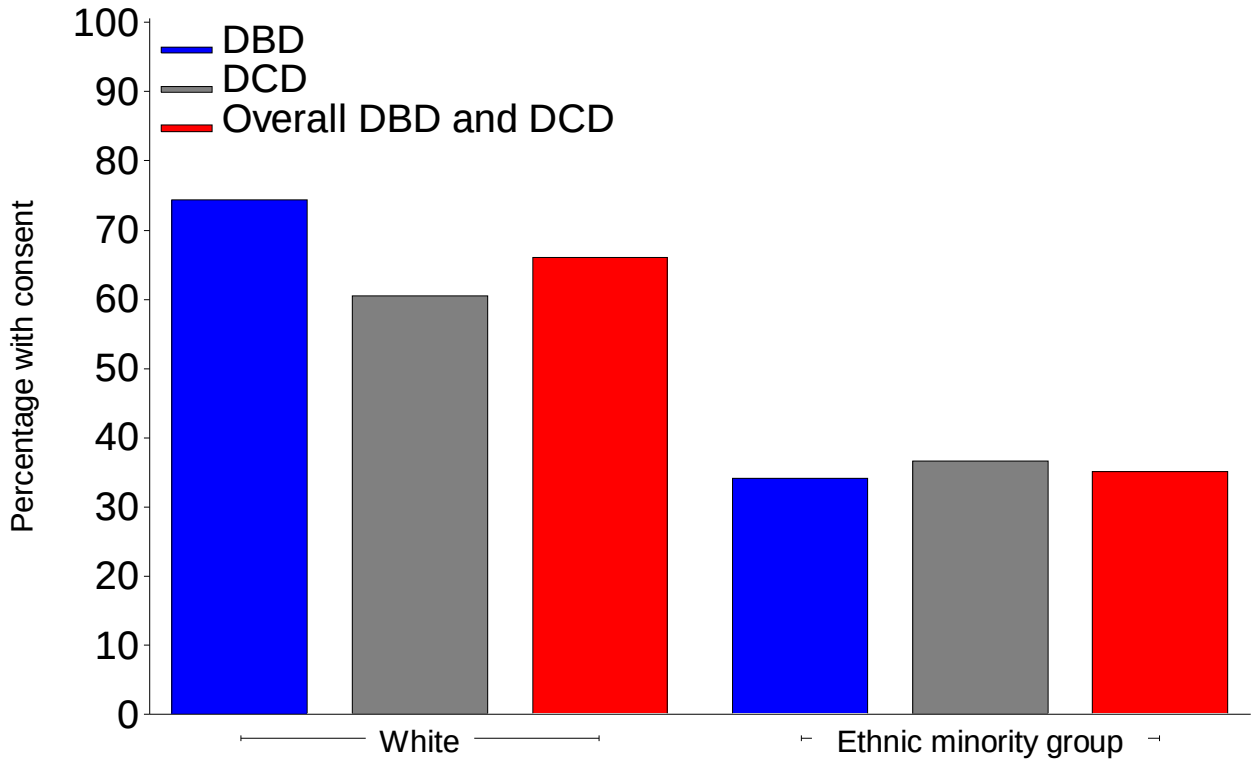
For eligible DCD, the consent/authorisation rates were 61% for white eligible DCD and 37% for eligible DCD from an ethnic minority group. The 95% confidence limits for DCD consent/authorisation rates are 58% - 63% for white eligible donors and 28% - 46% for eligible donors from an ethnic minority group.

The overall consent/authorisation rates were 66% for white eligible donors and 35% for eligible donors from an ethnic minority group. The 95% confidence limits for overall consent/authorisation rates are 64% - 68% for white eligible donors and 30% - 41% for eligible donors from an ethnic minority group.

The difference between consent/authorisation rates for white DBD eligible donors and DBD eligible donors from an ethnic minority group is statistically significant, p<0.0001. The difference between consent/authorisation rates for white DCD eligible donors and DCD

donors from a minority ethnic group is statistically significant, p<0.0001. The ethnicity effect remains highly significant after allowing for age, sex and month of death.

Figure 5 Ethnic group variation in consent/authorisation rate



10 SOLID ORGAN DONATION

Of the eligible donors whose families were approached for organ donation discussion consent/authorisation was ascertained, 89% of the eligible DBD and 54% of the eligible DCD went on to become actual solid organ donors. **Table 6** shows the reasons why consented/authorised eligible donors did not become actual solid organ donors.

For consented/authorised eligible DBD the main reason given for solid organ donation not proceeding was that the organs were deemed to be medically unsuitable by recipient centres in 41% of cases, and 10% was declined due to coroner/procurator fiscal refusal, 10% of family changed mind and 10% was due to cardiac arrest.

Likewise, 29% of non-proceeding DCD organs were declined by recipient centres as they were deemed to be medically unsuitable. The main reason given for consented/authorised eligible DCD not proceeding to become a solid organ donor was the prolonged time to asystole, with 45% cases.

Table 6 Reasons why solid organ donation did not happen following consent				
	DBD		DCD	
	N	%	N	%
Organs deemed medically unsuitable by recipient centres	40	40.8	141	28.8
Family changed mind	10	10.2	18	3.7
Coroner/ Procurator Fiscal refusal	10	10.2	24	4.9
Cardiac arrest	10	10.2	7	1.4
General instability	9	9.2	26	5.3
Other	7	7.1	33	6.7
Organs deemed medically unsuitable on surgical inspection	6	6.1	12	2.4
Positive virology	6	6.1	5	1.0
Prolonged time to asystole	0	0.0	222	45.3
Logistic reasons	0	0.0	2	0.4
Total	**98**	**100.0**	**490**	**100.0**

11 SUMMARY

In the year 1 April 2016 to 31 March 2017, there were 34,369 deaths audited for the PDA. Of these deaths, 1,775 and 6,204 patients met the referral criteria for DBD and/or DCD, respectively and 97% and 86% were referred to a SN-OD. Of the 1,775 patients for whom neurological death was suspected, 86% were tested.

Of the families approached, 69% and 58% consented to/authorised DBD and DCD donation. Of these, 89% and 54%, respectively, became actual solid organ donors. 100 families overruled their loved one's known wish to be an organ donor.

There was no statistically significant difference in the consent/authorisation rates form male and female patients for DBD or DCD. The difference in the consent/authorisation rate across the different age groups was statistically significant for DCD, with paediatric patients (0-17 years) having a much lower consent/authorisation rate than the adult age groups. There was no difference in the age groups for DBD.

There was a statistically significant difference in both the DBD and DCD consent/authorisation rate between white patients and patients from an ethnic minority group and this effect remains after adjusting for patient age, sex and month of patient death.

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NHS Blood and Transplant **May 2017**

Appendix I - Definitions

POTENTIAL DONOR AUDIT / REFERRAL RECORD	
Data excluded	Cardiothoracic ICUs, wards and patients aged over 75 years are excluded.
Donors after brain death (DBD)	
Suspected Neurological Death	A patient who meets all of the following criteria: Apnoea, coma from known aetiology and unresponsive, ventilated, fixed pupils. Excluding cases for which cardiac arrest occurred despite resuscitation, brainstem reflexes returned, and neonates - less than 2 months post term
Potential DBD donor	A patient who meets all four criteria for neurological death testing (ie suspected neurological death, as defined above)
DBD referral criteria	A patient with suspected neurological death. Excluding cases for which cardiac arrest occurred despite resuscitation, brainstem reflexes returned, and neonates - less than 2 months post term
Discussed with Specialist Nurse – Organ Donation	A patient with suspected neurological death discussed with the Specialist Nurse – Organ Donation (SN-OD)
Neurological death tested	Neurological death tests were performed
Eligible DBD donor	A patient confirmed dead by neurological death tests, with no absolute medical contraindications to solid organ donation
Family approached for formal organ donation discussion	Family of eligible DBD asked to support patient's expressed or deemed consent/authorisation, informed of an nominated/appointed representative, asked to make a decision on donation on behalf of their relative, or informed of a patient's opt-out decision via the ODR
Consent/Authorisation ascertained	Family supported expressed or deemed consent/authorisation, nominated/appointed representative gave consent, or where applicable the family gave consent/authorisation
Actual donors: DBD	Neurological death confirmed patients who became actual DBD as reported through the PDA
Actual donors: DCD	Neurological death confirmed patients who became actual DCD as reported through the PDA
Neurological death testing rate	Percentage of patients for whom neurological death was suspected who were tested
Referral rate	Percentage of patients for whom neurological death was suspected who were discussed with the SN-OD
Approach rate	Percentage of eligible DBD families or nominated/appointed representatives approached for formal organ donation discussion
Consent / authorisation rate	Percentage of families or nominated/appointed representatives approached for formal organ donation discussion where consent/authorisation was ascertained
SN-OD involvement rate	Percentage of formal organ donation discussions with families or nominated/appointed representatives where a SN-OD was involved
SN-OD consent / authorisation rate	Percentage of formal organ donation discussions with families or nominated/appointed representatives where a SN-OD was involved and consent/authorised donation was ascertained

Donors after circulatory death (DCD)	
Imminent death anticipated	A patient, not confirmed dead using neurological criteria, receiving assisted ventilation, a clinical decision to withdraw treatment has been made and death is anticipated within 4 hours
DCD referral criteria	A patient in whom imminent death is anticipated (as defined above)
Discussed with Specialist Nurse – Organ Donation	Patients for whom imminent death was anticipated who were discussed with the SN-OD
Potential DCD donor	A patient who had treatment withdrawn and death was anticipated within four hours
Eligible DCD donor	A patient who had treatment withdrawn and death was anticipated within four hours, with no absolute medical contraindications to solid organ donation
Family approached for formal organ donation discussion	Family of eligible DCD asked to support patient's expressed or deemed consent/authorisation, informed of an nominated/appointed representative, asked to make a decision on donation on behalf of their relative, or informed of a patient's opt-out decision via the ODR
Consent/Authorisation ascertained	Family supported expressed or deemed consent/authorisation, nominated/appointed representative gave consent, or where applicable the family gave consent/authorisation
Actual DCD	DCD patients who became actual DCD as reported through the PDA
Referral rate	Percentage of patients for whom imminent death was anticipated who were discussed with the SN-OD
Approach rate	Percentage of eligible DCD families or nominated/appointed representatives approached for formal organ donation discussion
Consent / authorisation rate	Percentage of families or nominated/appointed representatives approached for formal organ donation discussion where consent/authorisation was ascertained
SN-OD involvement rate	Percentage of formal organ donation discussions with families or nominated/appointed representatives where a SN-OD was involved
SN-OD consent / authorisation rate	Percentage of formal organ donation discussions with families or nominated/appointed representatives where a SN-OD was involved and consent /authorised donation was ascertained