

NHS BLOOD AND TRANSPLANT**National Organ Donation Committee****Analysis of the effect of Welsh Legislation on consent/authorisation rates: Quarter 4****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 2016. The percentage of eligible DBD and DCD donors approached where consent was ascertained, the consent rate, and the number of donors per million population (pmp) are compared between the four UK nations at similar time points.

CURRENT DATA

3. During 2016, 2635 families of eligible donors were approached regarding organ donation in England. In the same time period 259 families were approached in Scotland, 140 in Wales, and 92 in Northern Ireland. The highest overall consent rate in 2016 was 64.1% in Scotland, compared with 63.0% in England, 60.0% in Wales, and 58.7% in Northern Ireland. The number of donors pmp was highest in Scotland, 23.2 pmp, compared with 21.2 in England and Northern Ireland and 18.1 in Wales. 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. 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.

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January 2017

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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 from 1 January 2016 through the Potential Donor Audit (PDA). 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 or relative medical contraindications to solid organ donation.

3. The percentage of eligible donors whose families were approached and consent for donation was ascertained, the consent rate, and the number of donors per million population (pmp) are compared for the four UK nations at similar time points.

CURRENT DATA

4. **Table 1** shows the number of eligible donors whose families were approached and the corresponding consent/authorisation rate in 2016 and 2015 for comparison, by donor type and nation. In England, 2635 families of eligible donors were approached (1100 DBD and 1535 DCD) about organ donation. In the same time period 259 families were approached in Scotland (103 DBD and 156 DCD), 140 in Wales (46 DBD and 94 DCD), and 92 in Northern Ireland (49 DBD and 43 DCD).

5. The highest overall consent rate for the most recent time period was 64.1% in Scotland, compared with 63.0% in England, 60.0% in Wales, and 58.7% in Northern Ireland. Table 1 shows the DBD and DCD breakdown of these consent/authorisation rates.

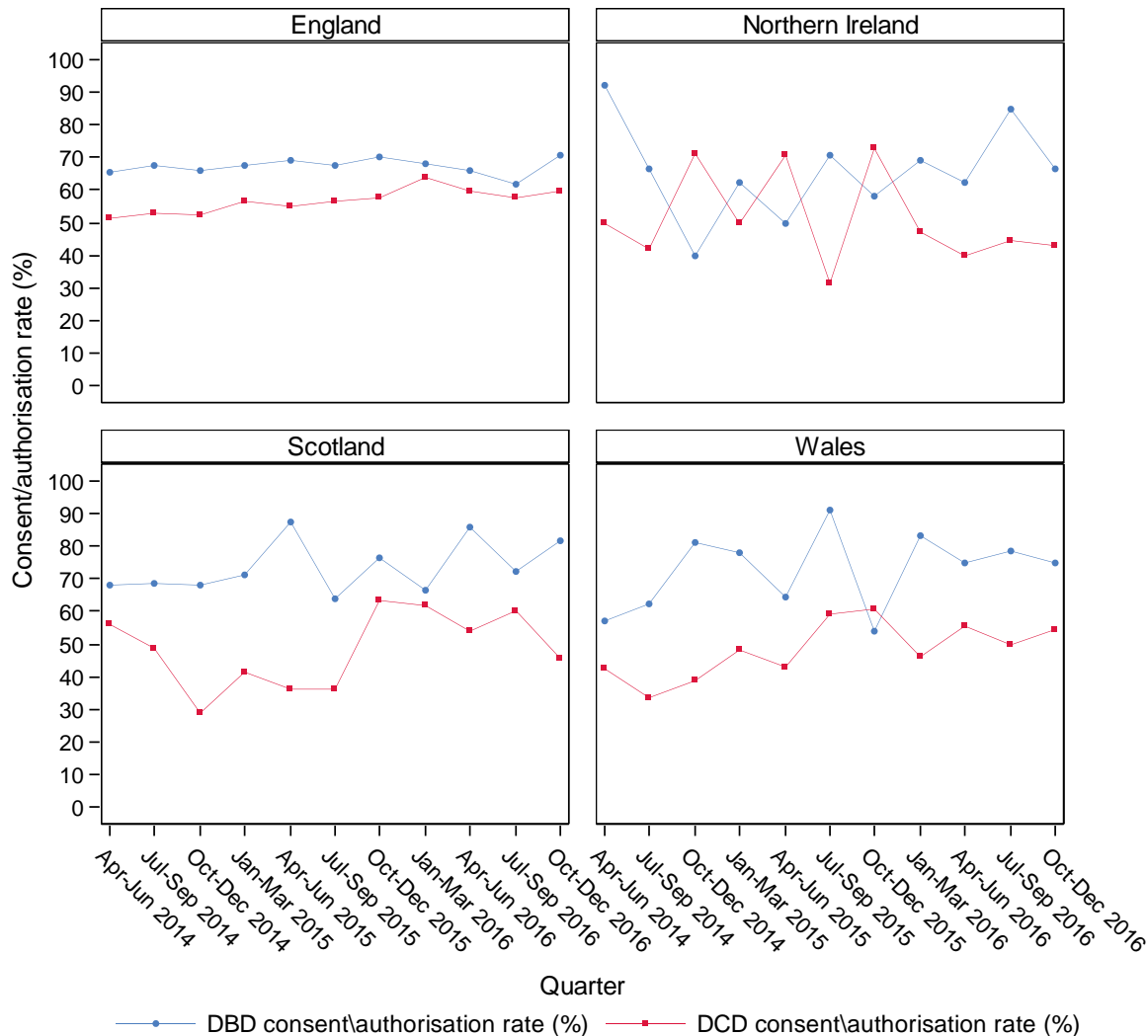
6. The number of donors pmp have increased in 2016 in both Scotland and England when compared to 2015. Scotland has seen the largest increase from 16.1 to 23.2 pmp. Table 1 shows the DBD and DCD breakdown of these donation rates.

Country	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	Jan 15 – Dec 15	1089	68.6	12.0	1603	56.5	8.4	2692	61.4	20.3
	Jan 16 – Dec 16	1100	66.6	12.0	1535	60.5	9.2	2635	63.0	21.2
Northern Ireland	Jan 15 – Dec 15	59	61.0	15.8	69	56.5	10.9	128	58.6	26.6
	Jan 16 – Dec 16	49	71.4	17.4	43	44.2	3.8	92	58.7	21.2
Scotland	Jan 15 – Dec 15	73	74.0	9.3	162	44.4	6.7	235	53.6	16.1
	Jan 16 – Dec 16	103	76.7	13.5	156	55.8	9.7	259	64.1	23.2
Wales	Jan 15 – Dec 15	47	70.2	10.0	112	53.6	8.1	159	58.5	18.1
	Jan 16 – Dec 16	46	78.3	11.3	94	51.1	6.8	140	60.0	18.1

* Population figures based on ONS 2013 Census figures. England, Isle of Man and Channel Islands (54.56 million), Northern Ireland (1.84 million), Scotland (5.35 million) and Wales (3.09 million)

7. **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 December 2016



SEQUENTIAL QUARTERLY ANALYSIS

8. 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.

9. 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 a system of presumed consent 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.

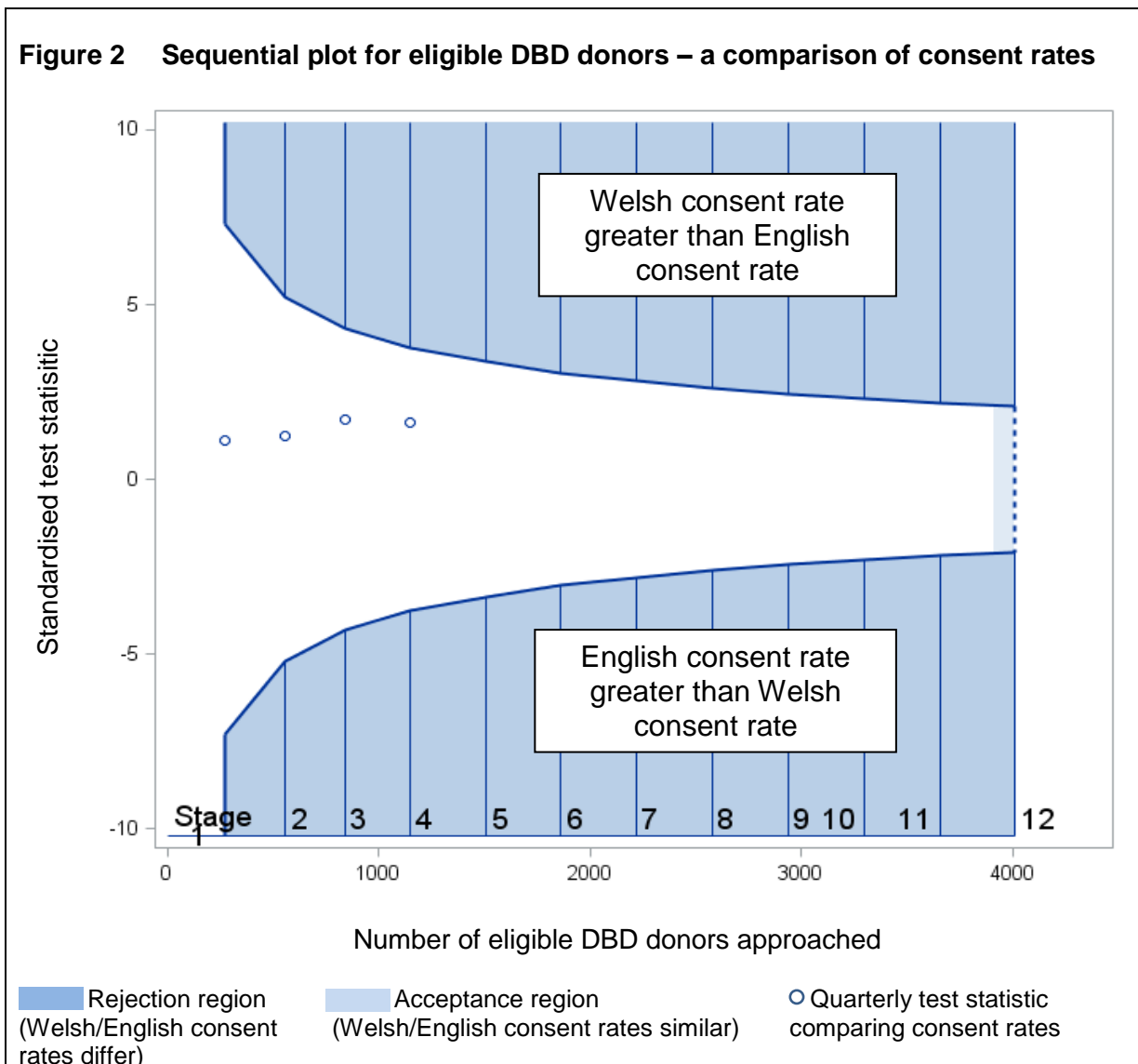
Assumptions

10. 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. An absolute difference in consent rate in England and Wales of 10% is appropriate for both DBD and DCD.
 - c. Current DCD screening practices are consistent across England and Wales.

DBD consent/authorisation rate comparison

11. **Table 2** shows quarterly DBD consent/authorisation rates in England and Wales for 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)	255	173	67.8	12	10	83.3
2 (Apr-Jun)	283	186	65.7	8	6	75.0
3 (Jul-Sep)	266	165	62.0	14	11	78.6
4 (Oct-Dec)	296	209	70.6	12	9	75.0



12. 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.

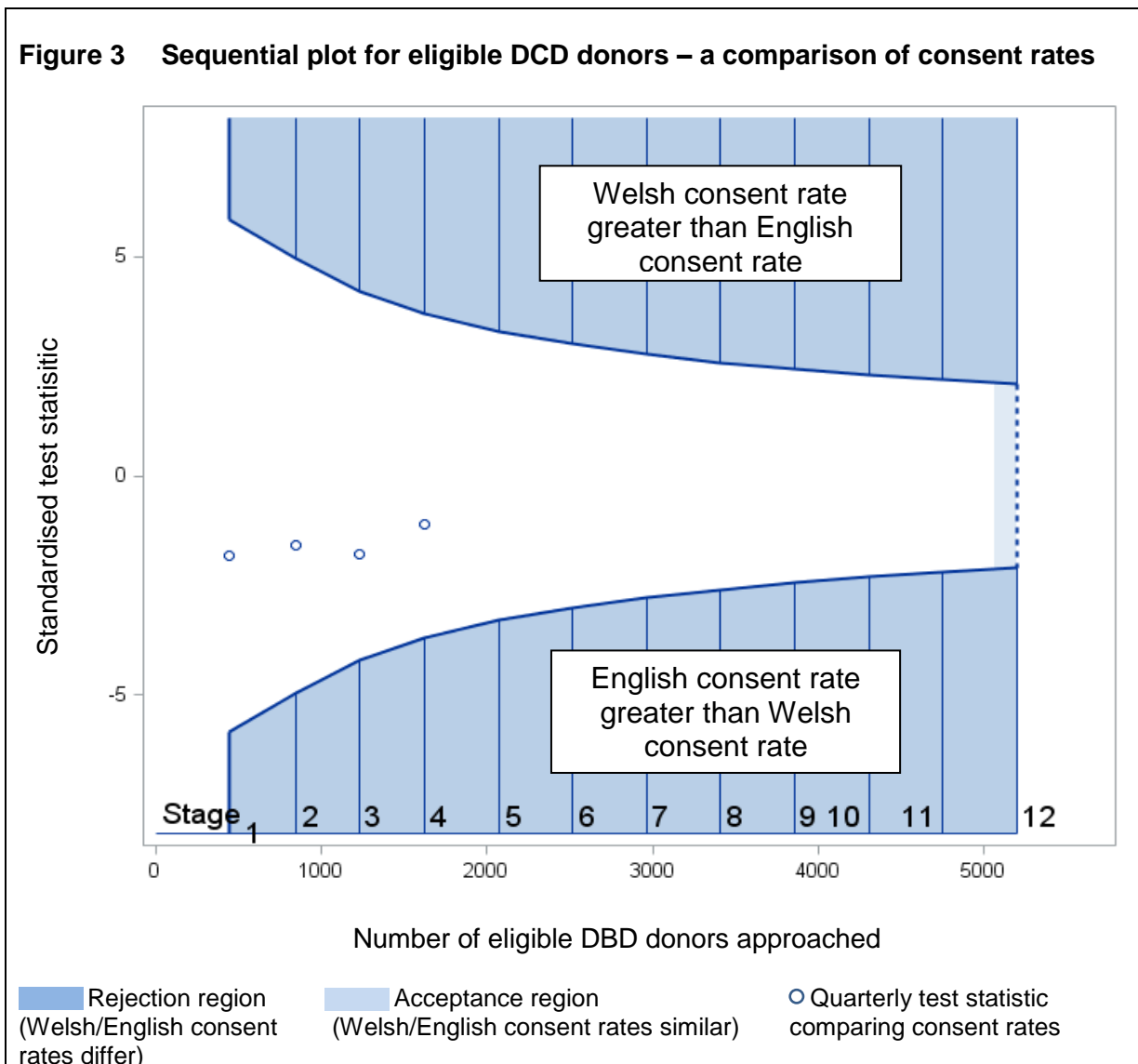
DCD consent/authorisation rate comparison

13. **Table 3** shows quarterly DCD consent/authorisation rates in England and Wales for 2016.

Table 3 Quarterly DCD data for 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)	416	266	63.9	26	12	46.2
2 (Apr-Jun)	389	233	59.9	18	10	55.6
3 (Jul-Sep)	349	201	57.6	28	14	50.0
4 (Oct-Dec)	381	228	59.8	22	12	54.5

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



14. 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

15. In 2016, there were improvements in overall consent rates in all four UK nations when compared with 2015. There were increases in both DBD and DCD consent rates in Scotland and Wales. Scotland had the highest overall consent rate and number of donors pmp in 2016.

16. 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.

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