POTENTIAL DONOR AUDIT SUMMARY REPORT FOR THE 12 MONTH PERIOD 1 APRIL 2010 - 31 MARCH 2011

1 INTRODUCTION

The Potential Donor Audit 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 2010 to 31 March 2011.

The dataset used to compile this report includes all audited patient deaths in UK Intensive Care Units (ICUs) and Emergency Departments as reported by 1 July 2011. 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.

2 DEFINITIONS

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

Potential donors after circulatory death (DCD) are defined as patients for whom imminent death was anticipated and treatment was withdrawn and who had no absolute or relative medical contraindications to solid organ donation.

Absolute or relative medical contraindications are defined as 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

In the 12-month period from 1 April 2010 to 31 March 2011, there were a total of 29,060 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.

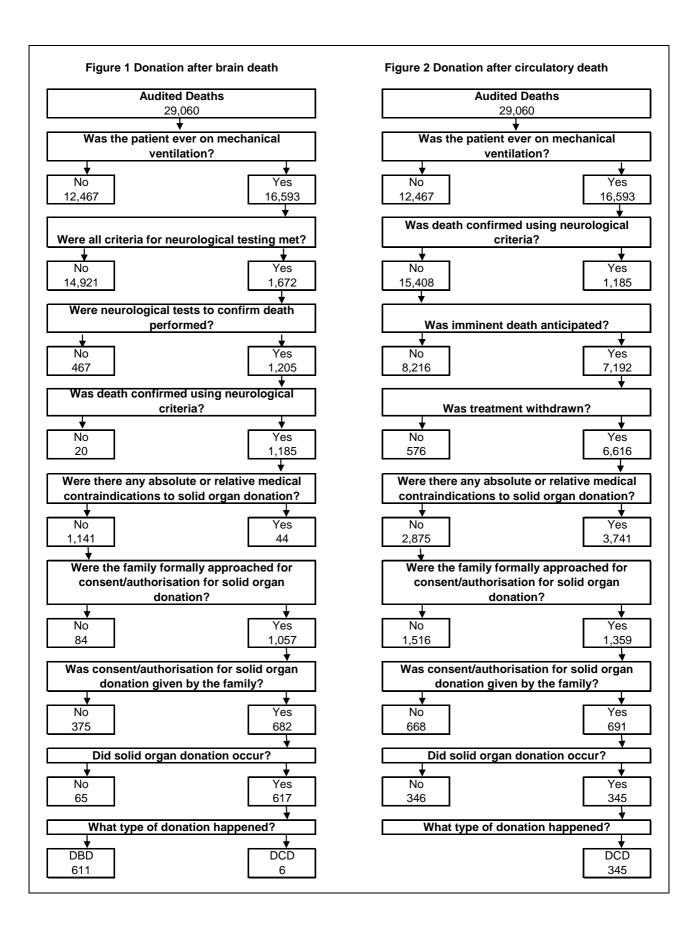


Table 1 Summary of data and key percentage	es				
	Potentia	Potential DBD		Potential DCD	
	N	%	N	%	
Patients on mechanical ventilation at some point during their stay in ICU	16,593		16,593		
Referral criteria met	1,672		7,192		
Referred to SN-OD (referral rate %)	1,414	(84.6)	3,188	(44.3)	
Neurological death tested (testing rate %)	1,205	(72.1)			
Potential donors	1,141		2,875		
Families who were approached for consent/authorisation (approach rate %)	1,057	(92.6)	1,359	(47.3)	
Consent/authorisation given for solid organ donation (consent/authorisation rate %)	682	(64.5)	691	(50.8)	
Actual solid organ donors (percentage of patients with family consent/authorisation %)	617	(90.5)	345	(49.9)	
Conversion rate %		54.1		12.0	

4 NEUROLOGICAL DEATH TESTING RATE

The neurological death testing rate was 72% 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 467 patients (28%) for whom neurological death was suspected. The primary reason given for not testing is shown in **Table 2**.

For 94 (20%) patients not tested, the reason given was the patient was haemodynamically unstable. Of these 94 patients, 78 (83%) 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 52 (11.1%) of patients.

Table 2 Reasons given for neurologic	al death tests not b	eing performed
	N	%
Patient haemodynamically unstable	94	20.1
Other	54	11.6
Clinical reason/Clinician's decision	52	11.1
Family declined donation	45	9.6
Cardiac arrest despite resuscitation	40	8.6
Continuing effects of sedatives	39	8.4
Unknown	37	7.9
Treatment withdrawn	31	6.6
Biochemical/endocrine abnormality	15	3.2
Inability to test all reflexes	12	2.6
Medical contraindication to donation	11	2.4
Family pressure not to test	10	2.1
Neonates - Less than 2 months post term	9	1.9
Coordinator advised that donor not suitable	9	1.9
Brain stem reflexes returned	5	1.1
Pressure on ICU beds	4	0.9
Total	467	100.0

5 REFERRAL RATE

A patient who meets the four criteria for neurological death tests or for whom imminent death is anticipated, i.e. a clinical decision to withdraw treatment has been made and the patient is ventilated, should be referred to a Specialist Nurse - Organ Donation (SN-OD). The DBD referral rate was 85% and the DCD referral rate was 44%. **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 30% of DBD and 32% of DCD was because the patient was not identified as a potential donor or organ donation was not considered. The reason given for 34% of DCD was medical contraindications.

Table 3 Reasons given why patient not referre	ed				
	!	DBD		DCD	
	N	%	N	%	
Not identified as a potential donor/organ donation not considered	78	30.2	1,279	31.9	
Other	52	20.2	477	11.9	
Family declined donation prior to neurological testing	35	13.6	21	0.5	
Family declined donation after neurological testing	24	9.3	-	-	
Neurological death not confirmed	21	8.1	8	0.2	
Medical contraindications	14	5.4	1,375	34.3	
Thought to be medically unsuitable	12	4.7	585	14.6	
Family declined donation following decision to withdraw treatment	10	3.9	107	2.7	
Reluctance to approach family	4	1.6	23	0.6	
Non-heartbeating donation not supported by ICU	3	1.2	80	2.0	
Coroner/Procurator Fiscal Reason	2	8.0	6	0.1	
Pressure on ICU beds	2	8.0	11	0.3	
Thought to be outside age criteria	1	0.4	32	8.0	
Total	258	100.0	4,004	100.0	

6 APPROACH RATE

Families of potential donors were approached in 93% and 47% of DBD and DCD cases, respectively. The information in **Table 4** shows the reasons given why the family were not approached.

For potential DBD, in 36% of cases the reason stated was the Coroner or Procurator Fiscal refused permission, whereas this reason only accounted for 2% of the potential DCD families not approached.

For potential DCD, in 964 (64%) cases the reason stated was 'other'. Investigating the text provided has shown that of the 964 cases where other was chosen, the text indicated that the patient was not identified as a potential donor or donation was not considered in 410 (43%) cases. The families of 18% of potential 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	30	35.7	22	1.5	
Other	19	22.6	964	63.6	
Family stated that they would not consent before they were formally approached	17	20.2	30	2.0	
Patient's general medical condition	7	8.3	265	17.5	
Family untraceable	6	7.1	22	1.5	
Family considered too upset to approach	3	3.6	39	2.6	
Other medical reason	2	2.4	111	7.3	
Resource failure	-	-	14	0.9	
Patient outside age criteria	-	-	49	3.2	
Total	84	100.0	1,516	100.0	

7 OVERALL CONSENT/AUTHORISATION RATE

The consent/authorisation rate is based on potential 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 65% and the 95% confidence limits for this percentage are 62% - 68%. The DCD consent/authorisation rate was 51% and the 95% confidence limits for this percentage are 48% - 54%.

When a patient is known to have expressed a wish to donate, for example they were registered on the Organ Donor Register, carried a donor card or expressed a wish to donate verbally or in writing, the DBD consent/authorisation rate was 94% compared to 50% when a patient hadn't expressed a wish to donate. For DCD, the rates were 80% compared with 39%.

When a SN-OD was involved in the approach to the family the DBD consent/authorisation rate was 72% compared with 50% when the SN-OD was not involved. Similarly, for DCD the rate was 68% compared with 31% when the SN-OD was not involved.

The reasons why the family did not give consent/authorisation are shown in **Table 5**. The main reason that families of potential DBD patients gave for no consent/authorisation was because the patient had stated in the past that they did not wish to be a donor (16%). The main reason that families of potential DCD patients gave for no consent/authorisation was because the family were not sure whether the patient would have agreed to donation (17%).

Table 5 Reasons given why family did not give	consent	i		
	DBD		DCD	
	N	%	N	%
Patient had stated in the past that they did not wish to be a donor	61	16.3	101	15.1
Family were not sure whether the patient would have agreed to donation	51	13.6	114	17.1
Family did not want surgery to the body	45	12.0	27	4.0
Strong refusal - probing not appropriate	43	11.5	73	10.9
Other	39	10.4	94	14.1
Family felt it was against their religious/cultural beliefs	29	7.7	19	2.8
Family did not believe in donation	21	5.6	56	8.4
Family were divided over the decision	19	5.1	45	6.7
Family felt the patient had suffered enough	19	5.1	39	5.8
Family felt the body needs to be buried whole (unrelated to religious or cultural reasons)	17	4.5	12	1.8
Family had difficulty understanding/accepting neurological testing	10	2.7	-	-
Family felt the length of time for donation process was too long	10	2.7	75	11.2
Family wanted to stay with the patient after death	4	1.1	4	0.6
Family concerned that other people may disapprove/be offended	3	0.8	1	0.1
Family concerned that organs may not be transplanted	2	0.5	6	0.9
Families concerned about organ allocation	1	0.3	2	0.3
Family concerned donation may delay the funeral	1	0.3	-	-
Total	375	100.0	668	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 January 2011 (75%) and lowest in October 2010 (58%), whereas the DCD consent/authorisation rate was highest in November 2010 (55%) and lowest in September 2010 (46%). The differences in the monthly consent/authorisation rates from 1 April 2010 to 31 March 2011 are not statistically significant for either DBD or DCD, p=0.8 and p=0.99, respectively.

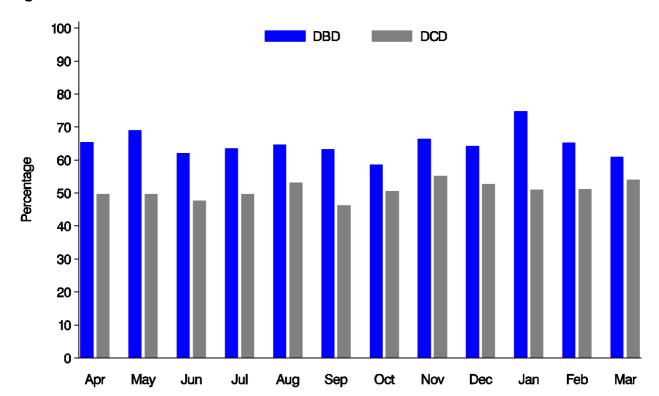


Figure 3 Month-to-month variation in consent/authorisation rate

9 EFFECT OF DEMOGRAPHIC VARIABLES ON THE CONSENT/AUTHORISATION RATE

The consent/authorisation rate for the 529 male potential DBD was 67% and the consent/authorisation rate for the 528 female potential DBD was 62%. The difference is not statistically significant, p=0.1. For the 795 male potential DCD the consent/authorisation rate was 54% and for the 564 female potential DCD was 46%. This difference is statistically significant, p=0.002.

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 1,057 potential DBD and 1,359 potential DCD whose families were approached) are illustrated in **Figure 4**. The highest consent/authorisation rate for potential DBD occurred in the 35-49 age group (66%) and for potential DCD in the 60+ age group (53%). The lowest consent/authorisation rate for potential DBD was in the 0-17 age group (56%). The lowest consent/authorisation rate for potential DCD was in the 0-17 age group (31%). The differences in consent/authorisation rate across the six age groups for DBD are not statistically significant and for DCD are not statistically significant, p=0.7 and p=0.08 for DBD and DCD respectively.

100 DBD DCD 90 80 70 60 Percentage 50 40 30 20 10 0 0 - 1718 - 2425 - 3435 - 4950 - 5960 +

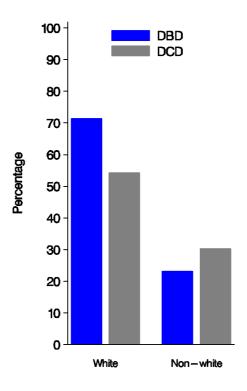
Figure 4 Age variation in consent/authorisation rate

To conduct a meaningful analysis, ethnicity has been split into white and known non-white groups and the rates are shown in **Figure 5**. For potential DBD, the consent/authorisation rates (for the 1,033 potential donors out of 1,057 for whom ethnicity was recorded) were 71% for white potential donors and 23% for known non-white potential donors. The 95% confidence limits for DBD consent/authorisation rates are 68% - 74% for white potential donors and 16% - 30% for known non-white potential donors.

For potential DCD, the consent/authorisation rates (for the 1,283 potential donors out of 1,359 for whom ethnicity was recorded) were 54% for white potential DCD and 30% for known non-white potential DCD. The 95% confidence limits for DCD consent/authorisation rates are 51% - 57% for white potential donors and 20% - 40% for known non-white potential donors.

The difference between consent/authorisation rates for white and known non-white DBD potential donors is statistically significant, p<.0001. The difference between consent/authorisation rates for white and known non-white DCD potential donors is statistically significant, p<.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 potential donors whose family consented to/authorised donation 91% of the potential DBD and 50% of the potential DCD went on to become actual solid organ donors. **Table 6** shows the reasons why consented/authorised potential donors did not become actual solid organ donors.

Table 6 Reasons why solid organ donation did not happen					
	DBD		DCD		
	N	%	N	%	
Organs deemed medically unsuitable by recipient centres	16	24.6	74	21.4	
Coroner/ Procurator Fiscal refusal	11	16.9	5	1.4	
Other	11	16.9	35	10.1	
Organs deemed medically unsuitable on surgical inspection	9	13.8	15	4.3	
Cardiac arrest	8	12.3	1	0.3	
Positive virology	5	7.7	6	1.7	
Family changed mind	4	6.2	17	4.9	
General instability	1	1.5	13	3.8	
Prolonged time to asystole	-	-	170	49.1	
Logistic reasons	-	-	2	0.6	
Family placed conditions on donation	-	-	2	0.6	
Retrieval team not available	-	-	6	1.7	
Total	65	100.0	346	100.0	

For consented/authorised potential DBD the main reason (25%) given for solid organ donation not proceeding was the organs were deemed medically unsuitable by the recipient centres, which was also the reason for 21% of potential DCD.

The main reason given for consented/authorised potential DCD not proceeding to become a solid organ donor was prolonged time to asystole (49%).

11 SUMMARY

In the year 1 April 2010 to 31 March 2011, there were 29,060 deaths audited for the PDA. Of these deaths, 1,672 and 7,192 patients met the referral criteria for DBD and DCD, respectively and 85% and 44% were referred to a SN-OD.

Of the 1,672 patients for whom neurological death was suspected, 72% were tested and there were 1,141 and 2,875 potential DBD and DCD, respectively. Families of these potential DBD and DCD were approached for consent to/authorisation for donation in 93% and 47%, respectively.

Of the families approached, 65% and 51% consented to/authorised DBD and DCD donation. Of these, 91% and 50%, respectively, became actual solid organ donors.

There was no statistically significant difference in the consent/authorisation rates across the different age groups for DBD or DCD. The difference in the consent rates for male and female patients was not statistically significant for DBD, however it was statistically significant for DCD. There was a statistically significant difference in both the DBD and DCD consent/authorisation rate between white and non-white patients and this affect remains after adjusting for patient age, sex and month of patient death.

Claire Counter and Cara Murphy NHS Blood and Transplant

July 2011

Appendix I - Definitions

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.
Discussed with Specialist Nurse - Organ	A patient with suspected neurological death discussed with the Specialist
Donation	Nurse – Organ Donation (SN-OD)
Neurological death tested	Neurological death tests were performed
Potential DBD	A patient whose death has been confirmed using neurological criteria, with no absolute contraindications or relative contraindications to solid organ donation
Absolute contraindications	Known or suspected CJD or known HIV positive
Relative contraindications	A relative contraindication is defined as any of:
	a) any malignancy within the past 12 months (excluding brain tumour) or
	b) multi-organ failure (Demonstrable failure of two or more vital organ systems and associated complications. Failure defined as requirement of organ support) or c) active untreated tuberculosis
Family approached for consent / authorisation	Family of potential DBD asked to make a decision on donation
Family consented / authorised	Family consented to / authorised donation
Actual donors: DBD	Neurological death confirmed patients that became actual DBD as reported through the PDA
Actual donors: DCD	Neurological death confirmed patients that became actual DCD as reported through the PDA
Neurological death testing rate	Percentage of patients for whom neurological death was suspected that were tested
Referral rate	Percentage of patients for whom neurological death was suspected that were discussed with the SN-OD
Approach rate	Percentage of potential DBD families approached for consent /authorisation for donation
Consent / authorisation rate	Percentage of families approached about donation that consented to / authorised donation
Adjusted consent / authorisation rate	Consent /authorisation rate adjusted for ethnicity case mix, based on those patients whose family were approached for consent /authorisation and patient ethnicity was known
Conversion rate	Percentage of potential DBD that became actual donors (either DBD or DCD)
Donors after circulatory death (DCD)	
Imminent death anticipated	A patient, not confirmed dead using neurological criteria, receiving assisted ventilation and a clinical decision to withdraw treatment has been made.
Discussed with Specialist Nurse – Organ Donation	Patients for whom imminent death was anticipated that were discussed with the SN-OD
Potential DCD	A patient in whom imminent death is anticipated, treatment has been withdrawn and who has no absolute or relative contraindication to organ donation.
Absolute medical contraindications	Known or suspected CJD or known HIV positive
Relative contraindications	A relative contraindication is defined as any of:
	a) any malignancy within the past 12 months (excluding brain tumour) or
	 b) multi-organ failure (Demonstrable failure of two or more vital organ systems and associated complications. Failure defined as requirement of organ support) or
	c) active untreated tuberculosis
Family approached for consent / authorisation	Family of potential DCD asked to make a decision on donation
Family consented / authorised	Family consented to / authorised donation
Actual DCD Referral rate	DCD patients that became actual DCD as reported through the PDA Percentage of patients for whom imminent death was anticipated that were
Approach rate	discussed with the SN-OD Percentage of potential DCD families approached for consent /authorisation
Consent / authorisation rate	for donation Percentage of families approached or made an approach about donation that consented to / authorised donation
Adjusted consent / authorisation rate	that consented to / authorised donation Consent /authorisation rate adjusted for ethnicity case mix, based on those patients whose family were approached for consent /authorisation and patient ethnicity was known
Conversion rate	
Conversion rate	Percentage of potential DCD that became actual DCD