

NHS BLOOD AND TRANSPLANT
OTDT Senior Management Team

Evaluation of the impact of opt out legislation on consent rates in England

Executive summary

The study to evaluate the impact of opt out legislation in England was designed before the COVID pandemic and agreed in February 2020. The study aimed to detect an anticipated 5% increase in the English consent rate (as a result of the law change) when compared to the opt-in baseline rate (assumed to be a continuation of the pre-COVID trend). Opt out legislation in England was implemented on 20 May 2020 during the height of the first COVID lockdown.

The evaluation of deemed legislation in England, indicated that the observed opt out consent rate, 61% for the study period, was significantly lower than the anticipated consent rate of 78%. Furthermore, results from the supplementary logistic regression modelling indicated a 29% decrease in the likelihood of consent, since the legislation change, having adjusted for other relevant factors known to influence consent.

Whilst this report concludes the study to evaluate the impact of opt out legislation on the consent rate in England, the monitoring of deemed consent/authorisation rates across all four UK nations will continue with the biannual Opt Out Summary report for National Organ Donation Committee.

Introduction

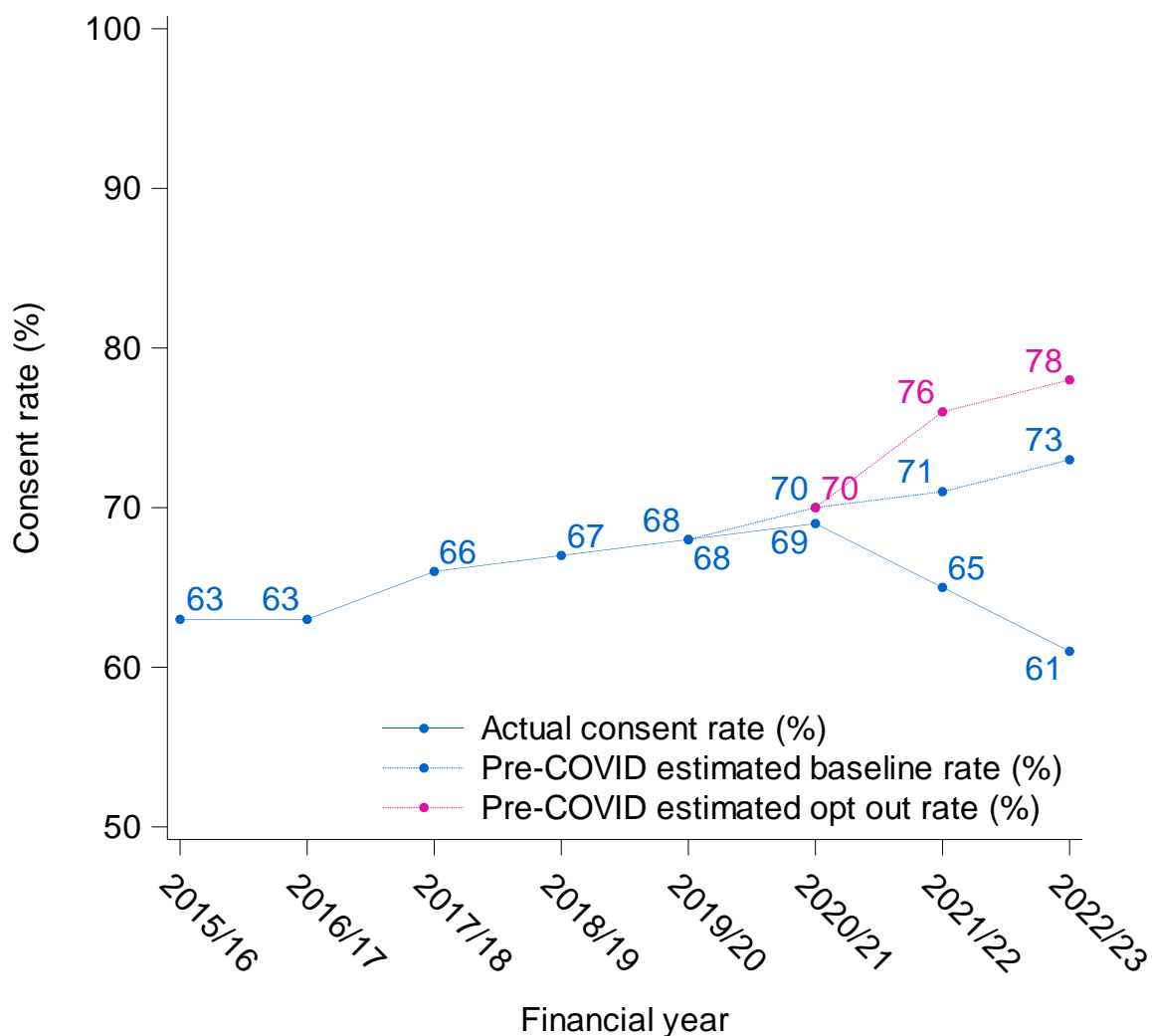
1. In February 2020, the plans to evaluate the impact of opt out legislation on organ donation consent rates, in England, was agreed with the Assistant Director Organ Donation and Nursing, the Associate Medical Director of Organ Donation and Transplantation, the National Clinical Lead for Organ Donation, and the Head of Legislation Implementation Programme as well as the Assistant Director of Statistics and Clinical Research.
2. The study was designed to detect a 5% change in the consent rate after a 2-year bedding in period supplemented by a detailed multivariable analyses to explore any observed differences allowing for relevant factors known to influence the chance of consent in the UK
3. Following the outbreak of COVID-19 in the UK, it was necessary to review the study plan to consider the potential impact of the pandemic on the results of the analyses. The two main concerns focused on legislation implementation delays and the possible impact on the consent rate. Following this review, it was agreed that the monitoring proposal would remain as is, on the assumption (at the time) that the COVID pandemic had not influenced the consent rate in the UK and in the knowledge that operational delays had been accounted for by allowing for a 2-year bedding in period in the original study design.

- A paper describing the study plan and conclusions following the COVID review was presented at OTDT SMT on 21 September 2020. The paper acknowledged that it may never be possible to distinguish between the COVID-19 and opt out legislation effect.

Results

- Annual consent rates in England, for the last 8 years, are presented in **Figure 1**. Included are the first 5 years of annual consent rates (upon which baseline and opt out consent rates were calculated), the estimated baseline consent rate (assuming no legislation change) and the estimated opt out consent rate which were calculated pre-COVID. The annual consent rates observed following the implementation of deemed consent legislation and the start of the COVID pandemic are also presented.

Figure 1: Actual annual consent rates in England, 2015/16 to 2022/23, and estimated baseline and deemed legislation rates



Final evaluation

6. Sample size calculations indicate 1161 observations would be required to detect a 5% change in the baseline consent rate. The study cohort, for the final evaluation, included the first 1161 donation decision conversations in England from 20 May 2022. The final donation decision conversation included in the study period occurred on 8 November 2022. This study period allowed for a 24-month bedding-in period for the new legislation before evaluating the impact on consent rate in England. A consent rate of 61% was observed for the study period.
7. For the final evaluation, a fixed sample two-sided Chi-square test was performed to test for a difference between the observed and estimated opt out consent rate of 78%. The observed consent rate was significantly lower than the estimated opt out consent rate under the new legislation ($p < 0.0001$).

Multivariable logistic regression

8. Multivariable logistic regression analysis was performed to further explore the change in consent rate in England. This risk-adjusted analysis accounts for other factors known to influence consent rates in the UK; namely donor type, patient's prior decision, patient ethnicity, whether a SNOD was present for the donation decision conversation, patient religion, socio-economic ACORN score and paediatric patients. This analysis included donation decision conversations in England between 1 April 2015 and 31 March 2023. It was a complete case analysis where 392 (2%) patients with unknown ethnicity and 21 (0.1%) patients with unknown prior decision were excluded. There were a total 20,151 donation decision included in the analysis. All donation decision conversations on or after 20 May 2020 were considered to be conducted under the new deemed consent legislation. This does not account for the phased roll out, due to COVID, whereby implementation of the new legislation was not in place across all teams until 20 July 2020.
9. The results of the risk-adjusted logistic regression analysis are presented in **Table 1**. Having adjusted for the known influential factors, including changes to the donor pool, the likelihood of consent is 29% less likely in England, since 20 May 2020 (OR 0.71, 95% CI: 0.7 – 0.8) when compared to the period prior to the change in legislation.

Table 1 Risk-adjusted analysis of the impact of opt out legislation on family consent, 1 April 2015 to 31 March 2023

Factor (overall p-value)	Donation decision conversations (N=20,151)	Consent obtained (N=13,192)	Odds ratio	95% CI
Donor type (< 0.001)				
DBD	8974	6308	1	
DCD	11177	6884	0.61	0.6 – 0.7
Patient's prior decision (< 0.001)				
No positive donation decision	12326	6024	1	
Opt in decision expressed to family/friends/will	1171	1099	14.7	11.4 – 18.8
Opt in decision expressed on ODR/donor card	6654	6069	10.0	9.1 – 11.0
Patient ethnicity (< 0.001)				
White	17679	12258	1	
Asian	1348	458	0.43	0.4 – 0.5
Black	709	237	0.27	0.2 – 0.3
Other	415	239	0.90	0.7 – 1.1
Nature of approach (< 0.001)				
Collaborative	15880	10925	1	
SNOD only	2442	1682	0.98	0.9 – 1.1
No SNOD present	1829	585	0.23	0.2 – 0.3
Patient religion (< 0.001)				
Christian	6698	4583	1	
Muslim	684	94	0.16	0.1 – 0.2
Hindu	261	148	1.38	1.0 – 1.9
Atheist	5116	3931	1.23	1.1 – 1.3
Other	650	364	0.78	0.6 – 0.9
Unknown	6742	4072	0.68	0.6 – 0.7
ACORN score (< 0.001)				
Affluent Achievers & Rising Prosperity	4999	3524	1	
Comfortable Communities	4781	3273	0.95	0.9 – 1.1
Financially Stretched & Urban Adversity	8373	5196	0.80	0.7 – 0.9
Not Private Households & Unknown postcode	1998	1199	0.72	0.6 – 0.8
Patient age (0.005)				
Adult	19319	12775	1	
Paediatric	832	417	1.27	1.1 – 1.5
Legislation (< 0.001)				
Pre-deemed consent legislation	13552	8916	1	
Deemed consent legislation	6599	4276	0.71	0.7 – 0.8

Summary

1. The study to evaluate the impact of opt out legislation in England was designed before the COVID pandemic and agreed in February 2020. Opt out legislation in England was implemented on 20 May 2020 during the height of the first COVID lockdown. In June 2020, the study proposal was re-evaluated given the significant disruption caused by the COVID pandemic. At that the time, consent rates remained similar to pre-COVID and operational implementation roll out delays were minimal, therefore it was agreed to proceed as planned. However, it was acknowledged that, as the new legislation coincided with COVID-19, it may never be possible to distinguish the true impact of opt out legislation from any COVID effect.
2. The final evaluation of opt out legislation in England, indicated that the observed consent rate, 61% for the study period, was significantly lower than the pre-COVID estimated opt out legislation consent rate of 78%. Furthermore, results from the supplementary logistic regression modelling indicated a 29% decrease in the likelihood of consent since 20 May 2020 having adjusted for other relevant factors known to influence consent.
3. Whilst this report concludes the study to evaluate the impact of opt out legislation on the consent rate in England, the monitoring of deemed consent/authorisation rates, across all four UK nations, will continue with the biannual Opt Out Summary report for NODC.

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Data and methodology

Data definitions

1. Data on the deceased donor consent rate in England have been obtained from the UK Potential Donor Audit (PDA).
2. Eligible donors are defined as patients with no absolute contraindication to solid organ donation and for whom death was confirmed following neurological tests, or imminent death was anticipated, and treatment was withdrawn.
3. The consent rate is defined as the percentage of eligible donors whose families were approached for a donation decision conversation for whom consent for organ donation was ascertained. The donation decision conversation includes the conversations whereby a family is informed of a patient's opt out registration on the Organ Donor Register (ODR). Such approaches are, therefore, included in the consent rate calculation. This prevents any bias in favour of consent rates under the new opt out system when compared to the previous system, where there was no requirement to register an opt out decision if the individual did not wish to be an organ donor.

Study design

Comparing consent rates and sample size

4. Pearson's Chi-squared tests were performed to formally test whether there was a significant difference between the observed and the estimated baseline consent rates. The study design was such that there was 80% power to detect an absolute difference of 5% in observed and baseline consent rates at the 5% significance level. Assuming a baseline rate of 73%, a total of 1161 eligible donors were required to detect a 5% change.

Estimating baseline consent rates

5. Baseline consent rates were estimated using univariable logistic regression to model activity from the five-year baseline period (Apr 2015 to Dec 2019). From this model the estimated baseline consent rate and 95% confidence interval were predicted.

Assumptions

6. The following assumptions were made when calculating the estimated consent rates: -
 - The proposed baseline consent rate estimate, without opt out legislation, was appropriate.
 - The influence of the main factors affecting consent would remain unchanged between the baseline and monitoring periods.

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- An absolute difference of 5%, under opt out legislation, was appropriate.
- Donor screening practices and recording of PDA data remain consistent and comparable between the baseline and monitoring period.
- COVID-19 had not significantly influenced the consent rate in the UK, and pre-COVID baseline estimates remained appropriate.

Retrospective multivariable analysis

7. Following the test for a change in the consent rate in England, a separate supplementary multivariable analysis was conducted to allow a more detailed exploration of the results. Using multivariable logistic regression, any observed differences were assessed, having adjusted for any changes in relevant factors known to influence consent. The multivariable analyses can also evaluate any changes in the chance of consent/authorisation over the various stages of implementation (pre-opt out, bedding-in period and established opt out legislation).

COVID-19 review

8. All teams, within England, were fully trained and implementing deemed consent from 20 July 2020. The 2-month delay was considered sufficiently small that it was covered by the planned 2-year bedding-in period. It was therefore considered appropriate to maintain an implementation date of 20 May in line with the official government launch date.
9. Baseline estimates, in the study design, were based on pre-COVID data so determined not be affected by the pandemic. At the time of re-evaluation, there was no evidence of an impact of COVID-19 on the consent rate. The consent rate in England was 69% (Apr – Aug 2020) which was slightly higher, but not dissimilar to 2019/20 at 68%.
10. In June 2020, it was agreed that the monitoring proposal would remain as planned in February 2020, on the assumption that the COVID pandemic had not influenced the consent rate and in the knowledge that operational delays were minimal. However, it was acknowledged that, as the new legislation landed at the same time as COVID-19, it may never be possible to distinguish between the COVID-19 and opt out legislation effect.