POTENTIAL DONOR AUDIT SUMMARY REPORT FOR THE 12 MONTH PERIOD 1 APRIL 2012 - 31 MARCH 2013

1 INTRODUCTION

The Potential Donor Audit (PDA) commenced in 2003, but in October 2009 changes to the data collection and definitions used were introduced. This report presents information on the financial year 1 April 2012 to 31 March 2013.

The dataset used to compile this report includes all audited patient deaths in UK Intensive Care Units (ICUs) and Emergency Departments as reported by 6 June 2013. Patients aged 76 years or older and those that died in a cardiothoracic ICU have not been audited.

This report summarises the main findings of the PDA over the 12-month period and should be read in conjunction with the PDA section of the Organ Donation and Transplantation Activity Report on the ODT website, available at http://www.organdonation.nhs.uk/statistics/transplant_activity_report/.

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Eligible donors after circulatory death (DCD) are defined as patients who had treatment withdrawn and death was anticipated within four hours, with no absolute medical contraindications to solid organ donation.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 were defined as follows during the time period: known HIV positive, known or suspected CJD, active untreated tuberculosis, any malignancy within the past 12 months (excluding brain tumour) and multi-organ failure.

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 2012 to 31 March 2013, there were a total of 28,966 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 rates.

Figure 1 Donation after brain death

Audited Deaths 28,966 Was the patient ever on mechanical ventilation? No Yes 13,531 15,435 Were all criteria for neurological testing met? Yes No 13,804 1,631 Were neurological tests to confirm death performed? No Yes 363 1,268 Was death confirmed using neurological criteria? No Yes 25 1,243 Were there any absolute medical contraindications to solid organ donation? No Yes 1,188 55 Were the family formally approached for consent/authorisation for solid organ donation? No Yes 88 1,100 Was consent/authorisation for solid organ donation given by the family? No Yes 356 744 Did solid organ donation occur? No Yes 676 68 What type of donation happened? **DBD** DCD 658 18

Figure 2 Donation after circulatory death

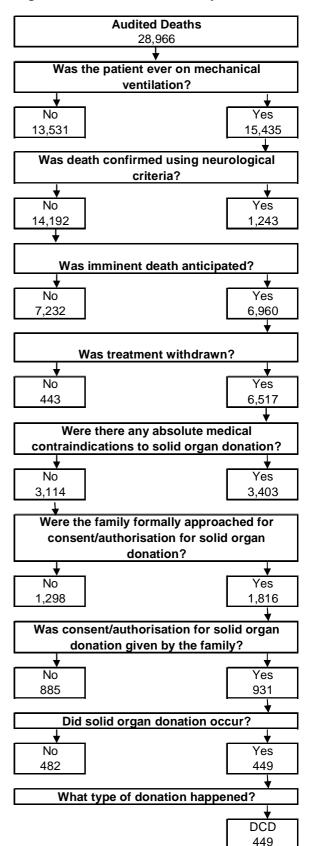


Table 1 Key numbers and rates		
	DBD	DCD
Patients meeting organ donation referral criteria ¹	1631	6960
Referred to SN-OD	1493	4344
Referral rate %	91.5%	62.4%
Neurological death tested	1268	
Testing rate %	77.7%	
Eligible donors ²	1188	3114
Family approached	1100	1816
Approach rate %	92.6%	58.3%
Family approached and SN-OD involved	868	1212
% of approaches where SN-OD involved	78.9%	66.7%
Consent/authorisation given	744	931
Consent/authorisation rate %	67.6%	51.3%
Actual donors from each pathway	676	449
% of consented/authorised donors that became actual donors	90.9%	48.2%

4 NEUROLOGICAL DEATH TESTING RATE

Table 2 Reasons given for neurological death tests not being performed				
	N	%		
Patient haemodynamically unstable	114	31.4		
Clinical reason/Clinicians decision	40	11.0		
Family declined donation	29	8.0		
Biochemical/endocrine abnormality	29	8.0		
Cardiac arrest despite resuscitation	28	7.7		
Other	28	7.7		
Continuing effects of sedatives	27	7.4		
Treatment withdrawn	18	5.0		
Inability to test all reflexes	11	3.0		
Family pressure not to test	9	2.5		
Medical contraindication to donation	9	2.5		
Unknown	9	2.5		
Neonates - Less than 2 months post term	5	1.4		
Pressure on ICU beds	3	0.8		
Brain stem reflexes returned	2	0.6		
SN-OD advised that donor not suitable	2	0.6		
Total	363	100.0		

¹ DBD - A patient with suspected neurological death 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

² DBD - Death confirmed by neurological tests and no absolute contraindications to solid organ donation DCD - Imminent death anticipated and treatment withdrawn with no absolute contraindications to solid organ donation

The neurological death testing rate was 78% 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. Neurological death tests were not performed in 363 patients (22%) for whom neurological death was suspected. The primary reason given for not testing is shown in **Table 2**.

For 114 (31%) patients not tested, the reason given was the patient was haemodynamically unstable. Of these, 103 (90%) had their blood pressure supported by fluids and/or inotropes. There was a clinical reason or it was the clinician's decision not to perform tests for 40 (11%) patients.

5 REFERRAL RATE

A patient who meets the four criteria for neurological death tests or for whom imminent death is anticipated, ie 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 92% and the DCD referral rate was 62%. **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.

Of the patients who met the referral criteria and were not referred, the reason given for 25% of DBD and DCD cases was because the patient was not identified as a potential donor or organ donation was not considered. The reason given for 42% of DCD was medical contraindications.

Table 3 Reasons given why patient not referred					
	İ	DBD	DCD		
	N	%	N	%	
Not identified as a potential donor/organ donation not considered	35	25.4	667	25.5	
Other	26	18.8	224	8.6	
Family declined donation prior to neurological testing	18	13.0	10	0.4	
Medical contraindications	16	11.6	1,107	42.3	
Family declined donation after neurological testing	15	10.9	-	-	
Thought to be medically unsuitable	10	7.2	425	16.2	
Coroner/Procurator Fiscal Reason	6	4.3	11	0.4	
Neurological death not confirmed	5	3.6	3	0.1	
Reluctance to approach family	4	2.9	21	0.8	
Family declined donation following decision to withdraw treatment	3	2.2	92	3.5	
Thought to be outside age criteria	-	-	21	0.8	
Pressure on ICU beds	-	-	6	0.2	
Donation after circulatory death not supported by ICU	-	-	29	1.1	
Total	138	100.0	2,616	100.0	

6 APPROACH RATE

Families of eligible donors were approached in 93% and 58% of DBD and DCD cases, respectively. The information in **Table 4** shows the reasons given why the family were not approached.

For eligible DBD, in 38% of cases the reason stated was Coroner or Procurator Fiscal refused permission, whereas this reason only accounted for 3% of the eligible DCD families not approached.

For eligible DCD, in 605 (47%) cases the reason stated was 'other'. Investigating the text provided has shown that of the 605 cases where other was chosen, the text indicated that the patient was not identified as a potential donor or donation was not considered in nearly half the cases. The families of 26% of eligible DCD were not approached because of the patient's general medical condition.

Table 4 Reasons given why family not formally approached					
	DBD		DCD		
	N	%	N	%	
Coroner/Procurator Fiscal refused permission	33	37.5	38	2.9	
Other	17	19.3	605	46.6	
Family stated that they would not consent/authorise before they were formally approached	12	13.6	43	3.3	
Other medical reason	9	10.2	130	10.0	
Family untraceable	7	8.0	42	3.2	
Patient's general medical condition	5	5.7	332	25.6	
Family considered too upset to approach	3	3.4	23	1.8	
Not identified as a potential donor / organ donation not considered	2	2.3	44	3.4	
Resource failure	-	-	21	1.6	
Pressure on ICU beds	-	-	1	0.1	
Patient outside age criteria	-	-	18	1.4	
Not reported	-	-	1	0.1	
Total	88	100.0	1,298	100.0	

7 OVERALL CONSENT/AUTHORISATION RATE

The consent/authorisation rate is based on eligible donors whose family were formally approached for consent to/authorisation for donation. The consent/authorisation rate is the proportion of these families who consented to/authorised solid organ donation.

During the financial year, the DBD consent/authorisation rate was 68% and the 95% confidence limits for this percentage are 65% - 70%. The DCD consent/authorisation rate was 51% and the 95% confidence limits for this percentage are 49% - 54%. The overall consent/authorisation rate was 57% and the 95% confidence limits for this percentage are 55% - 60%.

When a patient is known to have expressed a wish to donate, for example they were registered on the Organ Donor Register (ODR), carried a donor card or expressed a wish to donate verbally or in writing and the patient's wish was known at the time of potential donation, the DBD consent/authorisation rate was 96% compared to 55% when a patient hadn't expressed a wish to donate or the patient's ODR status was not known at the time of potential donation. For DCD, the rates were 83% compared with 40%. Overall, these rates were 88% compared with 46%. In total during the financial year, 105 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 72% compared with 52% when the SN-OD was not involved. Similarly, for DCD the rate was 61% compared with 31% when the SN-OD was not involved. The overall rate was 66% compared with 37%.

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 that the patient had stated in the past that they did not wish to be a donor (21% and 18%, respectively).

Table 5 Reasons given why family did not give consent/authorisation				
	DBD		DCD	
	N	%	N	%
Patient had stated in the past that they did not wish to be a donor	75	21.1	155	17.5
Family were not sure whether the patient would have agreed to donation	46	12.9	140	15.8
Family did not want surgery to the body	42	11.8	49	5.5
Family felt it was against their religious/cultural beliefs	30	8.4	26	2.9
Strong refusal - probing not appropriate	30	8.4	63	7.1
Other	28	7.9	103	11.6
Family felt the patient had suffered enough	23	6.5	67	7.6
Family were divided over the decision	20	5.6	52	5.9
Family did not believe in donation	16	4.5	35	4.0
Family felt the body needs to be buried whole (unrelated to religious or cultural reasons)	15	4.2	29	3.3
Family felt the length of time for donation process was too long	11	3.1	128	14.5
Family had difficulty understanding/accepting neurological testing	10	2.8	1	0.1
Family wanted to stay with the patient after death	4	1.1	12	1.4
Family concerned that organs may not be transplanted	3	0.8	21	2.4
Family concerned that other people may disapprove/be offended	2	0.6	3	0.3
Patients treatment may be or has been limited to facilitate organ donation	1	0.3	-	-
Families concerned about organ allocation	-	-	1	0.1
Total	356	100.0	885	100.0

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 July 2012 (79%) and lowest in October 2012 (58%). The DCD consent/authorisation rate was also highest in July 2012 (62%) and lowest in November 2012 (47%). The differences in the monthly consent/authorisation rates from 1 April 2012 to 31 March 2013 are not statistically significant for either DBD or DCD, p=0.36 and p=0.23, respectively.

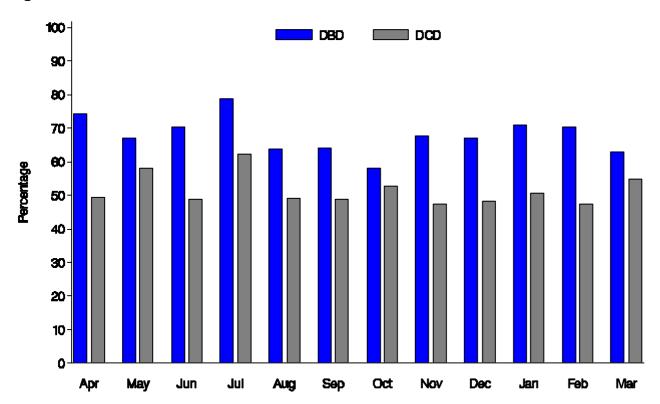


Figure 3 Month-to-month variation in consent/authorisation rate

9 EFFECT OF DEMOGRAPHIC VARIABLES ON THE CONSENT/AUTHORISATION RATE

The consent/authorisation rate for the 543 male eligible DBD was 69% and the consent/authorisation rate for the 557 female eligible DBD was 67%. The difference is not statistically significant, p=0.46. For the 1121 male eligible DCD the consent/authorisation rate was 52% and for the 695 female eligible DCD was 50%. This difference is not statistically significant, p=0.28.

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 1,100 eligible DBD and 1,816 eligible DCD whose families were approached) are illustrated in **Figure 4**. The highest consent/authorisation rate for eligible DBD and DCD occurred in the 35-49 age group (74% and 53%, respectively). The lowest consent/authorisation rate for eligible DBD and DCD was in the 0-17 age group (59% and 29%, respectively). The differences in consent/authorisation rate across the six age groups for DBD are not statistically significant (p=0.11) but for DCD are statistically significant (p=0.0073).

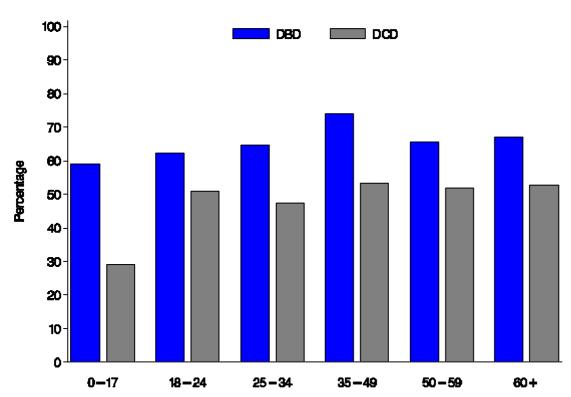


Figure 4 Age variation in consent/authorisation rate

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**. For eligible DBD, the consent/authorisation rates (for the 1,078 eligible donors out of 1,100 for whom ethnicity was recorded) were 72% for white eligible donors and 35% for eligible donors from an ethnic minority group. The 95% confidence limits for DBD consent/authorisation rates are 70% - 75% for white eligible donors and 27% - 44% for eligible donors from an ethnic minority group.

For eligible DCD, the consent/authorisation rates (for the 1,717 eligible donors out of 1,816 for whom ethnicity was recorded) were 54% for white eligible DCD and 31% for eligible DCD from an ethnic minority group. The 95% confidence limits for DCD consent/authorisation rates are 52% - 57% for white eligible donors and 22% - 39% for eligible donors from an ethnic minority group.

The overall consent/authorisation rates (for the 2,795 eligible donors out of 2,916 for whom ethnicity was recorded) were 61% for white eligible donors and 33% for eligible donors from an ethnic minority group. The 95% confidence limits for the overall consent/authorisation rates are 59% - 63% for white eligible donors and 27% - 39% for eligible donors from an ethnic minority group.

The difference between consent/authorisation rates for white eligible donors and eligible donors from an ethnic minority group is statistically significant for both DBD and DCD, both p<0.0001. The ethnicity effect remains highly significant after allowing for age, sex and month of death.

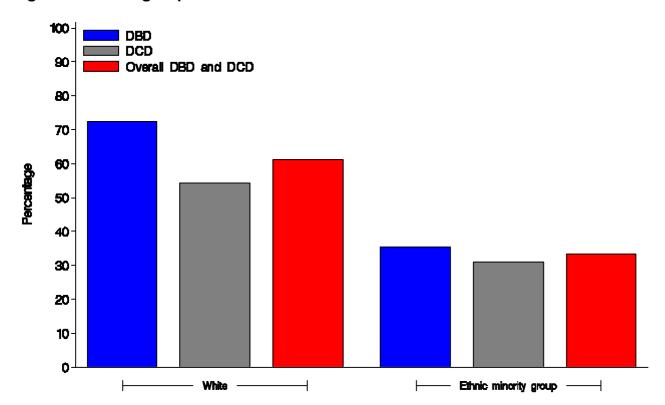


Figure 5 Ethnic group variation in consent/authorisation rate

10 SOLID ORGAN DONATION

Of the eligible donors whose family consented to/authorised donation, 91% of the eligible DBD and 48% 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 medically unsuitable by recipient centres (26%). This reason also accounted for 31% of DCD cases. However, the main reason given for consented/authorised eligible DCD not proceeding to become a solid organ donor was prolonged time to asystole, 44%.

Table 6 Reasons why solid organ donation did not happen					
	DBD		DCD		
	N	%	N	%	
Organs deemed medically unsuitable by recipient centres	18	26.5	149	30.9	
Coroner/ Procurator Fiscal refusal	12	17.6	26	5.4	
Organs deemed medically unsuitable on surgical inspection	12	17.6	14	2.9	
Family changed mind	7	10.3	25	5.2	
Cardiac arrest	7	10.3	4	8.0	
Other	6	8.8	25	5.2	
Positive virology	5	7.4	8	1.7	
General instability	1	1.5	15	3.1	
Prolonged time to asystole	-	-	211	43.8	
Logistic reasons	-	-	3	0.6	
Retrieval team not available	-	-	1	0.2	
Not reported	-	-	1	0.2	
Total	68	100.0	482	100.0	

11 SUMMARY

In the year 1 April 2012 to 31 March 2013, there were 28,966 deaths audited for the PDA. Of these deaths, 1,631 and 6,960 patients met the referral criteria for DBD and/or DCD, respectively and 92% and 62% were referred to a SN-OD.

Of the 1,631 patients for whom neurological death was suspected, 78% were tested and there were 1,188 and 3,114 eligible DBD and DCD, respectively. Families of these eligible DBD and DCD were approached for consent to/authorisation for donation in 93% and 58% of cases, respectively.

Of the families approached, 68% and 51% consented to/authorised DBD and DCD donation, respectively. Of these, 91% and 48%, respectively, became actual solid organ donors.

One hundred and five families overruled their loved one's known wish to be an organ donor.

There was no statistically significant difference in the consent/authorisation rates for male and female patients for DBD or DCD. The difference in the consent/authorisation rates across the different age groups was statistically significant for DCD, with paediatric patients (0 to 17 years) having a much lower consent/authorisation rate than the adult age groups. This was not statistically significant 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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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

Potential DBD donor

neurological death, as defined above)

DBD referral criteria

Discussed with Specialist Nurse - Organ

Donation

Eligible DBD donor

Neurological death tested

Absolute contraindications

Family approached for consent /

authorisation

Family consented / authorised

Actual donors: DBD

Actual donors: DCD

Neurological death testing rate

Referral rate

Approach rate

Consent / authorisation rate SN-OD involvement rate

SN-OD consent / authorisation rate

Donors after circulatory death (DCD)

Imminent death anticipated

DCD referral criteria Discussed with Specialist Nurse - Organ

Donation Potential DCD donor

Eligible DCD donor

Absolute contraindications

Family approached for consent / authorisation

Family consented / authorised

Actual DCD Referral rate

Approach rate

Consent / authorisation rate SN-OD involvement rate

SN-OD consent / authorisation rate

A patient who meets all of the following criteria: Apnoea, coma from known aetiology and

unresponsive, ventilated, fixed pupils.

A patient who meets all four criteria for neurological death testing (ie suspected

A patient with suspected neurological death

A patient with suspected neurological death discussed with the Specialist Nurse – Organ

Donation (SN-OD)

Neurological death tests were performed

A patient confirmed dead by neurological death tests, with no absolute medical

contraindications to solid organ donation

An absolute contraindication is defined as any of (during the time period):

a) Known or suspected CJD

b) known HIV positive

c) any malignancy within the past 12 months (excluding brain tumour)

d) multi-organ failure (Demonstrable failure of two or more vital organ systems and associated complications. Failure defined as requirement of organ support)

e) active untreated tuberculosis

Family of eligible DBD asked to make a decision on donation

Family consented to / authorised donation Neurological death confirmed patients who became actual DBD as reported through the

PDA

Neurological death confirmed patients who became actual DCD as reported through the

PDA

Percentage of patients for whom neurological death was suspected who were tested

Percentage of patients for whom neurological death was suspected who were discussed

with the SN-OD

Percentage of eligible DBD families approached for consent /authorisation for donation Percentage of families approached about donation that consented to / authorised donation

Percentage of family approaches where a SN-OD was involved

Percentage of families approached about donation by a SN-OD that consented to /

authorised donation

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

A patient in whom imminent death is anticipated (as defined above)

Patients for whom imminent death was anticipated who were discussed with the SN-OD

A patient who had treatment withdrawn and death was anticipated within four hours A patient who had treatment withdrawn and death was anticipated within four hours, with no absolute medical contraindications to solid organ donation

An absolute contraindication is defined as any of (during the time period):

a) Known or suspected CJD

b) known HIV positive

c) any malignancy within the past 12 months (excluding brain tumour)

d) multi-organ failure (Demonstrable failure of two or more vital organ systems and associated complications. Failure defined as requirement of organ support)

e) active untreated tuberculosis

Family of eligible DCD asked to make a decision on donation

Family consented to / authorised donation

DCD patients who became actual DCD as reported through the PDA

Percentage of patients for whom imminent death was anticipated who were discussed with

Percentage of eligible DCD families approached for consent /authorisation for donation Percentage of families approached about donation that consented to / authorised donation

Percentage of family approaches where a SN-OD was involved

Percentage of families approached about donation by a SN-OD that consented to /

authorised donation