

NHS BLOOD AND TRANSPLANT

National Organ Donation Committee

Analysis of the effect of Welsh Legislation on consent/authorisation rates: Quarter 11

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 at similar time points.

CURRENT DATA

3. During the first nine months of 2018, 2083 families of eligible donors were approached regarding organ donation in England. In the same time period 188 families were approached in Scotland, 131 in Wales, and 61 in Northern Ireland. The overall consent/authorisation rates were similar in all four UK nations; 73% in Wales, 67% in England and 64% and 63% in Northern Ireland and Scotland, respectively. **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. The latest data points for eligible DBD patients have crossed the upper boundary for the first time. This means that there is statistical evidence of a significant increase in DBD consent rates in Wales compared to England. Data points for eligible DCD patients show no increasing or decreasing trend.

CONCLUSIONS

5. In the first nine months of 2018, overall consent/authorisation rates for the four UK nations were similar ranging from 63% in Scotland to 73% in Wales. There is statistical evidence of an increase in the DBD consent rate in Wales, although there is no evidence of a similar trend in the DCD consent rate. Quarterly monitoring will continue to ensure the improvement in the DBD consent rate in Wales, is maintained. A multivariable analysis is also 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.

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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 30 September 2018. Data presented in this report are as at 8 October 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 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 the change in Welsh legislation, and the two and a half years since the change.

7. In the first nine months of 2018, 2083 families of eligible donors were approached to discuss organ donation in England (985 DBD and 1098 DCD). In the same time period, 188 families were approached in Scotland (78 DBD and 110 DCD), 131 in Wales (50 DBD and 81 DCD), and 61 in Northern Ireland (35 DBD and 26 DCD).

8. The overall consent/authorisation rates for the first nine months of 2018, were similar for all four nations; 73% in Wales, 67% in England and 64% and 63% in Northern Ireland and Scotland, respectively. **Table 1** shows the DBD and DCD breakdown of these consent/authorisation rates.

9. In the same time period, there were approximately 20.3 donors pmp in Wales, 18.4 donors pmp in England, 17.2 donors pmp in Northern Ireland, and 15.0 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 30 September 2018

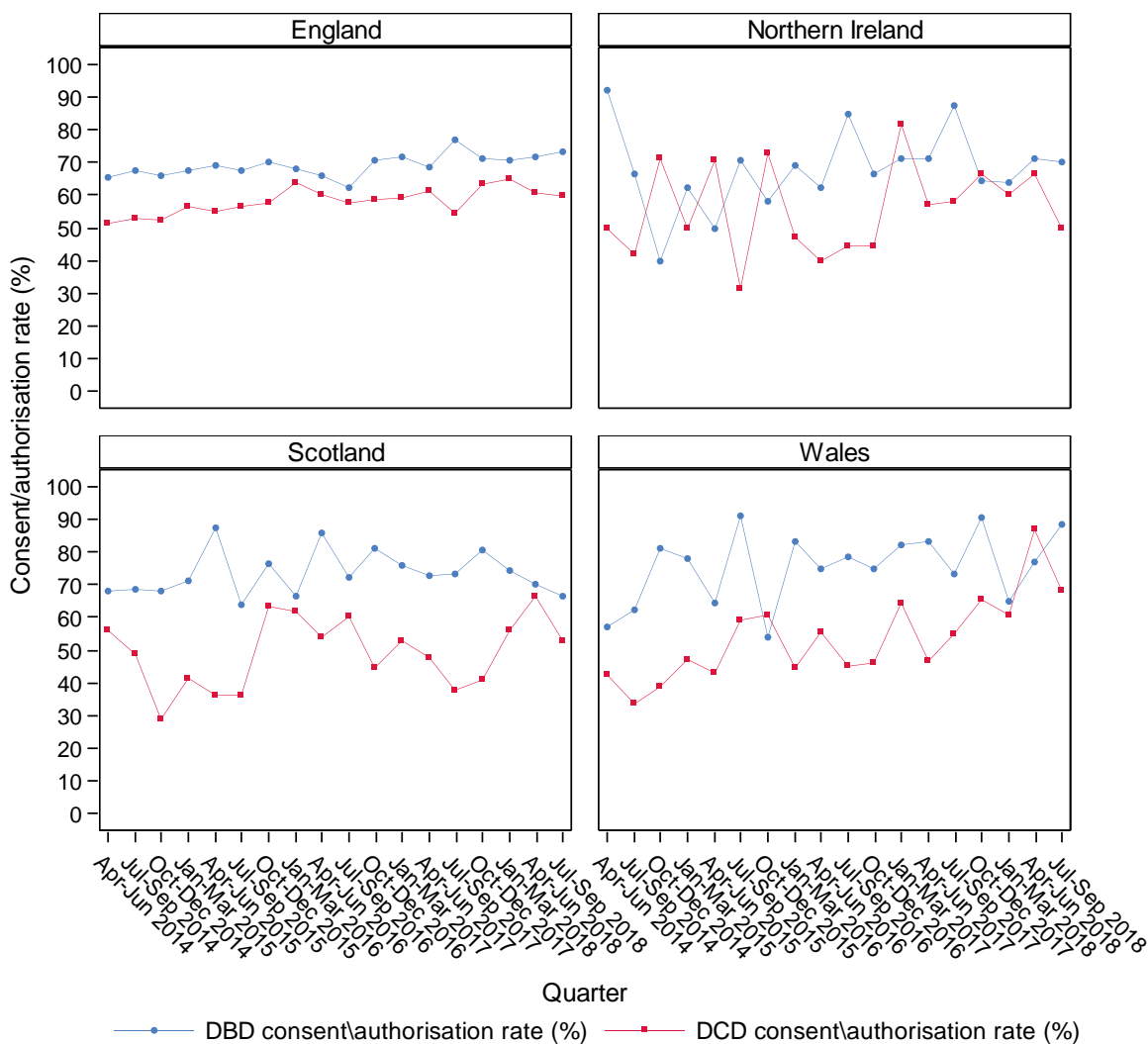


Table 1 Deceased consent/authorisation rates for England, Wales, Scotland, and Northern Ireland for eligible donors whose families were approached and donors pmp, 1 January 2015 to 30 September 2018, by country of donor hospital and donor type

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
	Jan-Sep 2018	985	71.9	11.6	1098	62.1	6.8	2083	66.7	18.4
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
	Jan-Sep 2018	35	68.6	10.8	26	57.7	6.5	61	63.9	17.2
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
	Jan-Sep 2018	78	70.5	9.4	110	58.2	5.6	188	63.3	15.0
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
	Jan-Sep 2018	50	76.0	10.9	81	70.4	9.3	131	72.5	20.3

* 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

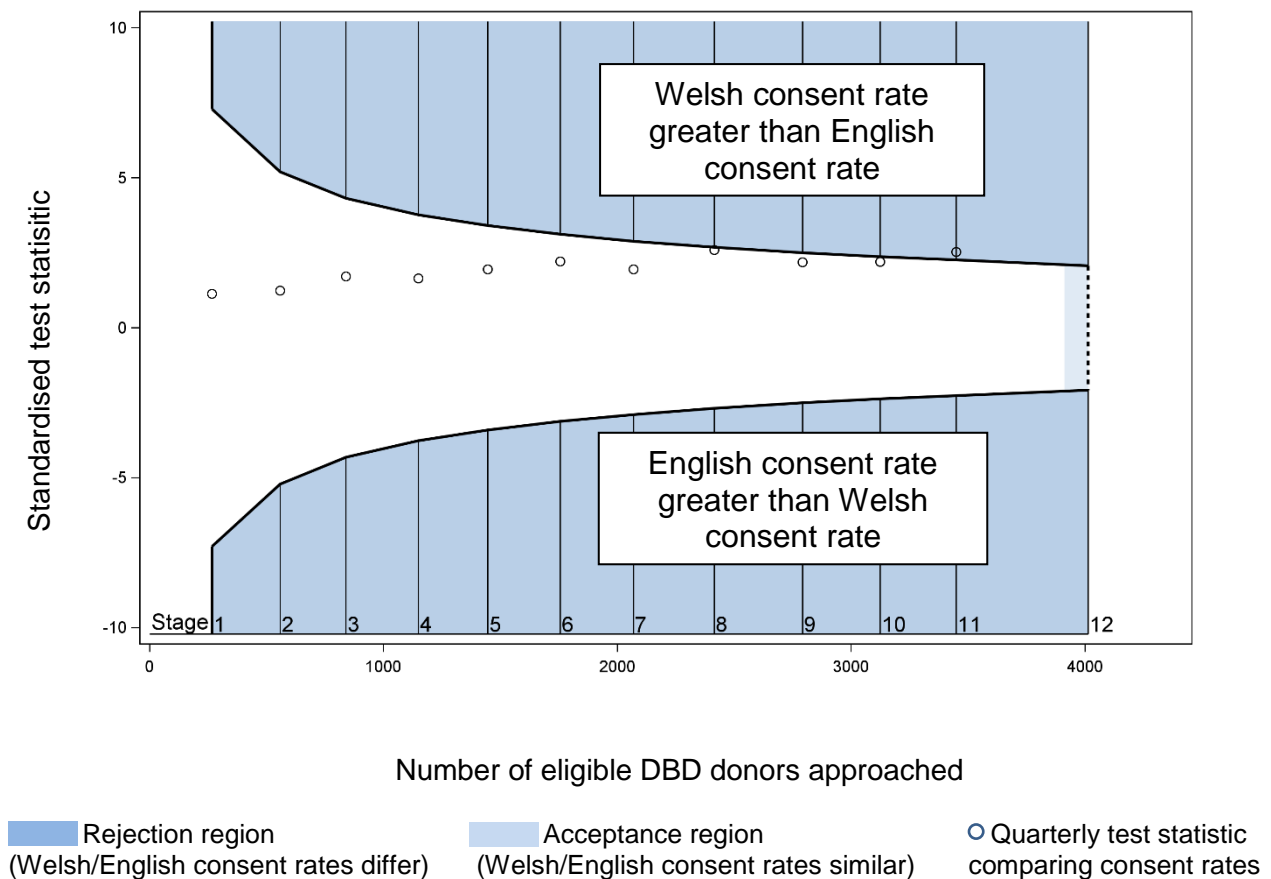
14. **Table 2** shows quarterly DBD consent/authorisation rates in England and Wales since 1 January 2016.

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**. The plotted points, have crossed the upper boundary for the first time. This means that there is statistical evidence of a significant increase in DBD consent rates in Wales compared to England. Quarterly monitoring will continue to ensure the improvement in DBD consent rate in Wales is sustained and a multivariable analysis is required to determine whether the observed increase in DBD consent rates in Wales is a result of the introduction of deemed consent.

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)	320	230	71.9	13	10	76.9
11 (Jul - Sep 18)	307	225	73.3	17	15	88.2

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

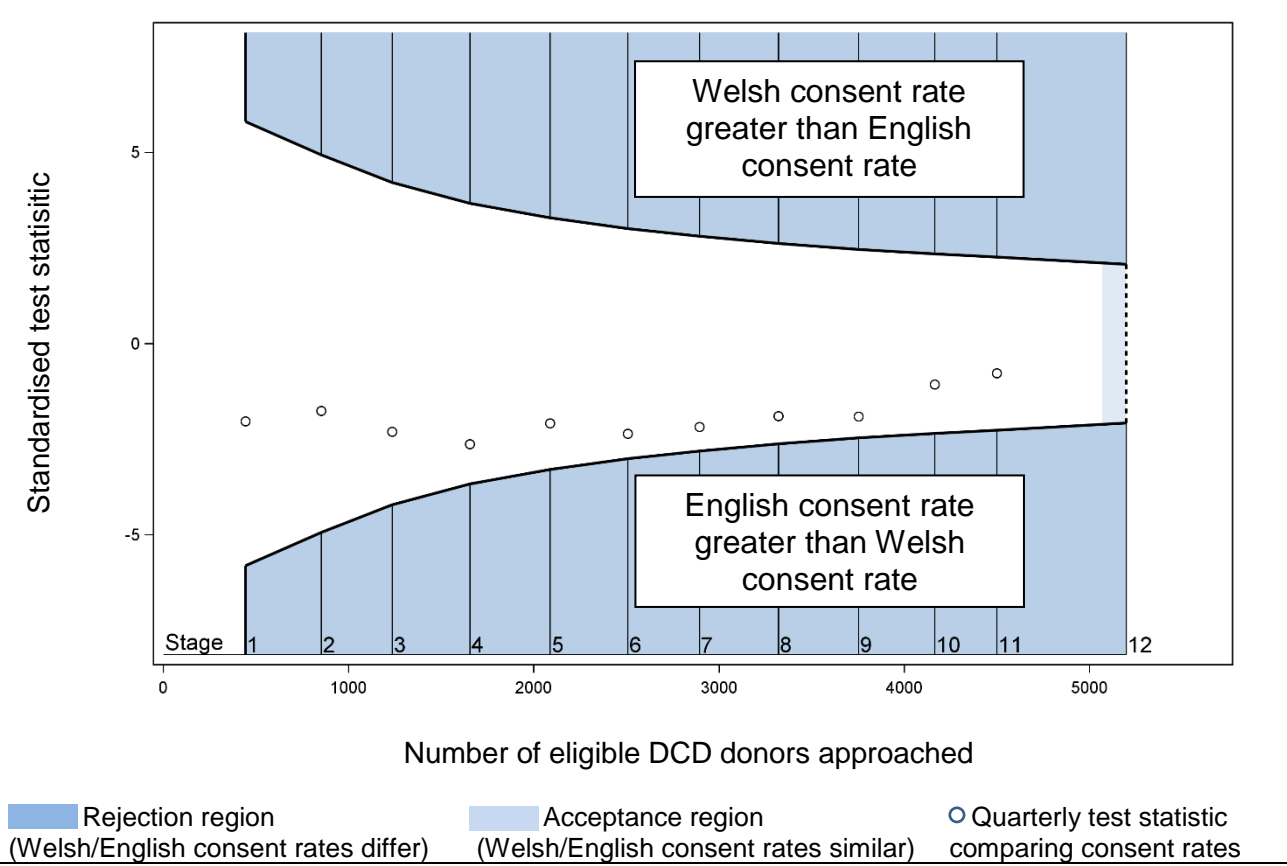


DCD consent/authorisation rate comparison

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)	387	236	61.0	23	20	87.0
11 (Jul - Sep 18)	311	186	59.8	25	17	68.0

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 plotted points for the last two quarters indicate DCD consent rates in Wales have improved, however the study is likely to conclude that there is no evidence of an increase or decrease in the DCD consent rate in Wales when compare to England for the duration of the study.

CONCLUSIONS

18. Between January and September 2018, the overall consent/authorisation rates were similar across all four UK nations, ranging from 63% in Scotland to 73% in Wales. DBD consent/authorisation rates ranged from 69% in Northern Ireland to 76% in Wales and DCD consent/authorisation rates ranged from 58% in Northern Ireland and Scotland to 70% in Wales.

19. The sequential plot for DBD consent rates has demonstrated, for the first time, a significant increase in the DBD consent rates in Wales when compared to England. However, the plotted points provide no evidence of a similar trend in DCD consent rates and with only one or two quarters remaining, the study is likely to conclude that there is no evidence of an increase or decrease in the DCD consent rate in Wales when compared to England.

20. Quarterly monitoring of both DBD and DCD consent rates will continue to ensure the improvement in the DBD consent rate in Wales is sustained and complete the assessment of the DCD consent rate. A multivariable analysis is also 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.

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