

NHSBT BOARD
28th September 2017

Impact of the Human Transplantation Act (Wales)

1. Status – Public

2. Executive Summary

This paper summarises organ donation activity and consent rates in Wales since the introduction of deemed consent on 1 December 2015. Activity prior to the change in legislation as well as that of the other UK nations is included for comparison.

Ongoing quarterly analysis of the effect of deemed consent on consent/authorisation rates indicates that, at present, there is insufficient evidence to conclude whether deemed consent in Wales has led to an increase in consent rates.

3. Background

From 1 December 2015 the Human Transplantation Act (HTA) (Wales) introduced that consent for organ donation would be deemed in certain circumstances:

- ***Patient died in Wales and is aged 18 years or over at time of death, and***
- ***Patient has lived in Wales for more than 12 months and is ordinarily resident there, and***
- ***Patient had the capacity to understand the notion of deemed consent for a significant period before their death***

4. Definitions

National Potential Donor Audit (PDA) provides all the data presented in this paper. The data comprise all audited patient deaths in UK Intensive Care Units (ICUs) and emergency departments, excluding wards and patients over 80 years of age, in the time period. Paediatric ICU data are included however neonatal ICU data have been excluded. The data are based on information received by 10 July 2017.

Eligible donors after brain death (DBD) are defined as patients for whom death was confirmed following neurological tests and who had no absolute medical contraindications to solid organ donation.

Eligible donors after circulatory death (DCD) are defined as patients who had treatment withdrawn and death was anticipated within four hours, with no absolute medical contraindications to solid organ donation.

Consent / authorisation rate is the percentage of eligible donor families or appointed/nominated representatives approached for formal organ donation discussion where consent/authorisation was ascertained. The terminology authorisation rate is employed in Scotland. Families of eligible donors who opted out via the ODR are included in the consent/authorisation rate calculation. These families are approached for a formal organ donation discussion to enable the SNOD to communicate the patient's decision not to be an organ donor and provide an opportunity for the family to inform the SNOD when a patient was known to have changed their mind.

Actual donors are eligible donors who became actual donors as reported through the PDA.

Donors per million population (pmp) is an estimate of the number of donors per million population by country of donor hospital. Population catchment figures per donor hospital are unknown. As a substitute, Office for National Statistics (ONS) population figures for the four countries have been used as an approximation of the population of the donor hospitals grouped by country. These population estimates do not account for patients who became a donor in a country which is not their country of normal residence. ONS 2013 Census figures are: England, Isle of Man and Channel Islands (54.56 million), Northern Ireland (1.84 million), Scotland (5.35 million) and Wales (3.09 million).

Sequential design analysis - this study has been designed to detect an absolute difference in consent rates between England and Wales of 10%.

Sequential analysis interpretation 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 significant difference between the two consent rates and thus no evidence that deemed consent resulted in increased consent rates.

Sequential analysis advantages The test procedure accounts for the multiple sequential testing, and is designed to avoid a conclusion being reached too early, when the data are more limited.

Sequential analysis limitations The test assumes; consent rates in England and Wales were similar prior to the change in Welsh legislation, an absolute difference in consent rate in England and Wales of 10% is appropriate, and all other practices are consistent across England and Wales.

4. Data analysis

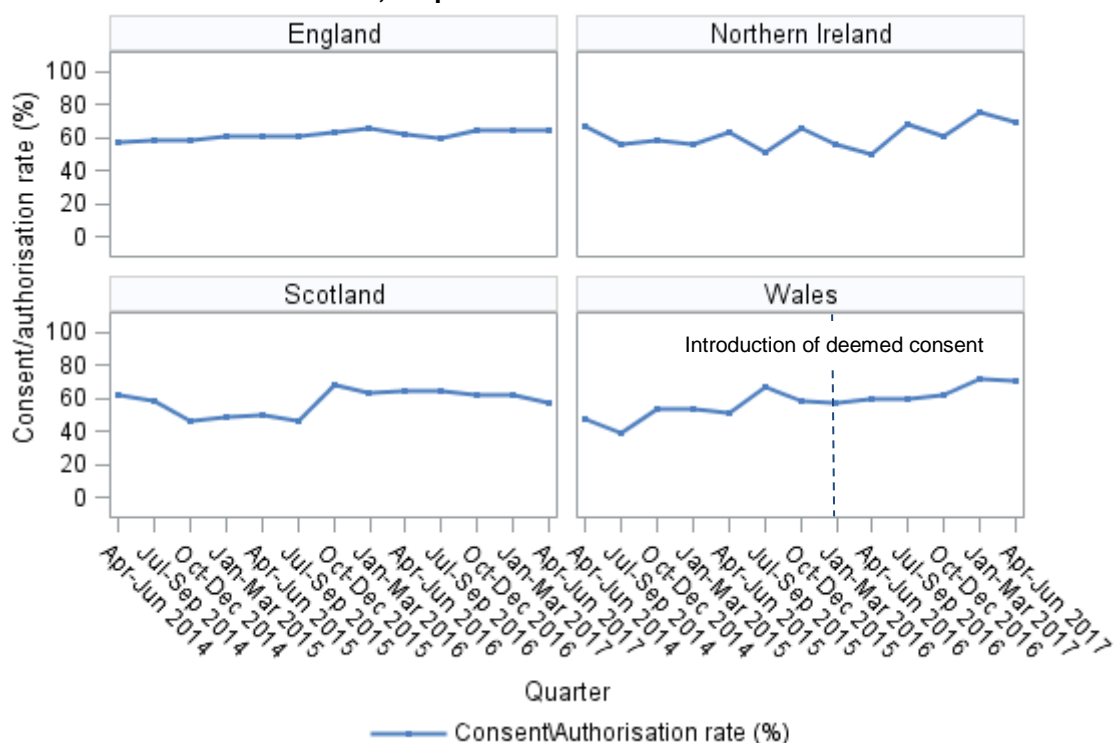
4.1 Consent/authorisation rates pre and post deemed consent

The consent rate in Wales increased from 58% in 2015 to 60% in 2016 following the introduction of deemed consent. In 2017, the consent rate has continued to improve to 72% in the first six months of the year.

4.2 Consent/authorisation rates across the four UK countries

Figure 1 shows the quarterly fluctuations in consent/authorisation rates in the four countries of the UK. Between 2015 and 2016, similar increases were observed in consent rates in Wales, England and Northern Ireland. In Scotland, there was a notable 19% increase in authorisation rate to 64%. Recently in 2017, Wales, England and Northern Ireland have continued to demonstrate increases in consent rates. Scotland's rate remains good, but lower than in 2016.

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



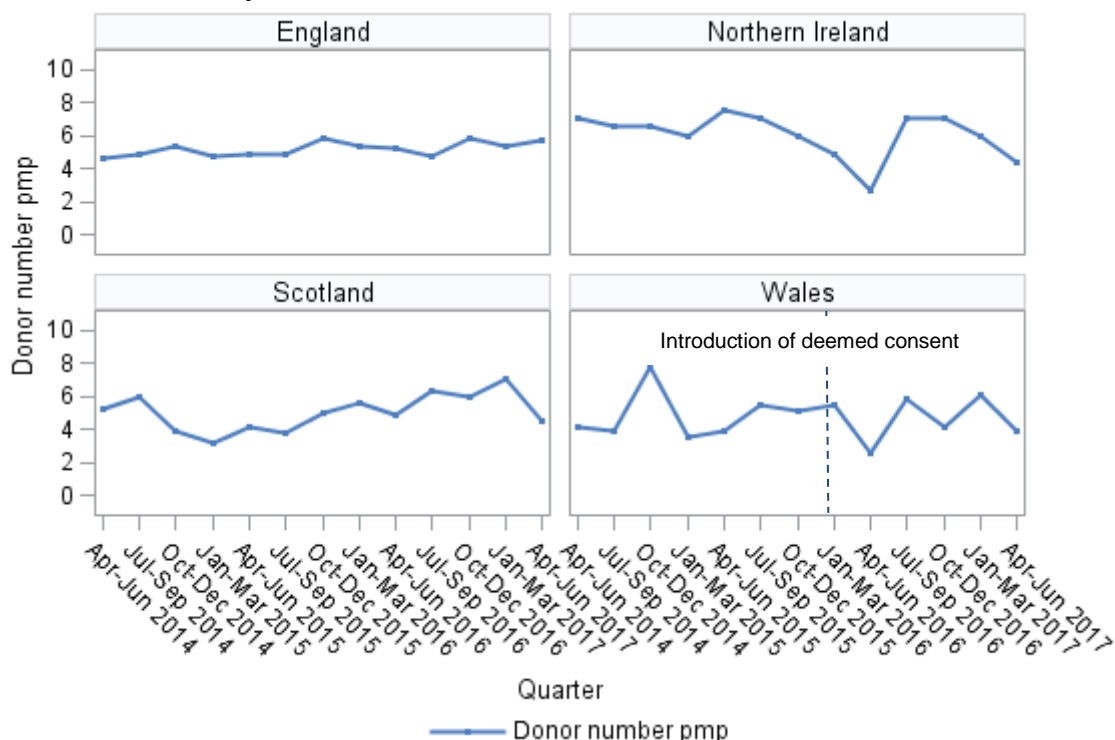
4.3 Actual donors per million population* (pmp)

As discussed, it is not possible to accurately determine the number of donors pmp by country of donor hospital. ONS population figures have been used to provide an approximation of the number of donors pmp by country of donor hospital which enables a comparison of donor rates across the four countries. These population figures do not account for patients who become a donor in a country which is not their country of residence.

Quarterly numbers of donors pmp, presented in **Figure 2**, have remained fairly consistent since 1 April 2014 in all four UK countries. There is greater

variation in Northern Ireland, Wales and Scotland due to the smaller number of donors compared to England.

Figure 2: Quarterly numbers of donors pmp* by country of donor hospital, 1 April 2014 to 30 June 2017



* Donors pmp are provided as indication of donation rates. Population figures for the country of donor hospital are an approximation and do not account for patients who become a donor in a country which is not their country of residence.

4.4 Sequential quarterly analysis

NHSBT Statistics and Clinical Studies team are continuing to monitor the effect of the change in Welsh legislation by comparing the consent rate for Wales with the rate for England. The results are shared with Welsh Government on a quarterly basis and the National Organ Donation Group on a bi-annual basis.

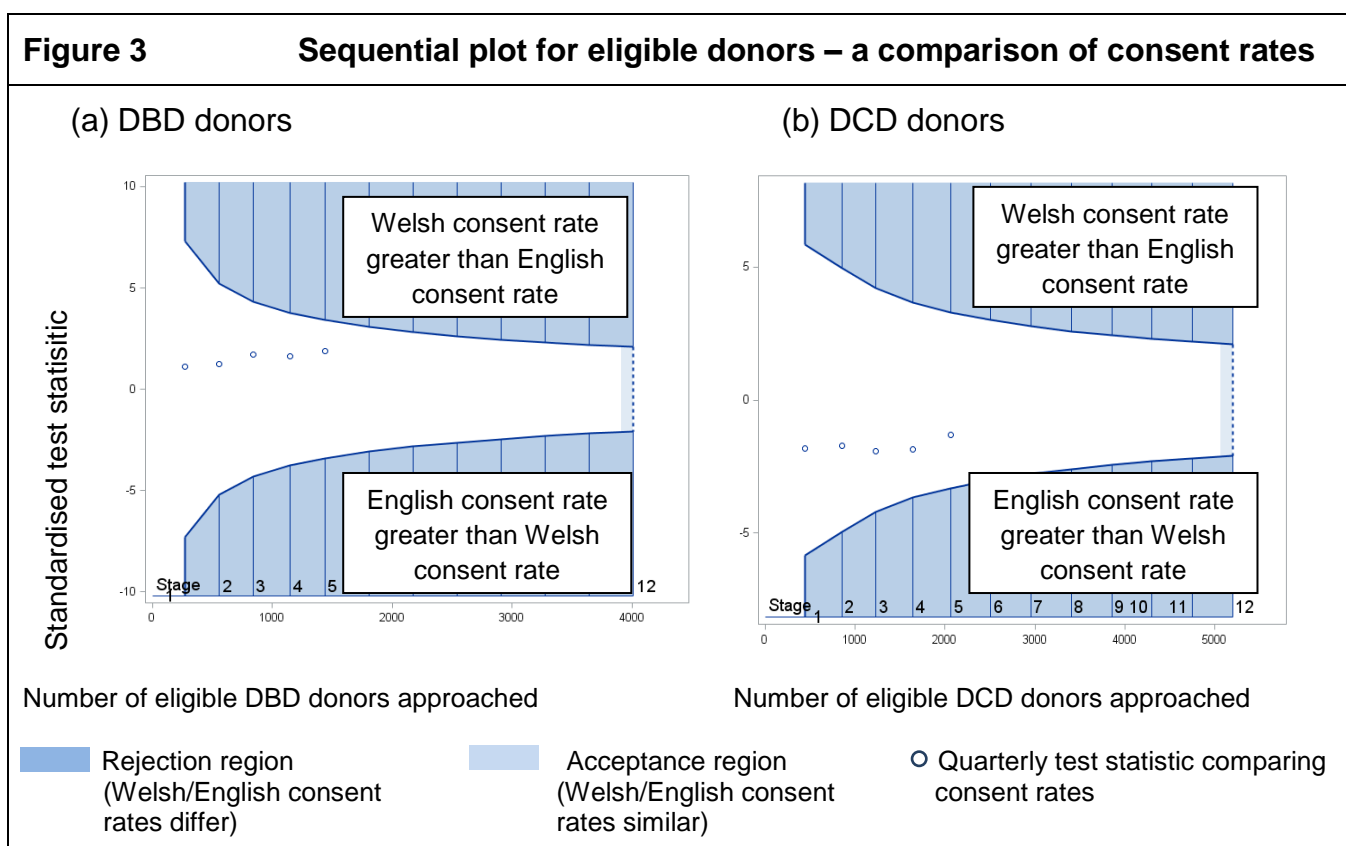
The study has been designed to detect a 10% difference in consent rates for both DBD and DCD donors. The analysis is performed on a quarterly basis but the study may take 3 to 4 years to reach a conclusion due to the small number of potential donors in Wales and associated fluctuations in numbers and rates.

At the start of the study it was agreed to compare Wales against England rather than the rest of the UK. Any trends in consent/authorisation rates in the comparator group should be consistent across countries for a valid sequential analysis. Comparisons with Scotland and Northern Ireland were considered inappropriate due to the possible introduction of an opt-out system and the instability of the quarterly consent/authorisation rates based on the small numbers of eligible donors approached.

Figure 3 sequentially plots the value of the test statistic comparing the difference between DBD (Figure 3a) and DCD (Figure 3b) consent rates in Wales and England.

In **Figure 3a**, the plotted points for DBD donors are proceeding towards the upper boundary. Crossing this would mean that there was significant evidence of an increase in the consent rate in Wales relative to the consent rate in England. Such a signal would prompt a detailed risk-adjusted analysis of the data to determine the true cause of the increased rate in Wales.

In **Figure 3b**, the plotted points for DCD donors show no discernible pattern. As yet there is no evidence of a trend towards an increased or decreased consent rate relative to England.



5. Summary

Following the introduction of deemed consent, the overall consent rate in Wales has increased from 58% in 2015 to 72% in the first six months of 2017. However, rates in England and Northern Ireland have also increased in the same time frame (61% to 64% in England and 59% to 74% in Northern Ireland) and statistical analysis suggests it is too early to determine whether the Welsh consent rate has improved relative to the English consent rate. The data continue to be monitored on a quarterly basis.

Authors

Sue Madden, Senior Statistician

Rachel Johnson, Assistant Director – Statistics and Clinical Studies

Responsible Director

Sally Johnson, Director Organ Donation and Transplantation