**NHS BLOOD AND TRANSPLANT**

**National Organ Donation Committee**

# Proposal for monitoring opt-out legislation in England

## Executive Summary

## Introduction

1. This paper describes the proposal for monitoring the impact of new opt-out legislation in England following its implementation in spring 2020. We propose a formal evaluation which will compare organ donation consent rates under the new legislation with those prior to the introduction of deemed consent.

## Study design

2. To monitor the impact of opt-out legislation in England the following analyses are proposed:-
   i. A fixed sample test comparing the consent rates in England, for donation after brain death (DBD) and donation after circulatory death (DCD) under opt-out legislation with estimated baseline consent rates based on a continuation of current trends without opt-out. This method aims to detect a 10% increase in DBD and DCD consent rates and will compare consent rates over the evaluation period at 12- and 24-months post implementation of opt-out legislation.
   ii. A detailed multivariable analysis comparing changes in the chance of consent in England over time, adjusted for all relevant risk factors.

3. **Figure 1** illustrates the time frames involved.

**Figure 1: Time frames for baseline assessment and time scales for formal evaluation**


## Actions

4. Members are asked to comment on the proposed analyses to monitor the impact of opt-out legislation in England and determine if it is agreeable to proceed.

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# Proposal for monitoring opt-out legislation in England

## Introduction

1. With the passing of Max and Keira's Law on the 15th March 2019, deemed consent will be implemented in England in spring 2020. As with the introduction of deemed consent in Wales in 2015, we will monitor the impact of this change in legislation in terms of deceased donor consent rates in England. We therefore propose a formal evaluation of the effect of introducing an opt-out system in England based on activity under the new legislation compare with activity prior to the introduction of deemed consent. This paper describes the methods that will be used to assess both DBD and DCD consent rates.

## Data

2. Data on deceased donor consent rates in England will be obtained from the UK Potential Donor Audit (PDA).

3. Eligible donors are defined as patients who had no absolute contraindication to solid organ donation and for whom death was confirmed follow neurological tests, or imminent death was anticipated, and treatment was withdrawn.

4. 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

5. A standard fixed sample test comparing two proportions will be used to formally evaluate the impact of opt-out legislation in England. Data on the observed DBD and DCD consent rates in England under the new opt-out legislation will be compared to estimated baseline consent rates without opt-out legislation. The difference in consent rates under the new legislation will be evaluated following the proposed bedding in periods. Study design definitions are defined below and **Figure 1** illustrates the time frames involved.

- **Baseline consent rates** will assume a continuation of current trends without opt-out legislation. The period, from which estimated baseline consent rates are calculated, will be a five-year period prior to the enactment of opt-out legislation and will not include the one-year communication strategy prior to the implementation of the new law.

- **Bedding in period** defines the settling in phase of the new legislation as clinical practice and Organ Donation Service Teams adjust to the changes in practice and language associated with the new law. Experience in Wales indicates that this period maybe one to two years, however it is not clear what the impact will be in England given the higher levels of activity and larger BAME population. The study has been designed to assume a bedding in period of two years (Evaluation II) but an initial evaluation will compare consent rates allowing for a one-year bedding in period (Evaluation I).

- **Evaluation period**, the length of the evaluation period will be defined by the relevant sample size calculations in the study design. The initial evaluation period will begin after a one-year bedding in period following implementation of opt-out legislation in April 2021 and the second and final evaluation period will commence two-years post implementation in April 2022.

**Figure 1: Time frames for baseline assessment and time scales for formal evaluation**

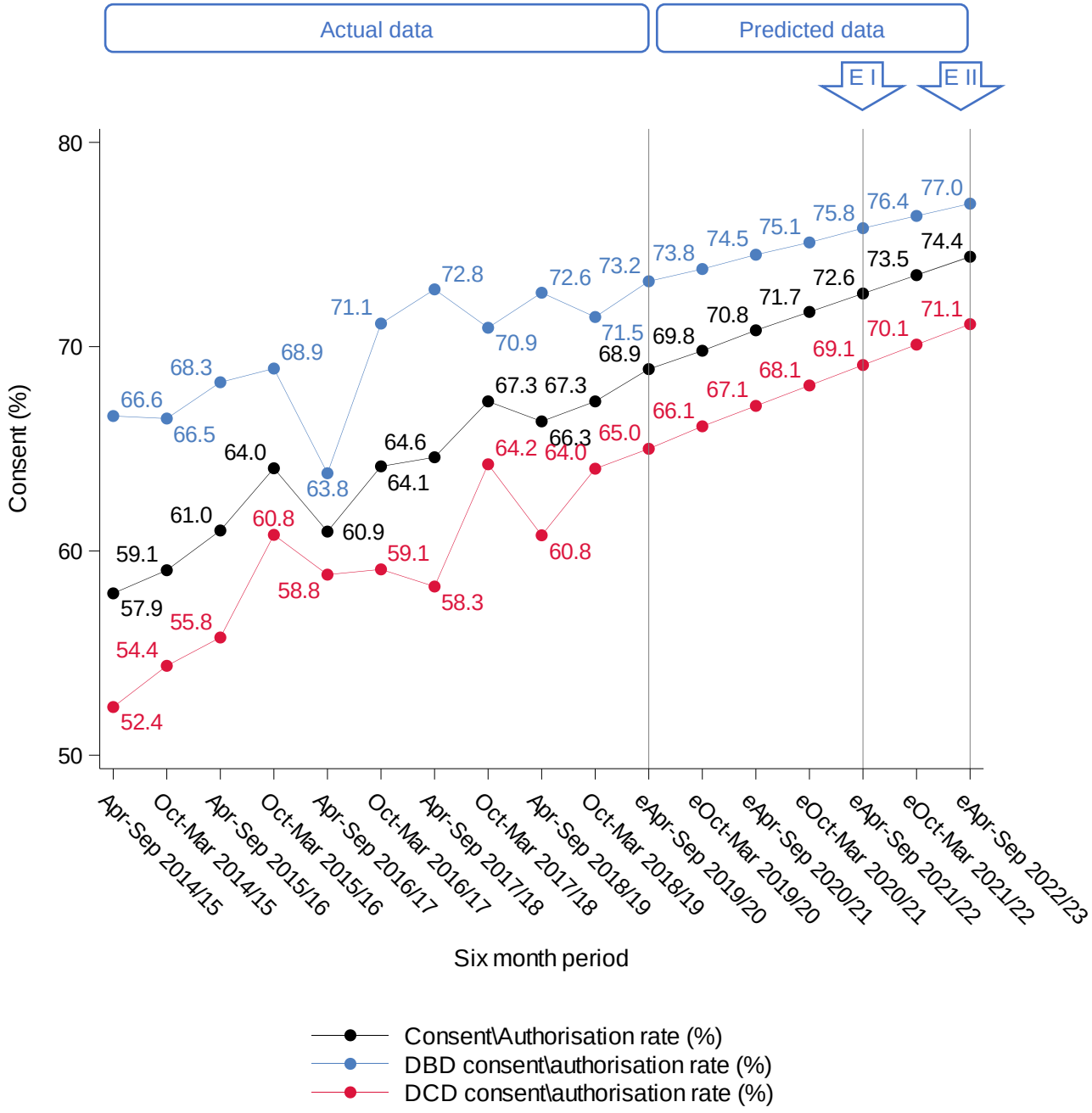

## Estimating baseline consent rates

6. DBD and DCD baseline consent rates will be estimated separately using simple logistic regression to model activity from the five-year baseline period. From these separate DBD and DCD models we can predict estimated baseline consent rates for the relevant evaluation period (and 95% confidence intervals).

7. **Figure 2** presents six-monthly consent rates for the five-year modelling period and subsequent predicted estimates, without opt-out legislation, up to September 2023. For the initial evaluation (E I), the predicted DBD and DCD baseline consent rates are 75.8% (95% Confidence Interval 72.1% - 79.1%) and 69.1% (95% Confidence Interval 65.7% - 73.4%), respectively. For the final evaluation (E II), the predicted baseline consent rates are 77.0% (95%

Confidence Interval 72.7% - 80.8%) and 71.1% (95% Confidence Interval 67.1% - 74.8%) respectively.

**Figure 2: Actual and predicted consent rates in England, 1 April 2014 – 30 September 2023**




## Comparing consent rates

8. At the end of each evaluation period Pearson's Chi-squared tests will be performed to formally test whether there is a significant difference between the observed and the estimated baseline consent rates in England. The study design will be such that there is 90% power to detect an absolute difference in observed and baseline consent rates of 10% as significant at the 5% level.

9. For a standard fixed sample test of the two proportions, comparing opt-in and opt-out systems in England each evaluation period would require a total of 322 eligible DBD donors and 403 eligible DCD donors to detect a 10% change from the respective estimated baseline consent rates (76% DBD and 69% DCD).

10. Based on current activity the recruitment of the sample size is such that each evaluation period (E I and E II) will be approximately 3 months in duration to ensure we have sufficient data to be able to test the impact of opt-out legislation in England on both DBD and DCD consent rates. The final evaluation will be conducted in the autumn of 2022 when full recruitment is complete.

11. By extending the evaluation period to around 6 months, the study design could detect a smaller increase of just 5%. In Wales DBD and DCD consent rates increased by 10 and 18 percentage points, respectively, over three years.

## Assumptions

12. The following assumptions have been made in this paper:-
    - Proposed baseline estimates for consent rates without opt-out legislation are appropriate
    - The influence of main risk factors will remain unchanged between the baseline and evaluation periods
    - An absolute difference of 10% is appropriate
    - Current screening practices and recording of PDA data are consistent and comparable between the baseline and evaluation periods

## Multivariable analysis

13. Following the formal evaluation of the impact of opt-out legislation on consent rates in England, supplementary multivariable analysis will be conducted to allow for a more detailed exploration of the results. Using multivariable logistic regression any observed differences may be assessed having accounted for any changes in relevant factors known to influence consent as well as any potential new factors not yet identified. The multivariable analysis can also evaluate any changes in the chance of consent over the various stages of implementation (pre-opt out, communication year, bedding-in period and established opt-out legislation).

## Summary

14. To monitor the impact of opt-out legislation in England the following analyses are proposed:-

    iii. A fixed sample test comparing the DBD and DCD consent rates in England under opt-out legislation with estimated baseline consent rates based on a continuation of current trends without opt-out. This method

aims to detect a 10% increase in DBD and DCD consent rates and will compare consent rates over the evaluation period at 12- and 24-months post implementation of opt-out legislation.

iv. A detailed multivariable analysis comparing changes in the chance of consent in England over time, adjusted for all relevant risk factors.

**Actions**

15. Members are asked to comment on the proposed analyses to monitor the impact of opt-out legislation in England and determine if it is agreeable to proceed. Specifically members are asked to consider whether: -
    i. The proposed baseline estimates are appropriate
    ii. An absolute increase of 10% is adequate to qualify a successful improvement
    iii. DBD and DCD consent rates should be monitored separately (monitoring of deceased donor consent rates would assume proportion of DBD and DCD donation remains consistent).

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