

NHS BLOOD AND TRANSPLANT

National Organ Donation Committee

Analysis of the effect of Welsh Legislation on consent/authorisation rates: Quarter 9

Executive Summary

INTRODUCTION

1. This paper reviews quarterly consent/authorisation rates for the four UK nations since the introduction of a system of deemed 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 quarter of 2018, 750 families of eligible donors were approached regarding organ donation in England. In the same time period 68 families were approached in Scotland, 50 in Wales, and 20 in Northern Ireland. The overall consent/authorisation rates were similar in all four UK nations; 68% in both Wales and England, 65% in Northern Ireland, and 63% 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 deemed 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. The latest data points for eligible DBD patients are very close to 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. Data points for eligible DCD patients are showing an increasing trend although they remain a long way from the upper boundary.

CONCLUSIONS

5. In the first quarter of 2018, overall consent/authorisation rates for the four UK nations were similar ranging from 63% in Scotland to 68% in Wales. At this stage there is insufficient statistical evidence to conclude whether deemed consent in Wales has led to an increase in consent rates when compared to England. Quarterly monitoring will continue.

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INTRODUCTION

1. This paper reviews quarterly consent/authorisation rates for the four UK nations since the introduction of a system of deemed 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 31 March 2018. Data presented in this report are as at 9 April 2018.

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 mid-2016 estimates from 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, and the first two years since the change.

7. In the most recent quarter, 750 families of eligible donors were approached to discuss organ donation in England (354 DBD and 396 DCD). In the same time period, 68 families were approached in Scotland (27 DBD and 41 DCD), 50 in Wales (18 DBD and 32 DCD), and 20 in Northern Ireland (11 DBD and 9 DCD).

8. The overall consent/authorisation rates for the first quarter of 2018, were similar for all four nations; 68% in both Wales and England, 65% in Northern Ireland, and 63% in Scotland. **Table 1** shows the DBD and DCD breakdown of these consent/authorisation rates.

9. In the same time period, there were approximately 6.8 donors pmp in England, 6.1 donors pmp in Scotland, 5.8 donors pmp in Wales, and 5.4 donors pmp in Northern Ireland. **Table 1** shows the DBD and DCD breakdown of these donation rates.

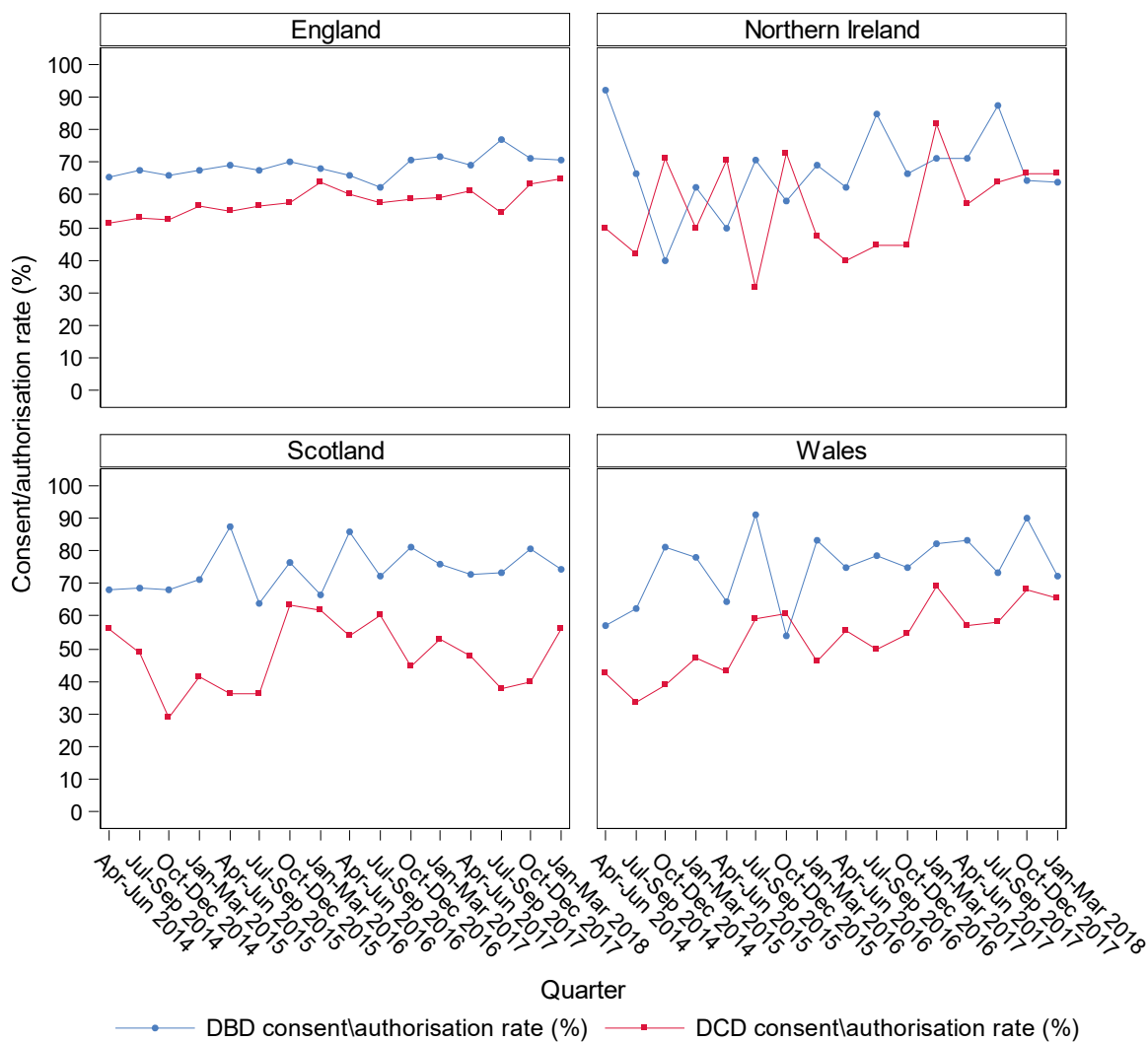
Table 1 Deceased consent/authorisation rates for England, Wales, Scotland, and Northern Ireland for eligible donors whose families were approached and donors pmp, 1 January 2015 to 31 March 2018, by country of donor hospital and donor type

Country of donor hospital	Period	DBD approaches	DBD consent/authorisation rate	DBD donors pmp*	DCD approaches	DCD consent/authorisation rate	DCD donors pmp*	All approaches	Overall consent/authorisation rate	Overall donors pmp*
England	2015	1089	68.6	11.8	1603	56.5	8.2	2692	61.4	20.0
	2016	1103	66.7	11.8	1553	60.3	9.1	2656	63.0	21.0
	2017	1197	72.2	13.8	1572	59.7	9.1	2769	65.1	22.8
	2018 Q1	354	70.6	4.2	396	65.2	2.6	750	67.7	6.8
Northern Ireland	2015	59	61.0	15.6	69	56.5	10.8	128	58.6	26.3
	2016	49	71.4	17.2	45	44.4	4.3	94	58.5	21.5
	2017	43	72.1	15.1	38	68.4	7.0	81	70.4	22.0
	2018 Q1	11	63.6	3.2	9	66.7	2.2	20	65.0	5.4
Scotland	2015	73	74.0	9.3	162	44.4	6.7	235	53.6	15.9
	2016	102	76.5	13.1	157	55.4	9.6	259	63.7	22.8
	2017	96	76.0	12.0	168	45.2	7.6	264	56.4	19.6
	2018 Q1	27	74.1	3.3	41	56.1	2.8	68	63.2	6.1
Wales	2015	47	70.2	10.0	113	53.1	8.0	160	58.1	18.0
	2016	46	78.3	11.3	94	51.1	7.1	140	60.0	18.3
	2017	64	82.8	15.1	87	64.4	9.3	151	72.2	24.4
	2018 Q1	18	72.2	3.5	32	65.6	2.3	50	68.0	5.8

* Donors pmp are provided as indication of donation rates. Population figures for the country of donor hospital are an approximation based on mid-2016 estimates from the ONS 2011 Census 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 (55.51 million), Northern Ireland (1.86 million), Scotland (5.4 million) and Wales (3.11 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 31 March 2018



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 deemed 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

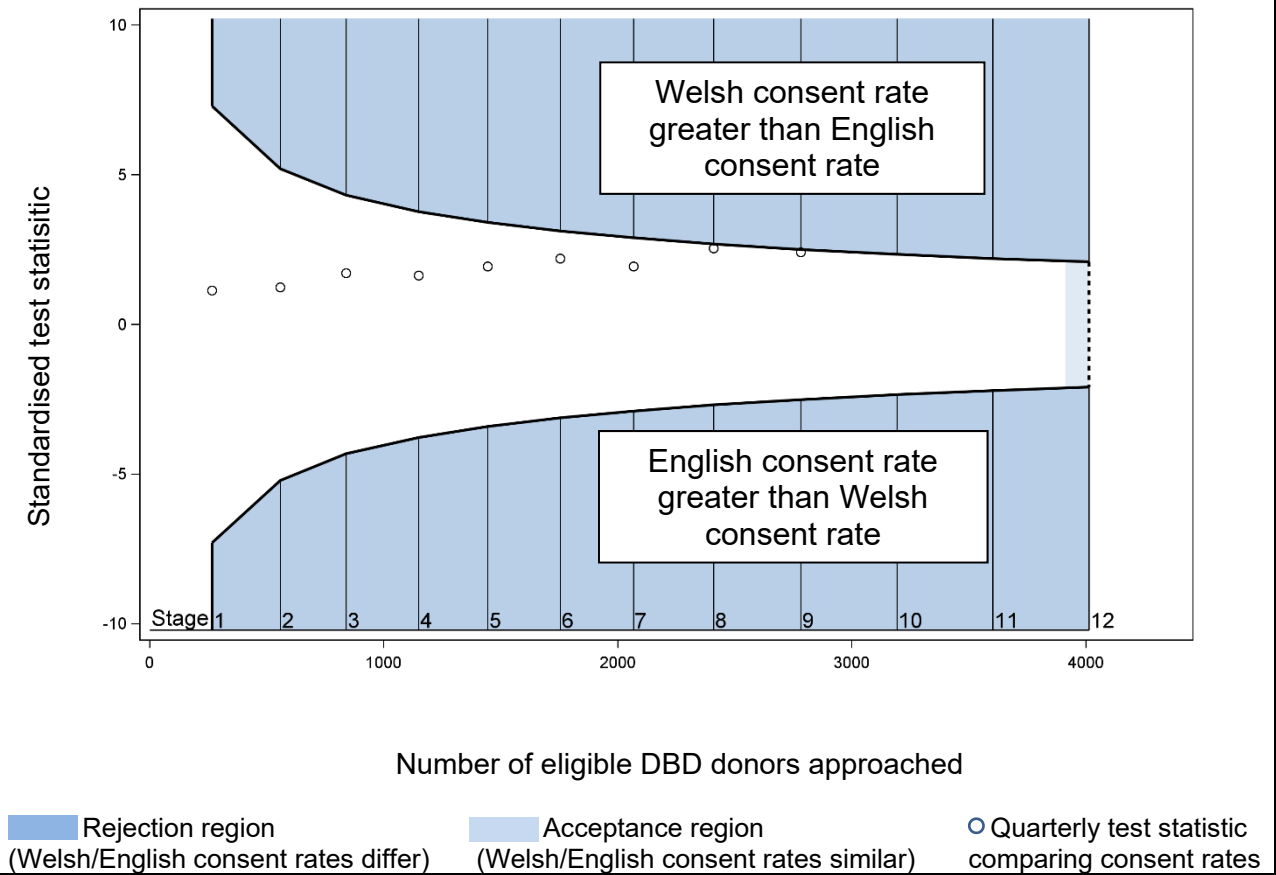
13. The following assumptions have been made in this paper:-
- a. DBD and DCD consent rates to be analysed separately due to the differences in consent rates prior to the changes in Welsh legislation.
 - b. DBD consent rates were similar in England and Wales, prior to the changes in Welsh legislation, 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.

Quarter	England			Wales		
	No. of approaches	No. where consent ascertained	DBD Consent rate (%)	No. of approaches	No. where consent ascertained	DBD Consent 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	17	14	82.4
6 (Apr – Jun 17)	297	205	69.0	12	10	83.3
7 (Jul – Sep 17)	299	230	76.9	15	11	73.3
8 (Oct – Dec 17)	322	229	71.1	20	18	90.0
9 (Jan – Mar 18)	354	250	70.6	18	13	72.2

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, although very close, have not yet crossed the upper boundary. Crossing this would mean that there was significant evidence of an increase in consent rates in Wales compared to the consent rates in England.

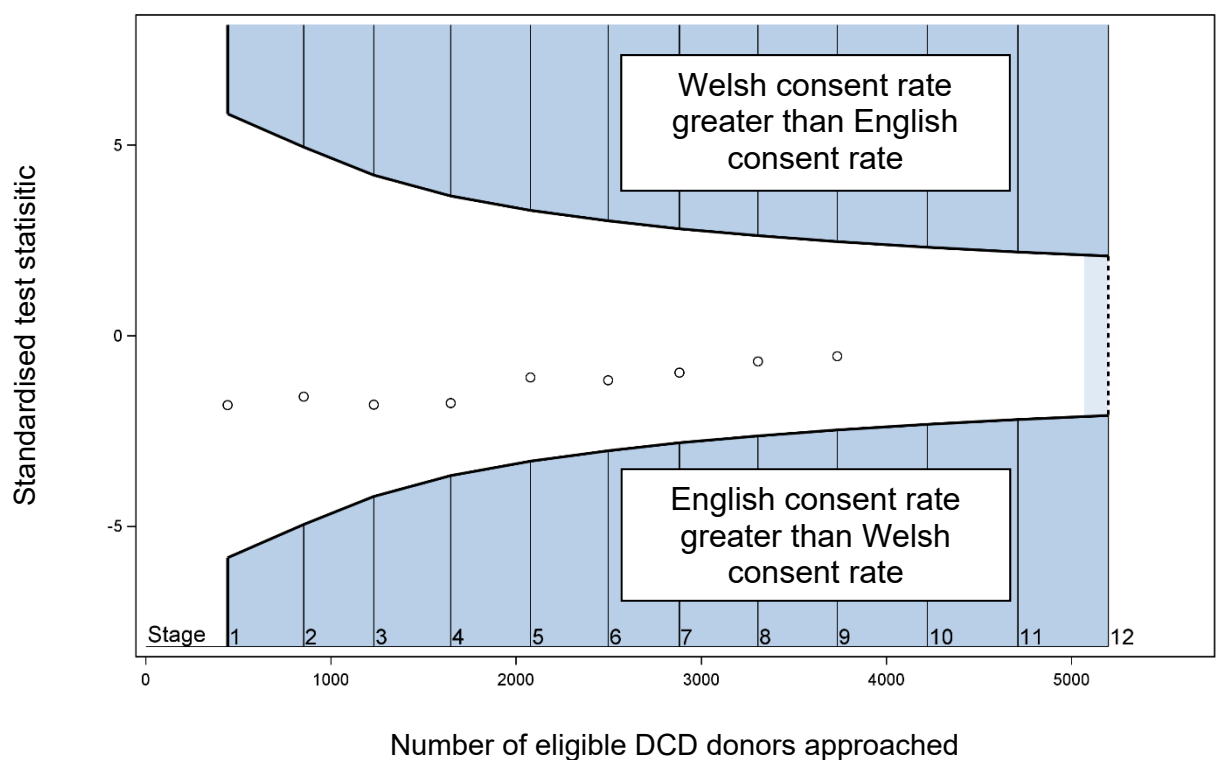
DCD consent/authorisation rate comparison

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		
	No. of approaches	No. where consent ascertained	DCD Consent rate (%)	No. of approaches	No. where consent ascertained	DCD Consent rate (%)
1 (Jan - Mar 16)	416	266	63.9	26	12	46.2
2 (Apr - Jun 16)	392	235	59.9	18	10	55.6
3 (Jul - Sep 16)	351	203	57.8	28	14	50.0
4 (Oct - Dec 16)	394	232	58.9	22	12	54.5
5 (Jan - Mar 17)	405	240	59.3	26	18	69.2
6 (Apr - Jun 17)	404	248	61.4	14	8	57.1
7 (Jul - Sep 17)	368	200	54.3	19	11	57.9
8 (Oct - Dec 17)	395	250	63.3	28	19	67.9
9 (Jan - Mar 18)	396	258	65.2	32	21	65.6

Figure 3 Sequential plot for eligible DCD donors – a comparison of consent rates



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**. The recent improving trend observed over the last 5 quarters indicates DCD consent rates in Wales have been improving relative to England.

CONCLUSIONS

18. In the first quarter of 2018, the overall consent/authorisation rates were similar across all four UK nations, ranging from 63% in Scotland to 68% in Wales. DBD consent/authorisation rates ranged from 64% in Northern Ireland to 74% in Scotland and DCD consent/authorisation rates ranged from 56% in Scotland to 67% in Northern Ireland.

19. Similarities in Welsh and English DBD consent rates in the most recent quarter have resulted in the DBD plotted points remaining below the upper boundary. The DCD plotted points indicate an improving trend but remain a long way from the upper boundary.

20. At this stage, there is insufficient statistical evidence to conclude an effect of introducing a system of deemed consent in Wales. Quarterly monitoring of both DBD and DCD consent rates will continue.

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