

NHS BLOOD AND TRANSPLANT**National Organ Donation Committee****Analysis of the effect of Welsh Legislation on consent/authorisation rates: Quarter 7****Executive Summary****INTRODUCTION**

1. This paper reviews quarterly consent/authorisation rates for the four UK nations since the introduction of a system of presumed consent in Wales from 1 December 2015. A formal evaluation of the effect of introducing an opt-out system in Wales based on accumulating data in England and Wales over the same time period is also presented. The DBD and DCD consent rates are analysed separately. This is only one method in a number of ongoing evaluations of the impact of Welsh legislation on organ donation performed by NHSBT and the Welsh Government.

DATA COLLECTION

2. Data on UK DBD and DCD quarterly consent rates for the four UK nations are monitored through the Potential Donor Audit (PDA) from 1 January 2015. The percentage of eligible DBD and DCD donors approached where consent was ascertained, the consent rate, and the approximate number of donors per million population (pmp) are compared between the four UK nations at similar time points.

CURRENT DATA

3. During the first three quarters of 2017, 2040 families of eligible donors were approached regarding organ donation in England. In the same time period 194 families were approached in Scotland, 99 in Wales, and 57 in Northern Ireland. The highest overall consent rate was 74% in Northern Ireland compared with 68% in Wales, 65% in England, and 57% in Scotland. **Table 1** shows the DBD and DCD breakdown of these consent/authorisation and organ donation rates.

SEQUENTIAL QUARTERLY ANALYSIS

4. Analyses of both DBD and DCD eligible donors for whom consent was ascertained have been performed using cumulative data since the introduction of a presumed consent system in Wales. This is based on a sequential analysis, full details of which are given in the paper presented at the NODC meeting in February 2016 (NODC(16)2). Briefly, so long as points lie between the boundaries there is no statistically significant difference between the consent rates for England and Wales. Both boundary plots indicate that differences in consent rates are not significant. Data for eligible DBD patients is tending towards the upper boundary. Crossing this would mean that there was significant evidence of an increase in consent rate in Wales compared to the consent rate in England. This pattern is not apparent for DCD data.

CONCLUSIONS

5. At this stage there is insufficient evidence to conclude whether deemed consent in Wales has led to an increase in consent rates. Quarterly monitoring of consent/authorisation rates for the four nations of the UK will continue.

NHS BLOOD AND TRANSPLANT

National Organ Donation Committee

Analysis of the effect of Welsh Legislation on consent/authorisation rates: Quarter 7

INTRODUCTION

1. This paper reviews quarterly consent/authorisation rates for the four UK nations since the introduction of a system of presumed consent in Wales from 1 December 2015. A formal evaluation of the effect of introducing an opt-out system in Wales based on accumulating data in England and Wales over the same time period is also presented. Sequential design analysis is used to monitor the DBD and DCD consent rates separately. This is only one method in a number of ongoing evaluations of the impact of Welsh legislation on organ donation performed by NHSBT and the Welsh Government.

DATA COLLECTION

2. Data on UK DBD and DCD quarterly consent/authorisation rates for the four UK nations are monitored through the Potential Donor Audit (PDA) from 1 January 2015 to 30 September 2017. Data presented in this report are as at 9 October 2017.

3. Eligible donors are defined as patients for whom death was confirmed following neurological tests or patients for whom imminent death was anticipated and treatment was withdrawn, and who had no absolute medical contraindications to solid organ donation.

4. The consent/authorisation rate is defined as the percentage of eligible donors whose families were approached and consent/authorisation for donation was ascertained. The number of eligible donor families approached includes the families of patients who had registered as an opt-out.

5. The population figures, used to determine the numbers of donors per million population (pmp) estimate, are based on the ONS 2013 Census residency figures for the four UK countries. These population estimates do not account for patients who became a donor in a country which differed from their country of residence.

CURRENT DATA

6. **Table 1** shows the number of eligible donors whose families were approached and the corresponding consent/authorisation rate, by donor type and nation. Data are presented for 2015, the year prior to the change in Welsh legislation, 2016 the first full year since the change and more recently the first three quarters of 2017.

7. In England, 2040 families of eligible donors were approached (871 DBD and 1169 DCD) about organ donation, in the first three quarters of 2017. In the same time period 194 families were approached in Scotland (70 DBD and 124 DCD), 99 in Wales (42 DBD and 57 DCD), and 57 in Northern Ireland (28 DBD and 29 DCD).

8. The highest overall consent rate for the most recent time period was 74% in Northern Ireland, compared with 68% in Wales, 65% in England, and 57% in Scotland. Table 1 shows the DBD and DCD breakdown of these consent/authorisation rates.

9. In the first three quarters of 2017, there were approximately 17.0 donors pmp in England, 15.8 donors pmp in Northern Ireland, 14.2 donors pmp in Scotland and 14.2 donors pmp in Wales. Table 1 shows the DBD and DCD breakdown of these donation rates.

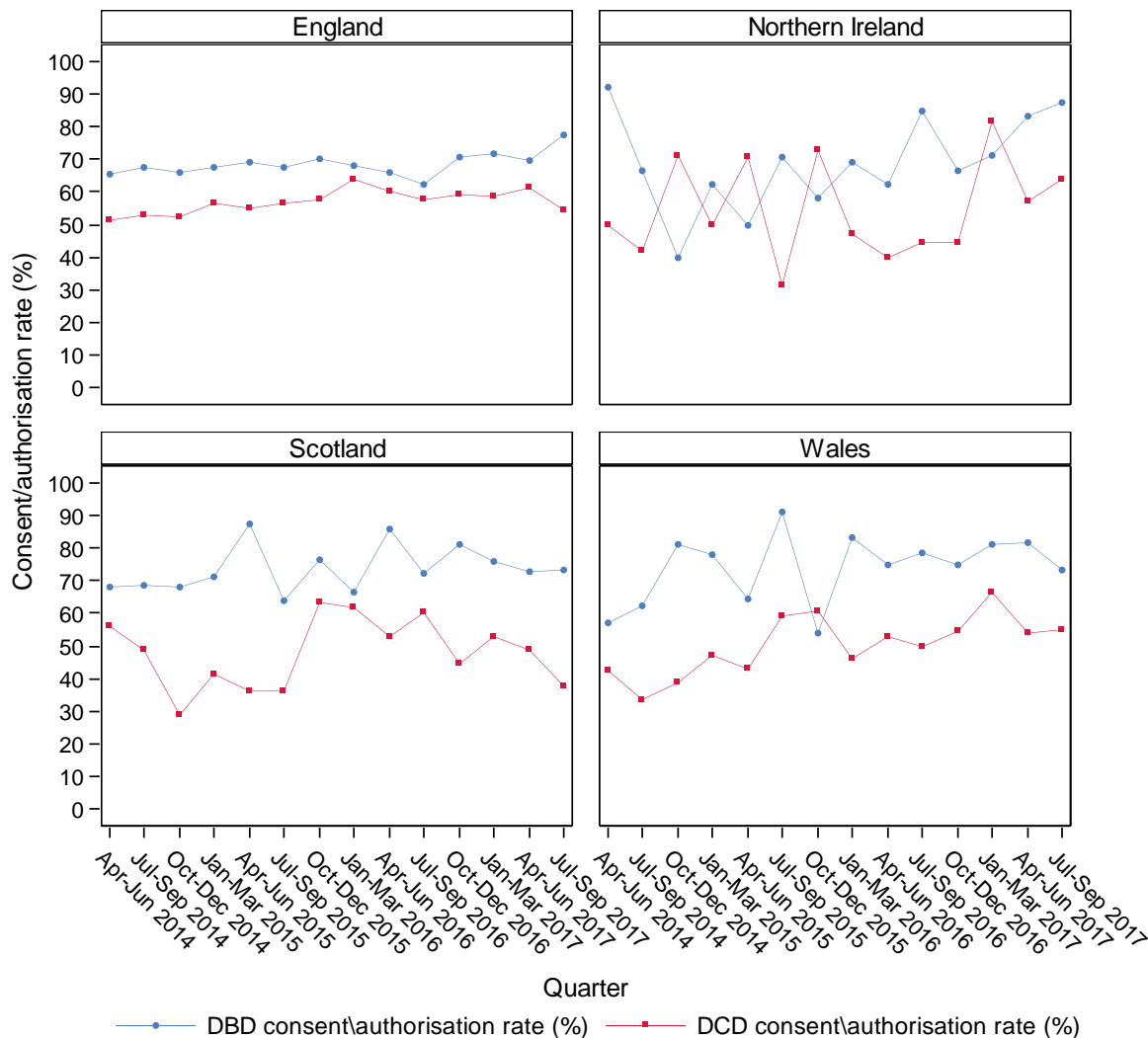
Table 1 Consent/authorisation rates for England, Wales, Scotland, and Northern Ireland for eligible donors whose families were approached and donors pmp, 1 January 2015 to 30 September 2017, by country of donor hospital and donor type

Country of donor hospital	Period	Eligible DBD donors whose family were approached	DBD Consent/authorisation rate	DBD donors pmp*	Eligible DCD donors whose family were approached	DCD Consent/authorisation rate	DCD donors pmp*	Eligible donors whose family were approached	Overall Consent/authorisation rate	Overall donors pmp*
England	2015	1089	68.6	12.0	1603	56.5	8.4	2692	61.4	20.3
	2016	1103	66.7	12.0	1554	60.3	9.3	2657	63.0	21.3
	Jan – Sep 2017	871	73.0	10.3	1169	58.3	6.7	2040	64.6	17.0
Northern Ireland	2015	59	61.0	15.8	69	56.5	10.9	128	58.6	26.6
	2016	49	71.4	17.4	45	44.4	4.3	94	58.5	21.7
	Jan – Sep 2017	28	78.6	10.9	29	69.0	4.9	57	73.7	15.8
Scotland	2015	73	74.0	9.3	162	44.4	6.7	235	53.6	16.1
	2016	102	76.5	13.3	156	55.1	9.5	258	63.6	22.8
	Jan – Sep 2017	70	74.3	8.6	124	47.6	5.6	194	57.2	14.2
Wales	2015	47	70.2	10.0	113	53.1	8.1	160	58.1	18.1
	2016	46	78.3	11.3	93	50.5	6.8	139	59.7	18.1
	Jan – Sep 2017	42	78.6	9.1	57	59.6	5.2	99	67.7	14.2

* Donors pmp are provided as indication of donation rates. Population figures for the country of donor hospital are an approximation based on ONS 2013 Census residency figures and do not account for patients who become a donor in a country which differed from their country of residence; England, Isle of Man and Channel Islands (54.56 million), Northern Ireland (1.84 million), Scotland (5.35 million) and Wales (3.09 million)

10. **Figure 1** shows the quarterly DBD and DCD consent/authorisation rates for all four nations since 1 April 2014. There is greater variation in the quarterly rates for Wales, Scotland, and Northern Ireland due to the smaller number of donors compared to England.

Figure 1 - Quarterly consent/authorisation rates in England, Wales, Scotland, and Northern Ireland, 1 April 2014 to 30 September 2017



SEQUENTIAL QUARTERLY ANALYSIS

11. Cumulative data on consent rates in Wales are compared with those in England on a quarterly basis from 1 January 2016. At the end of each quarter, the accumulating data are used to formally test whether there is a significant difference between the two underlying consent rates. A sequential design is used to detect an absolute difference in consent rates between England and Wales of 10%. The baseline consent rates are 67% for DBD and 53% for DCD. The statistical analysis presented here, has been described in more detail in the paper presented at the NODC meeting in February 2016 (NODC(16)2).

12. A hypothesis testing procedure is used to compare the proportion of eligible donors approached for whom consent for organ donation is ascertained. The test statistic is then plotted against the number of eligible donors approached. As soon as a point crosses the upper boundary, we would conclude there is evidence that the introduction of an opt-out

system has significantly increased the Welsh consent rate relative to the English consent rate. If a point crosses the lower boundary, we would conclude that presumed consent has significantly reduced the Welsh consent rate relative to the English consent rate, whereas if the study continues until a point crosses the vertical dotted line, we conclude that there is no difference between the two consent rates. This test procedure accounts for the multiple sequential testing, and is designed to avoid a decision being made too early, when the data are more limited.

Assumptions

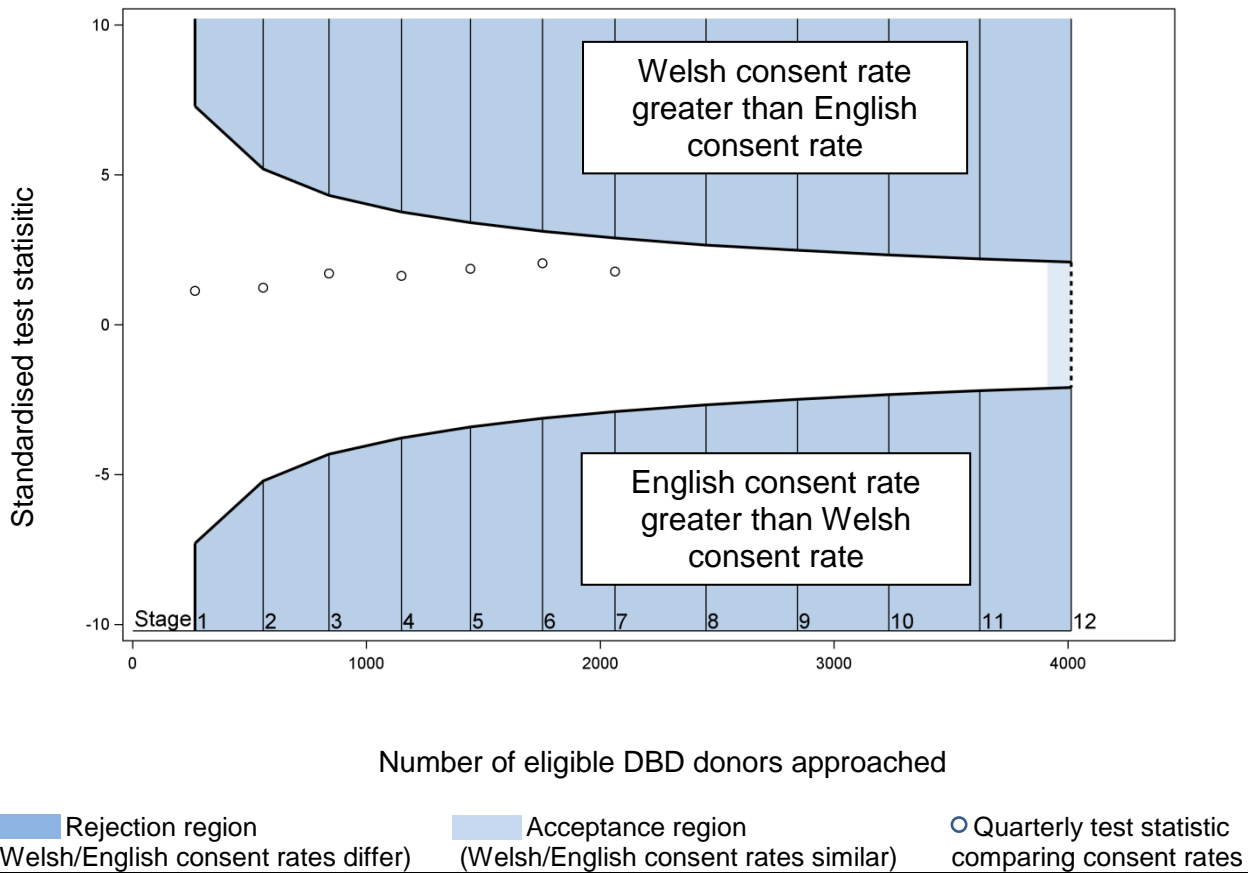
13. The following assumptions have been made in this paper:-
- a. DBD and DCD consent rates to be analysed separately due to the differences in consent rates prior to the changes in Welsh legislation.
 - b. DBD consent rates were similar in England and Wales, prior to the changes in Welsh legislation, as were DCD consent rates.
 - c. An absolute difference in consent rate in England and Wales of 10% is appropriate for both DBD and DCD.
 - d. Current DCD screening practices are consistent across England and Wales.

DBD consent/authorisation rate comparison

14. **Table 2** shows quarterly DBD consent/authorisation rates in England and Wales since 1 January 2016.

Table 2		Quarterly DBD data since 1 January 2016				
Quarter	England			Wales		
	Eligible DBDs whose family were approached	Eligible DBDs whose family were approached and consent was ascertained	DBD Consent/authorisation rate (%)	Eligible DBDs whose family were approached	Eligible DBDs whose family were approached and consent was ascertained	DBD Consent/authorisation rate (%)
1 (Jan - Mar 16)	255	173	67.8	12	10	83.3
2 (Apr - Jun 16)	283	186	65.7	8	6	75.0
3 (Jul - Sep 16)	267	166	62.2	14	11	78.6
4 (Oct - Dec 16)	298	211	70.8	12	9	75.0
5 (Jan - Mar 17)	279	200	71.7	16	13	81.3
6 (Apr – Jun 17)	297	207	69.7	11	9	81.8
7 (Jul – Sep 17)	295	229	77.6	15	11	73.3

Figure 2 Sequential plot for eligible DBD donors – a comparison of consent rates



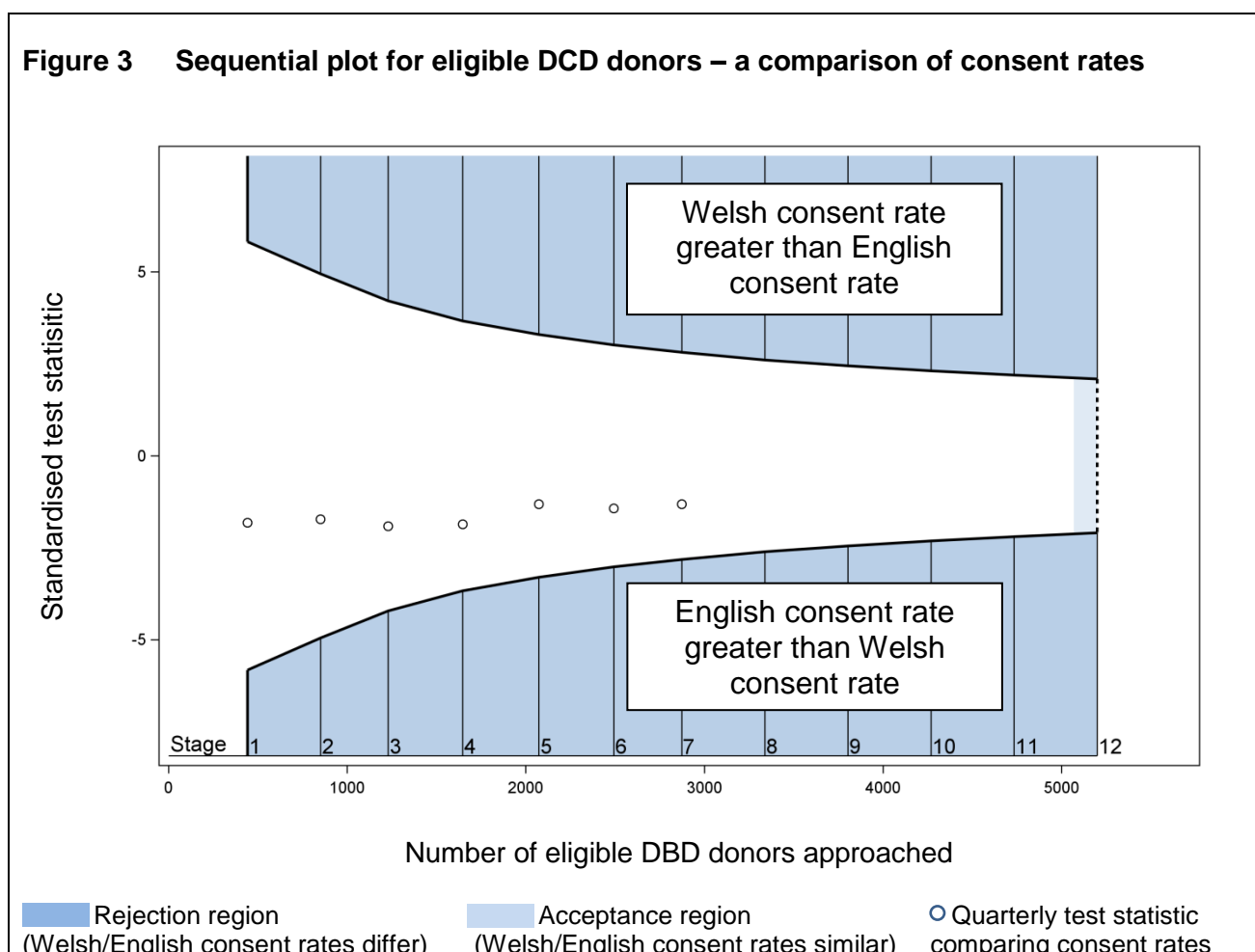
15. A plot of the values of the test statistic for testing the difference between the proportion of eligible DBD donors for whom consent was ascertained against the number of eligible donors approached, using the cumulative data, is presented in **Figure 2**. The plotted points are proceeding towards the upper boundary, and crossing this would mean that there was significant evidence of an increase in consent rates in Wales compared to the consent rates in England.

DCD consent/authorisation rate comparison

16. **Table 3** shows quarterly DCD consent/authorisation rates in England and Wales since 1 January 2016.

Table 3 Quarterly DCD data since 1 January 2016

Quarter	England			Wales		
	Eligible DCDs whose family were approached	Eligible DCDs whose family were approached and consent was ascertained	DCD Consent/authorisation rate (%)	Eligible DCDs whose family were approached	Eligible DCDs whose family were approached and consent was ascertained	DCD Consent/authorisation rate (%)
1 (Jan - Mar 16)	416	266	63.9	26	12	46.2
2 (Apr - Jun 16)	392	235	59.9	17	9	52.9
3 (Jul - Sep 16)	351	203	57.8	28	14	50.0
4 (Oct - Dec 16)	395	233	59.0	22	12	54.5
5 (Jan - Mar 17)	401	236	58.9	24	16	66.7
6 (Apr - Jun 17)	408	249	61.0	13	7	53.8
7 (Jul - Sep 17)	360	196	54.4	20	11	55.0



17. A plot of the values of the test statistic for testing the difference between the proportion of eligible DCD donors for whom consent was ascertained against the number of eligible donors approached, using the cumulative data, is presented in **Figure 3**. As yet there is no evidence of a trend towards an increased or decreased consent rate.

CONCLUSIONS

18. For the first three quarters of 2017, overall consent/authorisation rates in Northern Ireland, Wales and England are higher than the annual consent/authorisation rates in 2015 and 2016. The consent/authorisation rate in Scotland remains higher than 2015.

19. Quarterly monitoring of consent/authorisation rates will continue. At this stage, there was insufficient evidence to conclude an effect of introducing a system of presumed consent in Wales.

Sue Madden
Statistics and Clinical Studies

October 2017