

## NHS BLOOD AND TRANSPLANT

## National Organ Donation Committee

## Analysis of the effect of Welsh Legislation on consent/authorisation rates: Quarter 12

## 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/authorisation 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/authorisation was ascertained, the consent/authorisation rate, and the approximate number of donors per million population (pmp) are compared between the four UK nations.

## CURRENT DATA

3. During 2018, 2762 families of eligible donors were approached regarding organ donation in England. In the same time period 253 families were approached in Scotland, 169 in Wales, and 82 in Northern Ireland. The overall consent/authorisation rates in the four nations were 75% in Wales, 67% in England, 64% in Northern Ireland and 63% in Scotland. **Table 1** shows the DBD and DCD breakdown of these consent/authorisation rates 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. Based on a sequential analysis, the latest data points for eligible DBD patients have crossed the upper boundary. This means that there is statistical evidence of a significant increase in the DBD consent rate in Wales when compared to England. Equivalent data points for eligible DCD patients have reached the end of the chart without crossing either upper or lower boundary concluding there is no statistically significant difference between the DCD consent rates for England and Wales.

## CONCLUSIONS

5. In 2018, overall consent/authorisation rates for the four UK nations ranged from 64% in Scotland to 75% in Wales. The sequential study has reached its conclusion following the accumulation of sufficient data. There is statistical evidence of an increase in the DBD consent rate in Wales when compared to England, however there is no evidence of a difference in the DCD consent rates between the two nations. Further multivariable analysis is required to determine whether the observed increase in the DBD consent rate in Wales is a result of the introduction of deemed consent having accounted for other factors known to influence consent rates.

**Sue Madden**  
Statistics and Clinical Studies

**January 2019**

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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 December 2018. Data presented in this report are as at 7 January 2019.

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 all families informed of a patient's registered opt-out decision. In a small number of cases the patient's family were not informed of the registered opt-out decision when they should have been. For the purposes of this analysis, such cases have been reported as having been approached, accounting for 3% of all approaches in Wales, and are consequently included in the consent rate calculation. These families would have been approached in all other UK nations, and this inclusion ensures consent/authorisation rates are comparable between nations and prevents any bias in the Welsh consent rate presented.

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 and the three following the change in Welsh legislation.

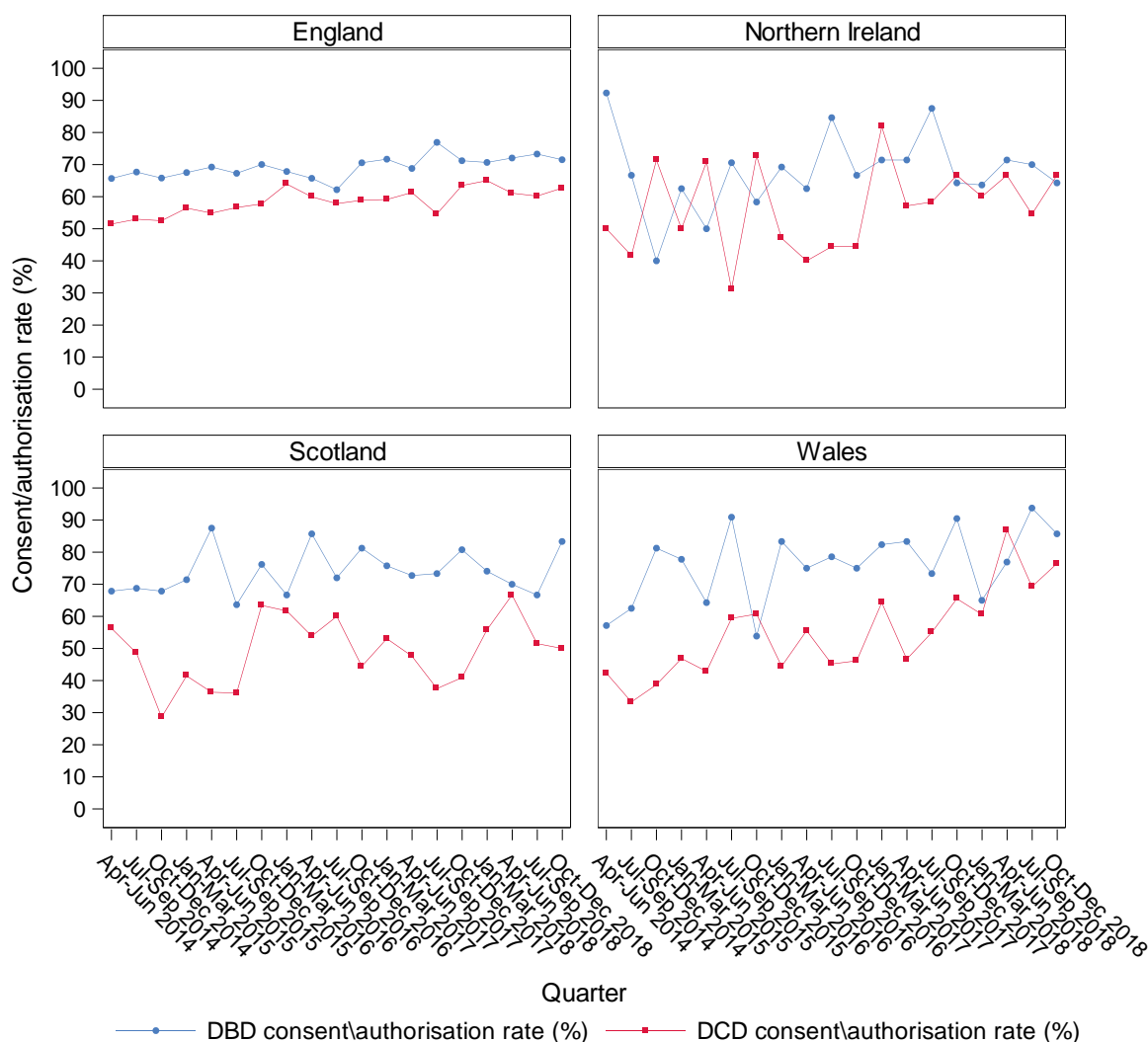
7. In 2018, 2762 families of eligible donors were approached to discussion organ donation in England (1296 DBD and 1466 DCD). In the same time period, 253 families were approached in Scotland (108 DBD and 145 DCD), 169 in Wales (70 DBD and 99 DCD), and 82 in Northern Ireland (49 DBD and 33 DCD).

8. The overall consent/authorisation rates in 2018, for all four nations were 75% in Wales, 67% in England, 65% in Northern Ireland and 64% Scotland, respectively. **Table 1** shows the DBD and DCD breakdown of these consent/authorisation rates.

9. In the same year, there were approximately 28.9 donors pmp in Wales, 24.3 donors pmp in England, 24.7 donors pmp in Northern Ireland, and 20.6 donors pmp in Scotland. **Table 1** shows the DBD and DCD breakdown of these donation rates.

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 December 2018**



**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 December 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	1104	66.7	11.8	1553	60.3	9.1	2657	62.9	21.0
	2017	1199	72.1	13.8	1574	59.7	9.1	2773	65.1	22.8
	2018	1296	71.8	15.3	1466	62.3	9.0	2762	66.8	24.3
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	39	66.7	7.0	82	69.5	22.0
	2018	49	67.3	15.6	33	60.6	9.1	82	64.6	24.7
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	167	45.5	7.6	263	56.7	19.6
	2018	108	74.1	13.1	145	55.9	7.4	253	63.6	20.6
Wales	2015	47	70.2	10.0	113	53.1	8.0	160	58.1	18.0
	2016	46	78.3	11.3	102	47.1	7.1	148	56.8	18.3
	2017	65	83.1	15.4	92	59.8	9.3	157	69.4	24.8
	2018	70	80.0	16.1	99	71.7	12.9	169	75.1	28.9

\* 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)

## 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. When plotted points cross the upper boundary, we would conclude there is evidence of a significant increase in the Welsh consent rate relative to the English consent rate. Conversely, if the plotted points cross the lower boundary, we would conclude that there is a significant reduction in the Welsh consent rate relative to the English consent rate, whereas if the study continues until the points cross the vertical dotted line, we would 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

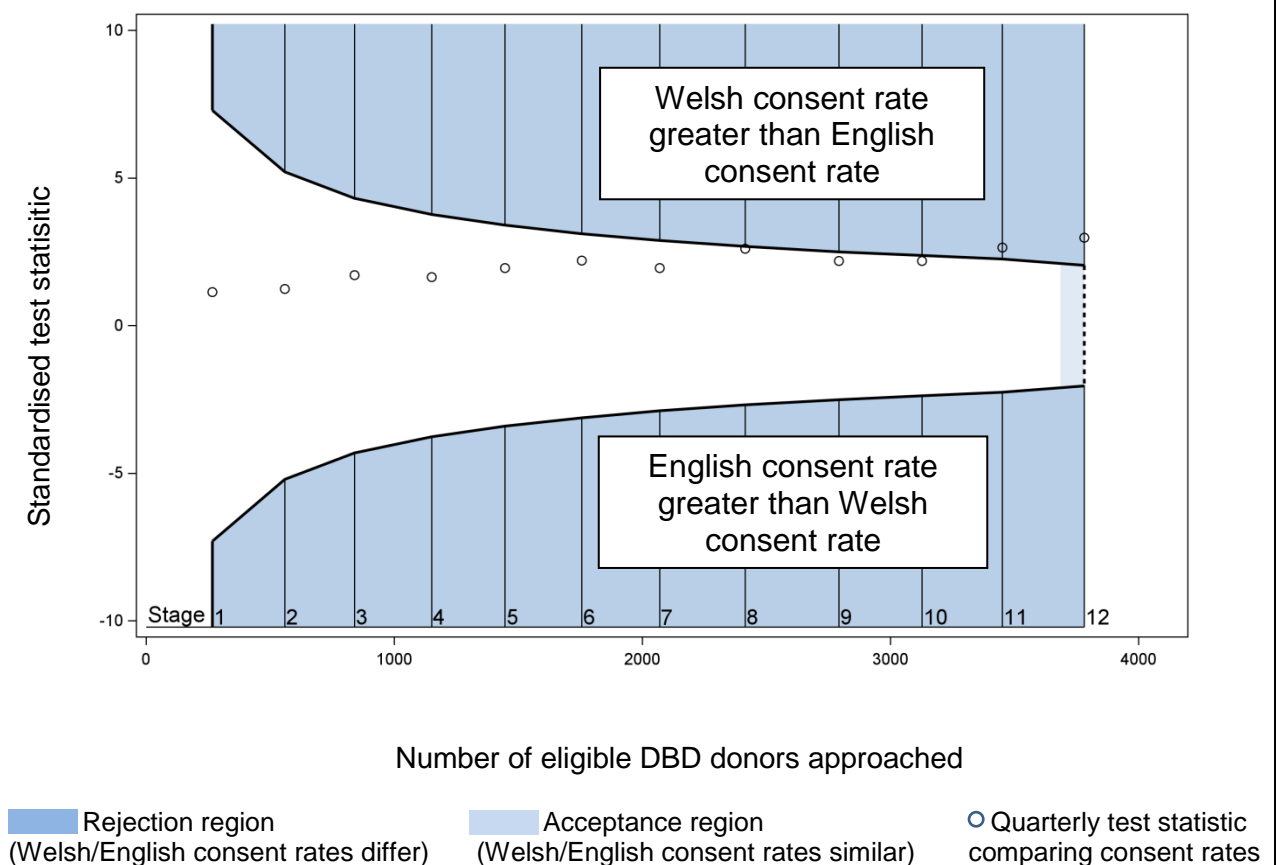
14. **Table 2** shows quarterly DBD consent/authorisation rates in England and Wales since 1 January 2016.

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**. In the last two quarters, the plotted points crossed and remained above the upper boundary. This means that, following the introduction of deemed consent, there is statistical evidence of a significant increase in the DBD consent rate in Wales when compared to England.

**Table 2** Quarterly DBD data 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)	299	211	70.6	12	9	75.0
5 (Jan - Mar 17)	279	200	71.7	17	14	82.4
6 (Apr - Jun 17)	298	205	68.8	12	10	83.3
7 (Jul - Sep 17)	299	230	76.9	15	11	73.3
8 (Oct - Dec 17)	323	230	71.2	21	19	90.5
9 (Jan - Mar 18)	358	253	70.7	20	13	65.0
10 (Apr - Jun 18)	322	232	72.0	13	10	76.9
11 (Jul - Sep 18)	307	225	73.3	16	15	93.8
12 (Oct - Dec 18)	309	221	71.5	21	18	85.7

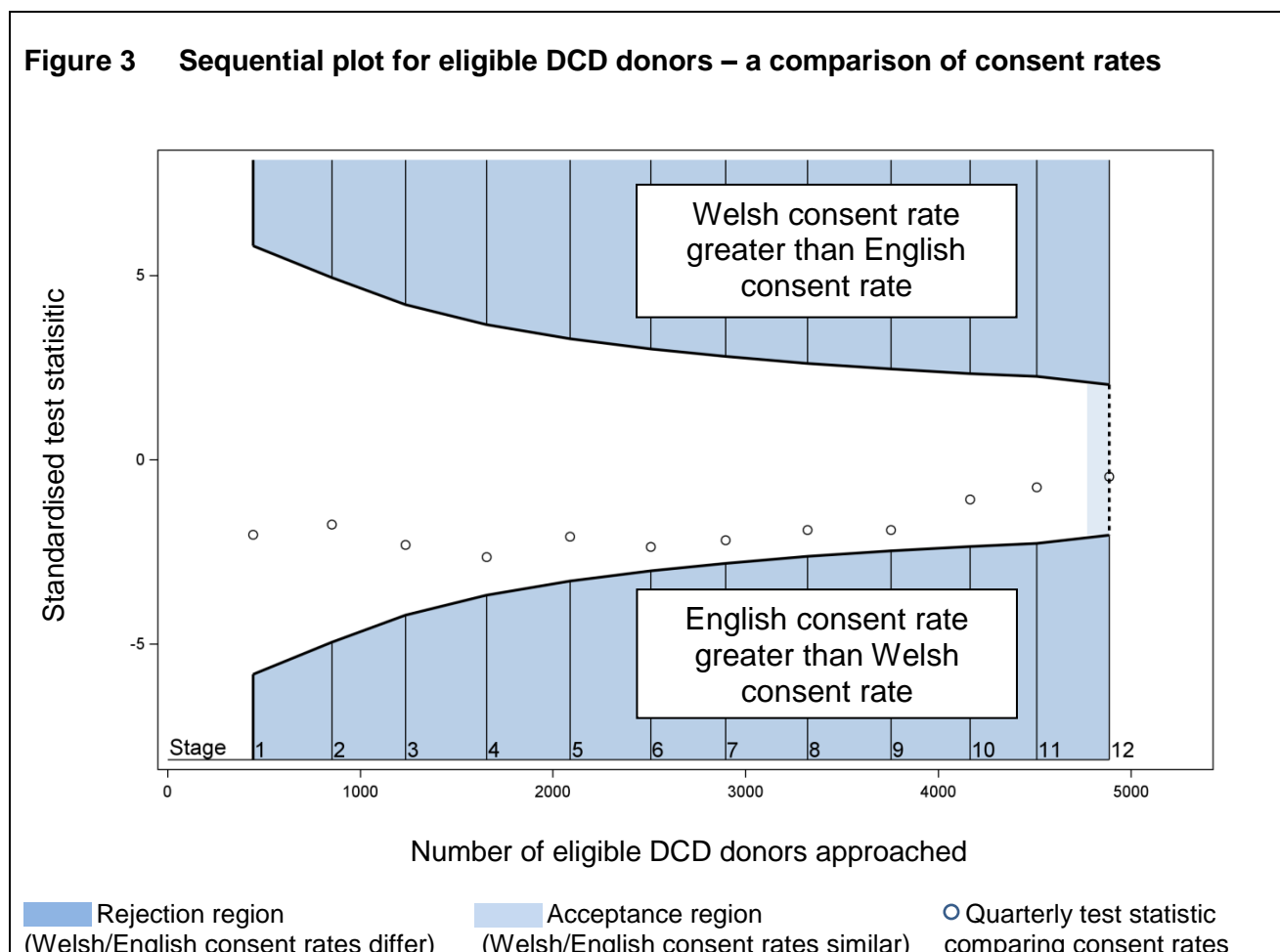
**Figure 2** Sequential plot for eligible DBD donors – a comparison of consent rates



**DCD consent/authorisation rate comparison**

16. **Table 3** shows quarterly DCD consent/authorisation rates in England and Wales 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	27	12	44.4
2 (Apr - Jun 16)	392	235	59.9	18	10	55.6
3 (Jul - Sep 16)	351	203	57.8	31	14	45.2
4 (Oct - Dec 16)	394	232	58.9	26	12	46.2
5 (Jan - Mar 17)	406	240	59.1	28	18	64.3
6 (Apr - Jun 17)	403	247	61.3	15	7	46.7
7 (Jul - Sep 17)	368	201	54.6	20	11	55.0
8 (Oct - Dec 17)	397	252	63.5	29	19	65.5
9 (Jan - Mar 18)	400	260	65.0	33	20	60.6
10 (Apr - Jun 18)	388	237	61.1	23	20	87.0
11 (Jul - Sep 18)	319	192	60.2	26	18	69.2
12 (Oct - Dec 18)	359	225	62.7	17	13	76.5



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 sequential study has come to an end following the accumulation of sufficient data. The plotted points have reached the acceptance region at the end of the plot resulting in the conclusion that there is no evidence of either an increase or decrease in the DCD consent rate in Wales when compare to England for the duration of the study.

## **CONCLUSIONS**

18. In 2018, the overall consent/authorisation rates in the four UK nations, ranged from 64% in Scotland to 75% in Wales. DBD consent/authorisation rates ranged from 67% in Northern Ireland to 80% in Wales and DCD consent/authorisation rates ranged from 56% in Scotland to 72% in Wales.

19. The sequential study monitoring the impact of deemed consent on consent rates in Wales in comparison to England has reached its conclusion for both DBD and DCD consent rate comparisons. The study concludes that:

- i. There is evidence of a significant increase in the DBD consent rate in Wales when compared to England in the three years since the introduction of deemed consent.
- ii. There is no evidence of an increase or decrease in the DCD consent rate in Wales when compared to England for the duration of the study.

20. Further work is required to determine whether the observed increase in DBD consent rates in Wales is a result of the introduction of deemed consent having accounted for other factors known to influence consent rates.

**Sue Madden**  
**Statistics and Clinical Studies**

**January 2019**