NHS BLOOD AND TRANSPLANT

National Organ Donation Committee

Proposal for monitoring opt out legislation in the UK

Executive Summary

Introduction

1. This paper describes the proposal for monitoring the impact of new opt out legislation in England and Scotland following its implementation in 2020. This paper also presents a proposal for regular monitoring of opt out legislation throughout the UK.

Monitoring proposals

2. To monitor the impact of opt out legislation in England, Scotland and the UK, the following analyses are proposed:-

    i. Fixed sample tests comparing the DBD and DCD consent rates in England under opt out legislation with estimated baseline consent rates in England, 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 monitoring period at 12- and 24-months post implementation of opt out legislation.

    ii. Sequential analyses comparing the DBD and DCD authorisation rates in Scotland under opt out legislation with estimated baseline authorisation rates in Scotland, based on a continuation of current trends without opt out. This method allows for small numbers and aims to detect a 10% increase in DBD and DCD authorisation rates and will compare accumulating data on a quarterly basis following a 12 month bedding in period post implementation of opt out legislation.

    iii. Detailed multivariable analyses comparing changes in the chance of consent/authorisation in England and Scotland over the various stages of implementation and established opt out legislation, adjusted for all relevant risk factors.

    iv. Quarterly reporting of ODR registrations and consent/authorisation rates for all four UK nations will be ongoing. These reports will include funnel plot comparisons of the consent/authorisation rates by nation.

Actions

3. Members are asked to comment on the proposed analyses to monitor the impact of opt out legislation in England, Scotland and the UK and agree how to proceed.

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National Organ Donation Committee

Proposal for monitoring opt out legislation in the UK

Introduction

1. With the introduction of opt out legislation in both England and Scotland in 2020 this paper details proposals for evaluating the impact of the new opt out systems on consent/authorisation rates in England and Scotland. This paper also describes the proposal for the ongoing monitoring of opt out legislation in Wales and the UK.

Data

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

3. 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.

4. The consent/authorisation rate is defined as the percentage of eligible donors whose families were approached for a donation decision conversation for whom consent/authorisation 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/authorisation rate calculation. This prevents any bias in favour of consent/authorisation 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.

Monitoring impact of opt out legislation in England - Study design

5. The proposal for monitoring opt out legislation in England has been described in more detail in the paper presented a the NODC meeting in June 2019 (NODC(19)18).

6. In brief, data on the observed DBD and DCD consent rates in England under the new opt out legislation will be compared to the estimated baseline consent rates without opt out legislation. Due to the large number of eligible donors approached in England a sequential analysis is not required and a standard fixed sample test comparing two proportions will be used to evaluate the impact of opt out legislation in England. 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). **Figure 1** illustrates the time frames involved.

Figure 1: Time frames for baseline assessment and time scales for formal evaluation of English legislation

* Evaluation dates are dependent on the implementation date and may change if the implementation date changes

Comparing consent rates

7. At the end of each monitoring 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. As in the evaluation of deemed consent in Wales, 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. Each monitoring period would require a total of 644 eligible DBD donors and 806 eligible DCD donors to detect a 10% change from the respective estimated baseline consent rates (currently defined as 76% DBD and 69% DCD).

8. Based on current activity, the recruitment of the sample size is such that each monitoring period will be approximately six months in duration to ensure there are sufficient data to be able to test the impact of opt out legislation in England on both DBD and DCD consent rates. Assuming opt out legislation is implemented in April 2020, the final evaluation will be conducted in the autumn of 2022 when sample recruitment is complete.

Estimating baseline consent rates

9. During the June NODC meeting there was considerable discussion regarding the suitability of the baseline estimates and the most appropriate baseline period. The initial proposal estimated DBD and DCD baseline consent rates using simple logistic regression models based on activity from the five-year baseline period (2014/15 to 2018/19). The separate DBD and DCD models were used to predicted baseline consent rates and 95% confidence intervals (CI) for each monitoring period.

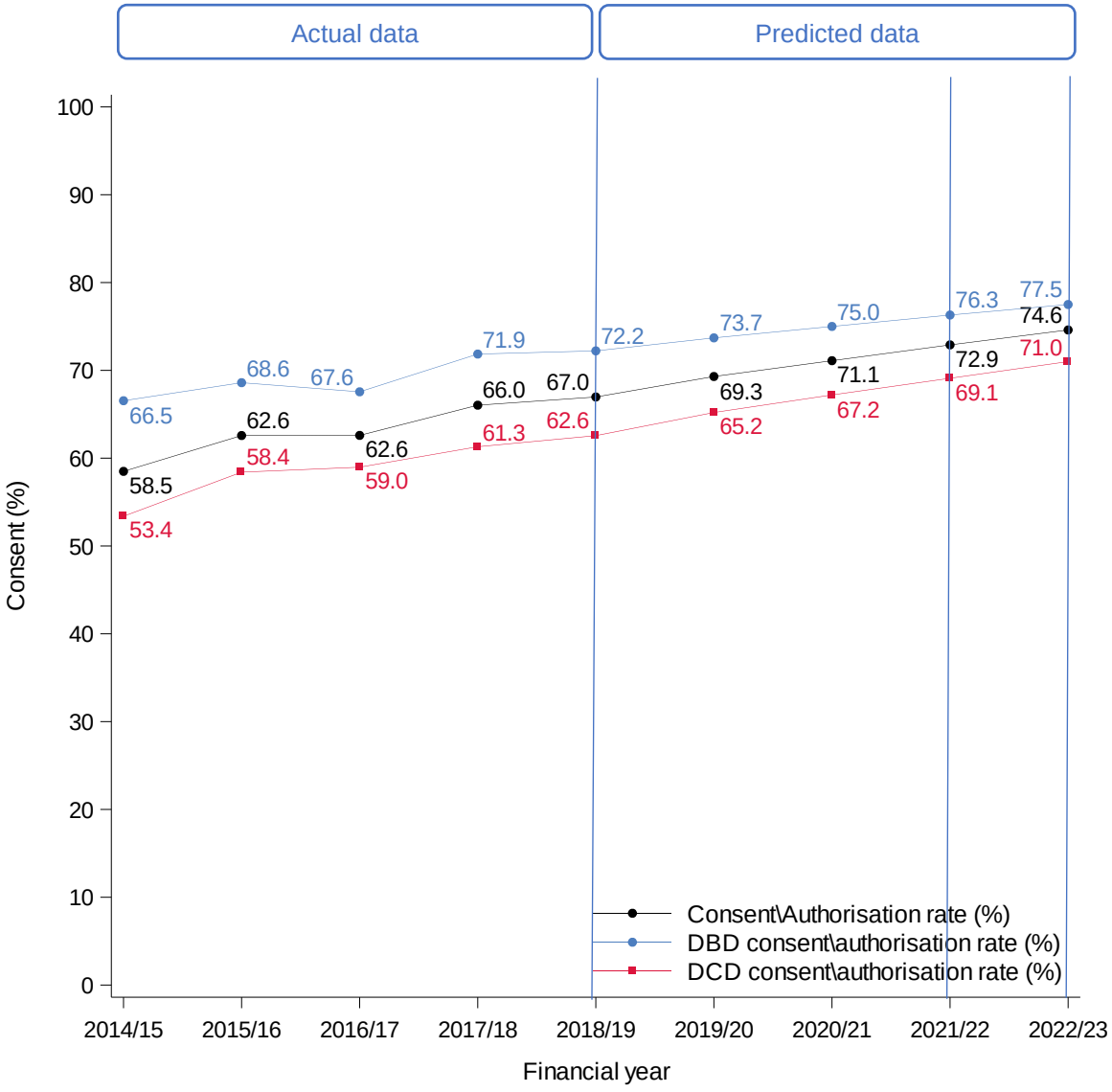
10. Alternative options for predicting baseline consent rates have been considered and are summarised in **Appendix A**. To ensure consistency with the proposal for monitoring opt out legislation in Scotland, the recommended

option is to predict based on annual consent rates over the five-year baseline period, 2014/15 to 2018/19.

11. **Figure 2** presents annual consent rates, in England, for the five-year modelling period and associated predicted annual baseline consent rates, without opt out legislation, up to 2022/23.

12. For the initial evaluation in 2021/22, the predicted DBD and DCD baseline consent rates and 95% CI are 76.3% (95% CI: 72.4% - 79.7%) and 69.1% (95% CI: 65.5% - 72.6%), respectively. For the final evaluation, the predicted baseline consent rates are 77.5% (95% CI: 73.0% - 81.4%) and 71.0% (95% CI: 67.8% - 74.9%) respectively.

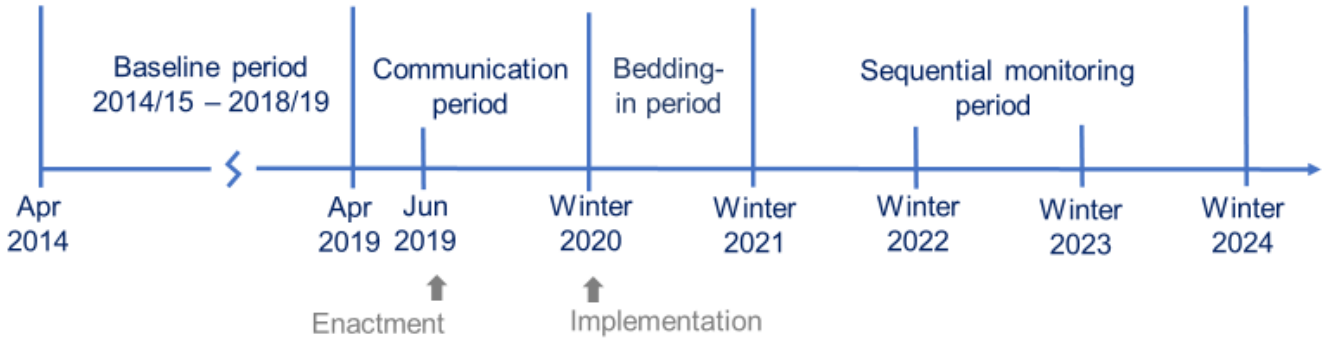
Figure 2: Actual and predicted annual consent rates in England, 2014/15 to 2022/23



Monitoring impact of opt out legislation in Scotland - Study design

13. Due to the small numbers of eligible donors approached in Scotland, the proposal to monitor the impact of opt out legislation in Scotland includes a sequential quarterly analysis as per the analysis of the impact of deemed consent in Wales (see NODC(19)15). However, unlike the Welsh analysis, there is no suitable control group, therefore cumulative data on authorisation rates will be compared with the estimated baseline authorisation rates without opt out legislation, as in the evaluation for England. **Figure 3** illustrates the time frames involved.

Figure 3: Time frames for baseline assessment and time scales for formal evaluation of Scottish legislation



* Evaluation dates are dependent on the implementation date and may change if the implementation date changes

Comparing authorisation rates

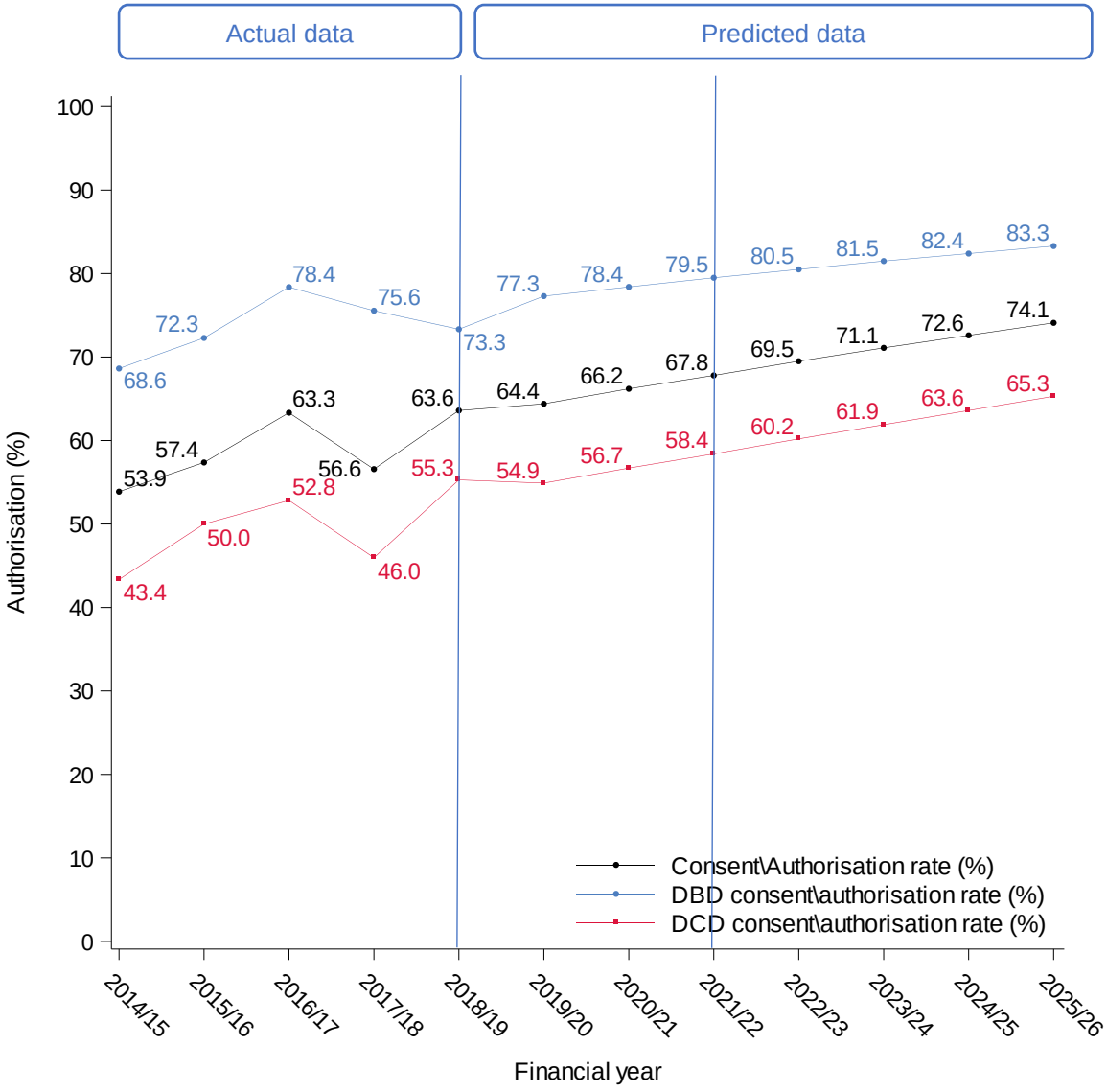
14. A hypothesis testing procedure is used to compare the proportion of eligible donors approached for whom authorisation for organ donation is ascertained. The test statistic is then plotted on a sequential basis on a chart against the number of eligible donors approached. This chart will show whether the difference in the two consent rates is increasing, remains constant or is decreasing. This chart will also show boundary lines, constructed in such a way that a significant difference is declared when plotted points cross the boundary (see example in **Appendix A4**). 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.

15. As in the evaluation of deemed consent in Wales, the study design will be such that there is 90% power to detect an absolute difference in observed and baseline authorisation rates of 10% as significant at the 5% level.

16. If a standard fixed sample test of the two proportions, comparing opt-in and opt out systems in Scotland were to be carried out, a total of 532 eligible DBD donors and 976 eligible DCD donors would be needed to detect a 10% change from the respective predicted baseline consent rates (currently defined as 80% DBD and 58% DCD). Based on current activity the recruitment of the sample size is such it may take 5-6 years to complete the evaluation of the impact of opt out legislation in Scotland. In the proposed

sequential design, the data may be legitimately reviewed every quarter, and the chart boundaries allow for this. The corresponding expected sample sizes in the sequential study are 571 (DBD) and 1013 (DCD) if there is no difference between the proportions of authorising eligible donors, but 395 (DBD) and 701 (DCD) if there is a difference of 10%, shortening the study by around 2 years.

Figure 4: Actual and predicted annual authorisation rates in Scotland, 2014/15 to 2024/25



Estimating baseline authorisation rates

17. DBD and DCD baseline authorisation rates, in Scotland, will be estimated separately using simple logistic regression to model activity from the five-year baseline period (2014/15 to 2018/19). From these models we can predict estimated baseline authorisation rates for the relevant monitoring period and 95% confidence intervals.

18. **Figure 4** presents annual authorisation rates for the five-year modelling period and subsequent predicted estimates, without opt out legislation, up to

2023/24. The sequential analysis would begin with predicted DBD and DCD baseline authorisation rates of 79.5% (95% CI: 64.9% - 89.0%) and 58.4% (95% CI: 44.7% - 70.9%), respectively. During the sequential analyses the baseline authorisation rates would increase as illustrated in **Figure 4**.

Assumptions

19. The following assumptions have been made in both these study designs:-
    - Proposed baseline estimates for consent/authorisation rates without opt out legislation are appropriate
    - The influence of the main factors influencing consent/authorisation will remain unchanged between the baseline and monitoring periods
    - An absolute difference of 10% is appropriate
    - Current donor screening practices and recording of PDA data remain consistent and comparable between the baseline and monitoring periods

Multivariable analysis for both England and Scotland

20. Following the formal evaluation of the impact of opt out legislation on consent rates in England and authorisation rates in Scotland, 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, accounting for any changes in relevant factors known to influence consent/authorisation, as well as any potential new factors not yet identified. The multivariable analysis can also evaluate any changes in the chance of consent/authorisation over the various stages of implementation (pre-opt out, communication year, bedding-in period and established opt out legislation).

Ongoing monitoring of impact of opt out legislation in UK

21. In addition to the proposed monitoring of the new opt out systems in England and Scotland, there will be regular monitoring of ODR registrations and consent/authorisation rates across the UK in a quarterly report. These reports will include:

    ODR registrations:
    - Current snapshot of number of opt in/opt out registrations pmp by nation
    - Number of opt in/opt out registrations over time by nation
    - Proportion of all approaches by ODR opt out over time by nation
    - Number of opt in/opt out BAME registrations over last 12 months by nation

    Consent/authorisation
    - Line/bar charts showing consent numbers and rates over time by nation
    - DBD/DCD line charts showing consent rates over time
    - Deceased donor and DBD and DCD funnel plots comparing consent/authorisation rates by nation

All tables and figures will include data for Wales, England, Scotland and Northern Ireland. Where appropriate, tables will also include figures for Jersey, Guernsey and the Isle of Man.

Summary

4. To monitor the impact of opt out legislation in England, Scotland and the UK, the following analyses are proposed:-

    v. Fixed sample tests comparing the DBD and DCD consent rates in England under opt out legislation with estimated baseline consent rates in England, 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 monitoring period at 12- and 24-months post implementation of opt out legislation.

    vi. Sequential analyses comparing the DBD and DCD authorisation rates in Scotland under opt out legislation with estimated baseline authorisation rates in Scotland, based on a continuation of current trends without opt out. This method allows for small numbers and aims to detect a 10% increase in DBD and DCD authorisation rates and will compare accumulating data on a quarterly basis following a 12 month bedding in period post implementation of opt out legislation.

    vii. Detailed multivariable analyses comparing changes in the chance of consent/authorisation in England and Scotland over the various stages of implementation and established opt out legislation, adjusted for all relevant risk factors.

    viii. Quarterly reporting of ODR registrations and consent/authorisation rates for all four UK nations will be ongoing. These reports will include funnel plot comparisons of the consent/authorisation rates by nation.

Actions

22. Members are asked to comment on the proposed analyses to monitor the impact of opt out legislation in England, Scotland and the UK and agree a way to proceed. Specifically, members are asked to consider whether the proposed baseline estimates are acceptable.

Sue Madden
NHSBT Statistics and Clinical Studies **November 2019**

Figure A1 Example of sequential chart

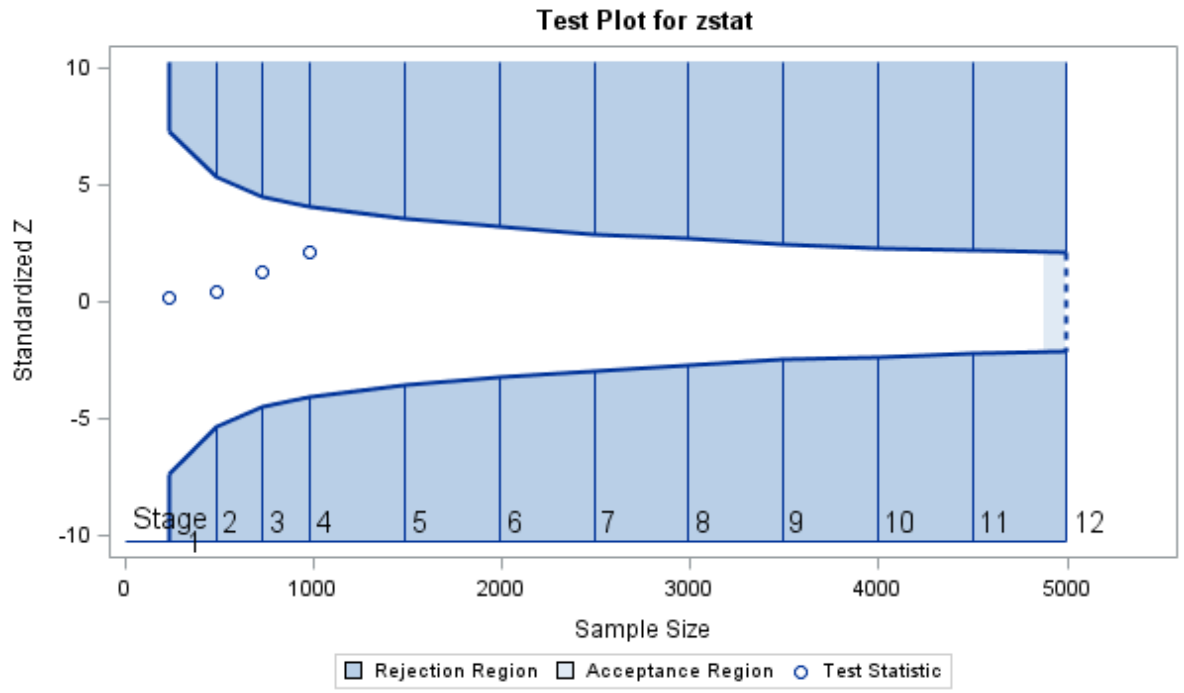


Table A1 **Alternative options for predicting baseline consent/authorisation rates**

Options	Baseline	Pros	Cons
Option 1 (recommended)	5 year baseline period for England and Scotland	• Consistent approach for both studies • Annual rates more robust to account for small numbers in Scotland • Lower DCD/higher DBD authorisation rates maintained • Predictions visually reasonable based on historic data • Allows for expected increases over time without opt out	• Assumes future increases would continue at the same rate as over the last 5 years
Option 2	2 year baseline period for England* 5 year baseline period for Scotland	• Lower DBD rate for England, DCD rate consistent with 5 year baseline period	• Assumes no change, without opt out for English DBD rate • Inconsistent approach for England and Scotland
Option 3	2 year baseline period for England* and Scotland combined	• Consistent approach for both nations with robust data	• Comparing Scottish rates to baseline rates heavily influenced by English rates • Lower DCD, high DBD rates in Scotland not accounted for (although not statistically different)
Option 4	2017/18 baseline period as per DHSC	• Consistent with DHSC approach for opt out in England	• Assumes no change without opt out • Already observed small increases in 2018/19
Option 5	Expert elicitation	• Baseline estimates agreed by expert panel	• Identifying appropriate panel members • Subjective

* Two-year baseline actual and predicted quarterly consent/authorisation rates presented in **Table A2** and illustrated in **Figure A1**.

Table A2 Actual and predicted consent / authorisation rates comparing 2- and 5-year baseline periods

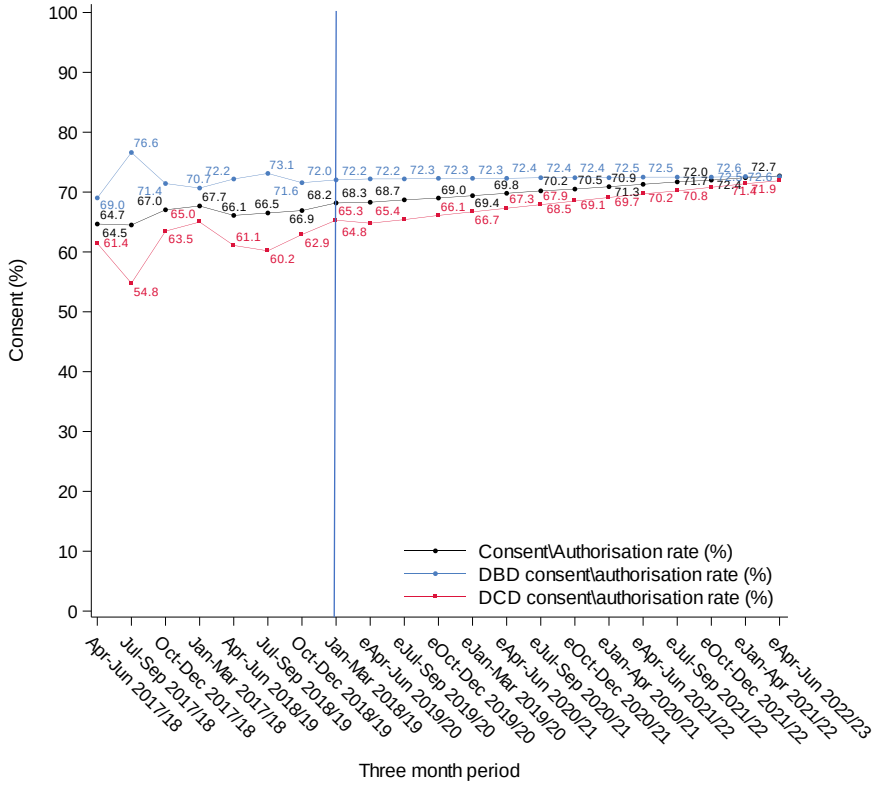
Consent / authorisation rate	Baseline period (years)	Actual consent / authorisation rate (%)		Predicted consent / authorisation rate without opt out (%)						
		2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
England DBD	5	71.9	72.2	73.7	75.0	76.3	77.5	-	-	-
England DCD	5	61.3	62.6	65.2	67.2	69.1	71.0	-	-	-
Scotland DBD	5	75.6	73.3	77.3	78.4	79.5	80.5	81.5	82.4	83.3
Scotland DCD	5	46.1	55.3	54.9	56.7	58.4	60.2	61.9	63.6	65.3
		Apr-Jun 2017	Apr-Jun 2018	Apr-Jun 2019	Apr-Jun 2020	Apr-Jun 2021	Apr-Jun 2022	Apr-Jun 2023	Apr-Jun 2024	Apr-Jun 2025
England DBD	2*	69.0	72.2	72.2	72.3	72.5	72.6	-	-	-
England DCD	2*	61.4	61.1	64.8	67.3	69.7	71.9	-	-	-
Scotland DBD	2*	73.3	70.0	74.3	74.2	74.2	74.1	74.1	74.0	74.0
Scotland DCD	2*	47.6	66.7	58.0	64.4	70.3	75.6	81.3	84.2	87.4

First evaluation Final evaluation

* Two-year baseline actual and predicted quarterly consent/authorisation rates illustrated in **Figure A1**.

Figure A2 Illustration of quarterly consent/authorisation rates based on a two year baseline period

Actual and predicted quarterly consent rates in England, 1 April 2017 – 31 March 2024



Actual and predicted quarterly authorisation rates in Scotland, 1 April 2017 – 31 March 2025