

# NHS BLOOD AND TRANSPLANT

## RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP

### IMPACT OF CHANGES TO RESEARCH CONSENT/AUTHORISATION QUESTIONS

#### SUMMARY

#### BACKGROUND

- 1 The consent/authorisation questions on the Core Donor Data Form (CDDF) were changed on 6 January 2016. This paper compares consent/authorisation rates for research before and after the change. It also investigates the availability of organs for research as a result.

#### DATA AND METHODS

- 2 Research consent/authorisation rates were analysed for solid organ donors in the UK from 1 January 2008 to 31 August 2017.
- 3 Availability of organs for research where organs were retrieved and not transplanted were analysed from 20 February to 31 August over a 5 year period. This time frame was selected to reflect the change in the research allocation scheme which occurred on 20 February 2017 and hence to compare periods of equal length.

#### SUMMARY

- 4 The change in consent/authorisation questions on the CDDF does not appear to have impacted the overall UK consent/authorisation rate which was 92% in 2015 and also in 2017 (using data up until 31 August 2017).
- 5 Looking specifically at the effect of changes to consent questions for England, Wales and Northern Ireland collectively, there also appeared to be little impact upon the consent rate; 93% in 2015 and also in 2017 (using data up to 31 August 2017). The change in authorisation questions could however have had a positive impact on Scotland as the authorisation rate increased from 77% in 2015 to 87% in 2017 (using data up until 31 August 2017). However, there are fewer donors in Scotland and so the rate may be more susceptible to fluctuations than in England, Wales and Northern Ireland collectively.
- 6 The change in consent/authorisation questions may have slightly increased the number of organs available for research as the percentage of organs retrieved but not transplanted that did not have consent/authorisation for research was 9.1%, 10.5 and 7.3% in 2013, 2014 and 2015 respectively. This decreased in 2017 (using data up until 31 August 2017) to 6.5%.

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**September 2017**

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#### IMPACT OF CHANGES TO RESEARCH CONSENT/AUTHORISATION QUESTIONS

#### BACKGROUND

- 1 As part of a review by NHSBT, the consent/authorisation questions on the Core Donor Data Form (CDDF) were changed on 6 January 2016. Questions about consent/authorisation for research and education/training remain different for Scotland than the rest of the UK.
- 2 Unfortunately, when the new CDDF was introduced in January 2016, the wording of the consent questions was not consistent with the wording in other documents used by SNODs in discussion with donor families. SNODs were therefore advised to leave part of the CDDF blank until final amendments were made to the consent/authorisation questions on the CDDF on 7 April 2016.
- 3 A new research allocation scheme was introduced in UK on the 20 February 2017. This paper compares consent/authorisation rates for research before and after the change in questions. It also investigates the availability of organs for research from the introduction of the new research allocation scheme.

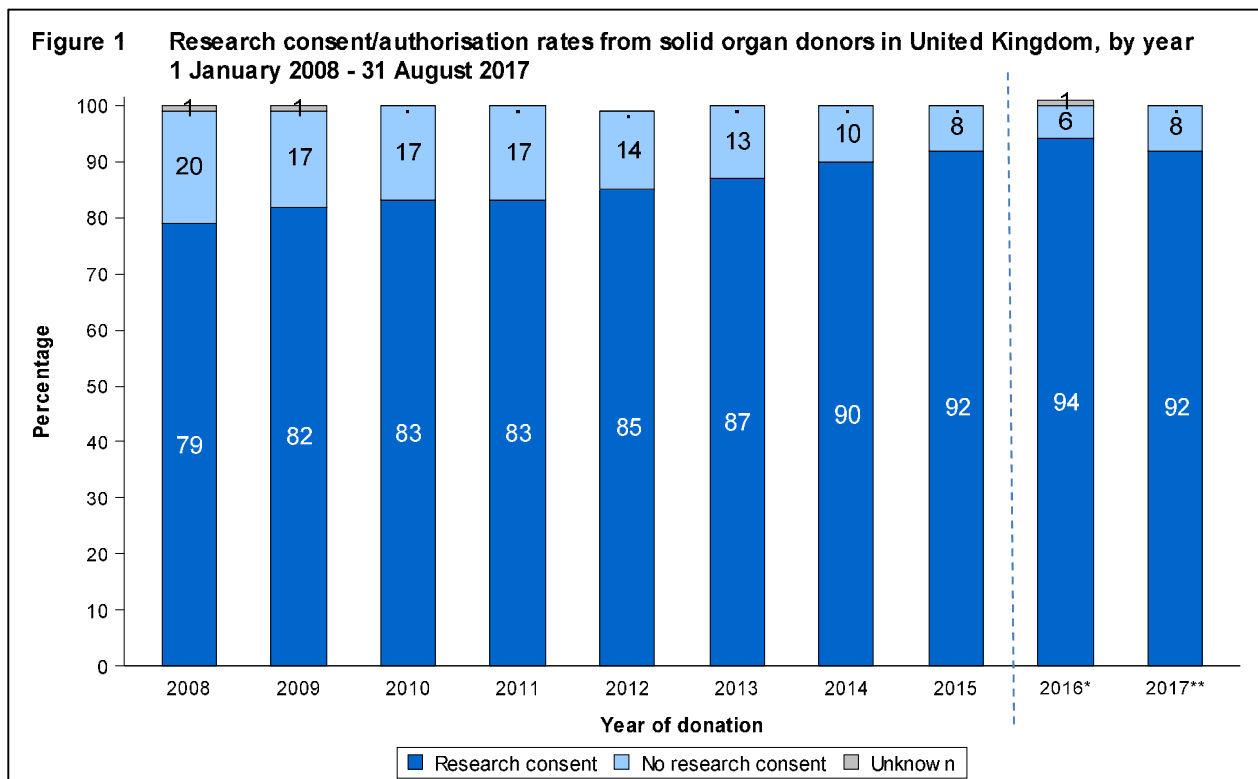
#### DATA AND METHODS

- 4 Research consent/authorisation rates were analysed for solid organ donors in the UK from 1 January 2008 to 31 August 2017. The consent/authorisation questions on the CDDF both prior to the change on 6 January 2016 and after the final change on 7 April 2016 are highlighted in red in the **Appendix**. Scotland has been analysed separately to England, Wales and Northern Ireland on some occasions due to the difference in questions.
- 5 Due to the wording issues highlighted in paragraph 2, consent/authorisation information was not robust for analysis from 6 January – 6 April 2016. Figures for 2016 have been reported in the paper for completeness but should not be interpreted.
- 6 Availability of UK donor organs for research, where organs were retrieved and not transplanted, was analysed from 20 February to 31 August per year over the past 5 years. This time period was selected due to the change in allocation scheme on 20 February 2017 and to compare time periods of equal length. Research outcome was split into three categories; no research consent, organ used for research and organ disposed of with research consent.
- 7 The number of organs recorded as used for research may be an underestimate due to differences in the reporting of liver hepatocytes. There are inconsistencies in reporting as sometimes transplanted liver hepatocytes have been recorded as used for research and at other times recorded as not used for research.

## RESULTS

### Research consent/authorisation rates

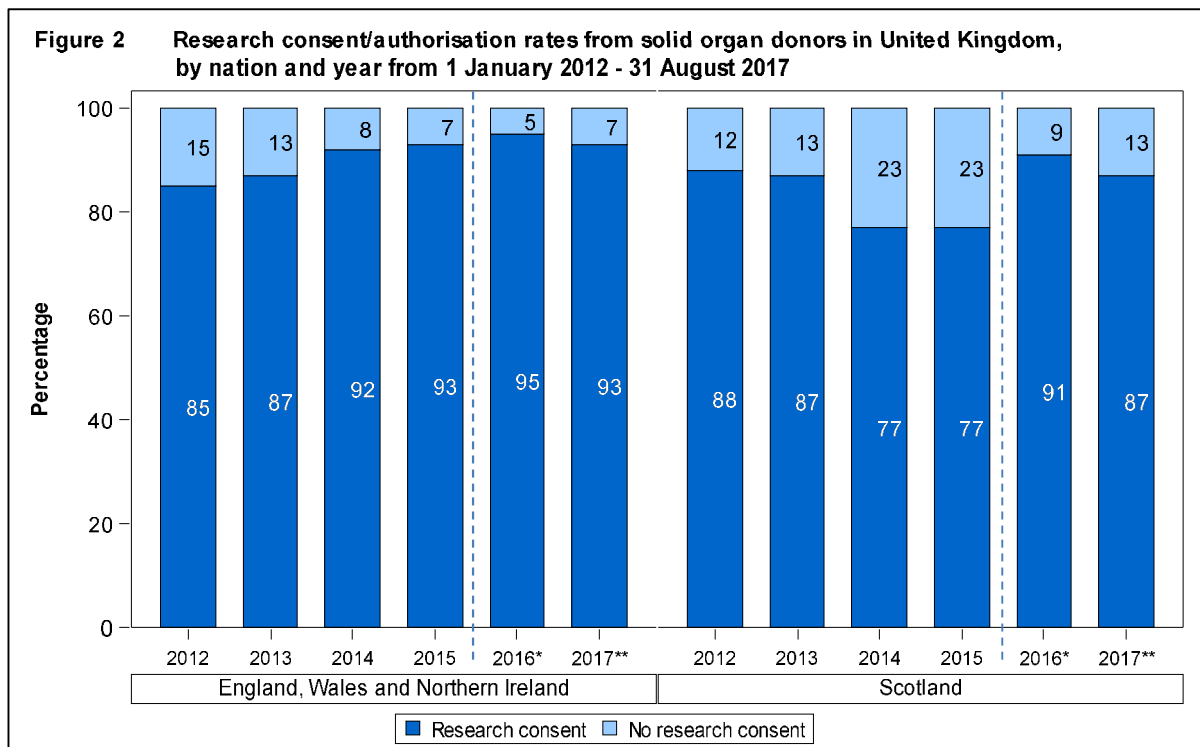
- 8 **Figure 1** shows that the annual overall UK research consent/authorisation rate for solid organ donors has progressively increased since 2008. The rate was 92% in 2015, the year prior to any change, and also 92% in 2017 (using data up until 31 August 2017). This would suggest that the change in consent/authorisation question in 2016 has not impacted the consent/authorisation rate for research.



\* Inaccurate data between 6 January to 6 April 2016 due to inconsistencies in consent questions

\*\* 1 January – 31 August 2017

- 9 **Figure 2** illustrates the change in authorisation rate for Scotland donors over time, compared with the change in consent rate over time for donors in England, Wales and Northern Ireland. Consent rates for research for England, Wales and Northern Ireland appear to be similar in the years prior to the changes compared with 2017 (using data until 31 August 2017). The change in authorisation questions could however have had a positive impact in Scotland as the authorisation rate increased from 77% in 2015 to 87% in 2017 (using data up until 31 August 2017). However, there are fewer donors in Scotland and so the rate may be more susceptible to fluctuations than in England, Wales and Northern Ireland collectively.

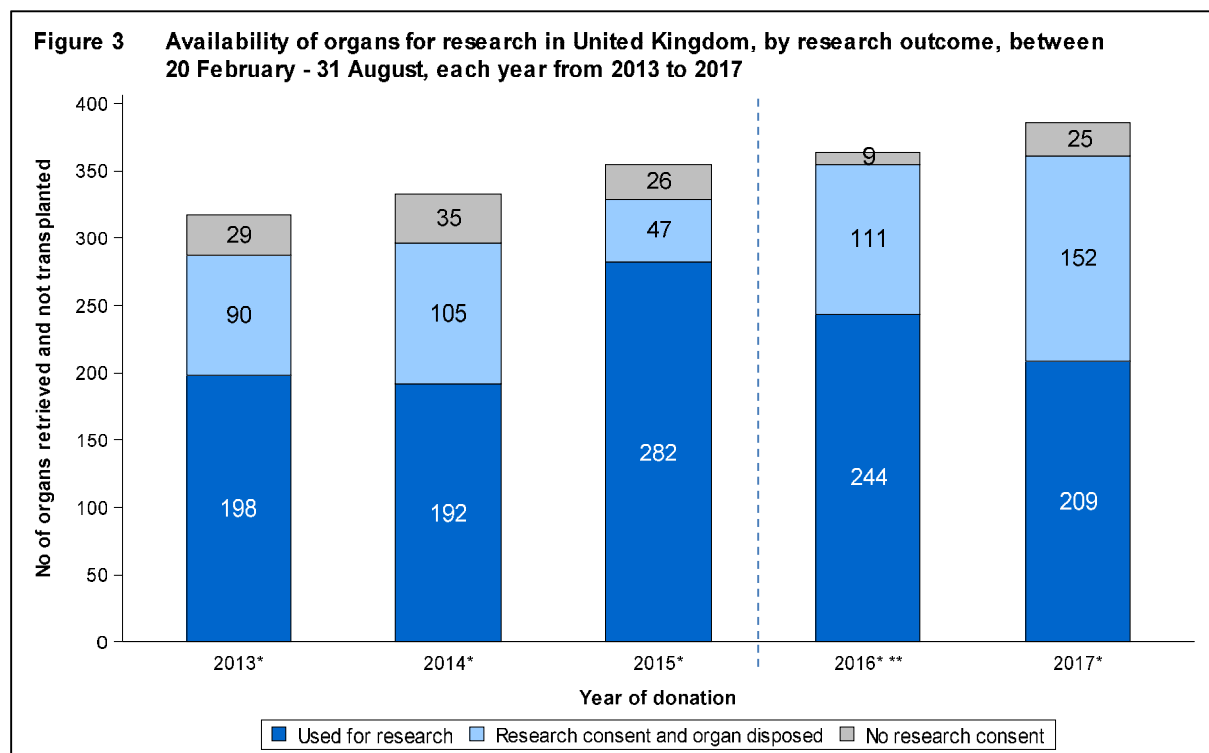


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\*\* 1 January – 31 August 2017

### Availability of organs for research

10 **Figure 3** shows the availability of organs for research, as the number of organs retrieved and not transplanted, in the UK broken down by research outcome; no research consent, organ used for research and organ disposed of with research consent.

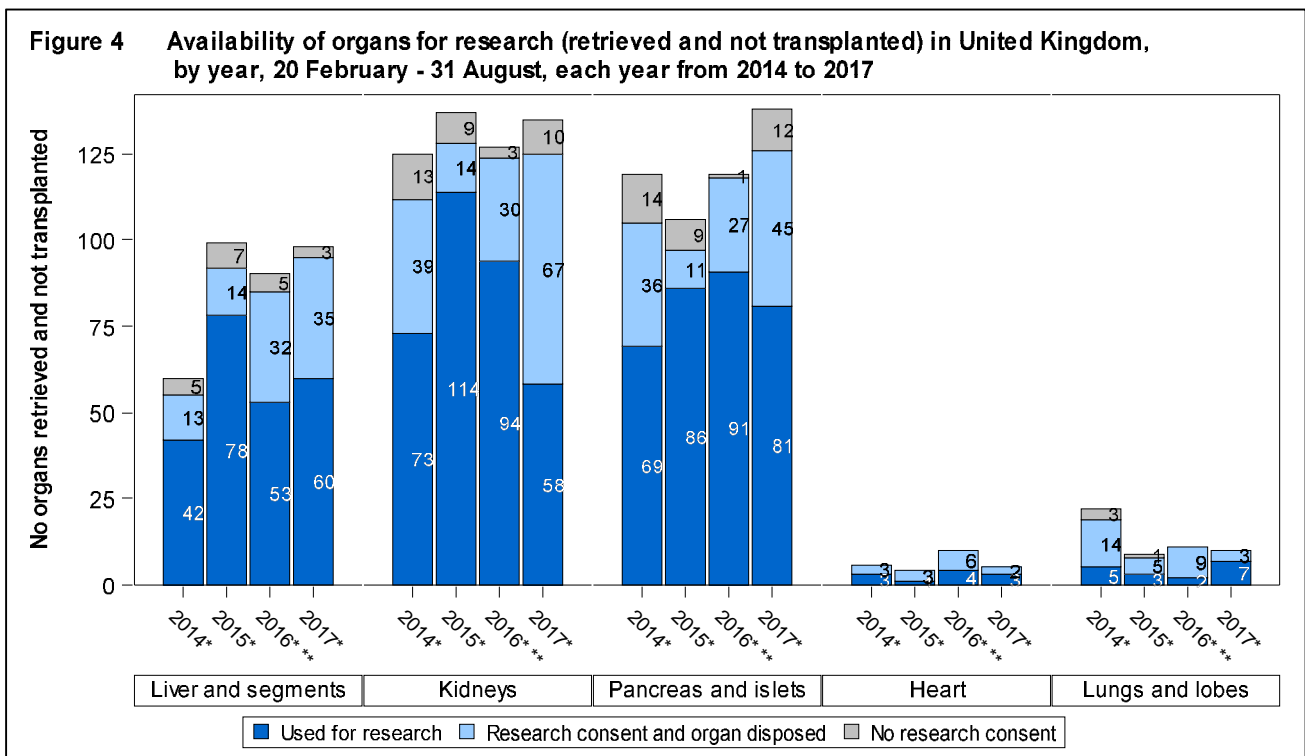


\* Inaccurate data between 6 January to 6 April 2016 due to inconsistencies in consent questions

\*\* 1 January – 31 August 2017

11 The percentage of organs retrieved but not transplanted that did not have consent/authorisation for research was 9.1%, 10.5 and 7.3% in 2013, 2014 and 2015 respectively. This decreased in 2017 (using data up until 31 August 2017) to 6.5%.

12 **Figure 4** breaks down the availability of organs for research in the UK by research outcome and organ; small bowel and the pancreas head are excluded. This shows that the percentage of organs retrieved but not transplanted which did not have research consent in 2014, 2015 and 2017 (using data up until 31 August 2017) respectively were 10.4%, 6.6%, 7.4% for kidney and 11.8%, 8.5%, 8.7% for pancreas and islets. It does not therefore appear that the change in questions affected the availability of kidney or pancreas organs for research. The numbers remain small for hearts, lungs and lobes. The figures for livers are subject to inconsistencies in hepatocytes reporting.



\* 20 February – 31 August

\*\* Inaccurate data between 6 January to 6 April 2016 due to inconsistencies in consent questions

Please note: liver hepatocytes has been recorded inconsistently –see paragraph 7

**CONCLUSION**

- 13 The change in consent/authorisation questions on the CDDF does not appear to have impacted the overall UK consent/authorisation rate which was 92% in 2015 and also in 2017 (using data up until 31 August 2017).
- 14 Looking specifically at the effect of changes to consent questions for England, Wales and Northern Ireland collectively, there also appeared to be little impact upon the consent rate; 93% in 2015 and also in 2017 (using data up to 31 August 2017). The change in authorisation questions could however have had a positive impact in Scotland as the authorisation rate increased from 77% in 2015 to 87% in 2017 (using data up until 31 August 2017). However, there are fewer donors in Scotland and so the rate may be more susceptible to fluctuations than in England, Wales and Northern Ireland collectively.
- 15 The change in consent/authorisation questions may have slightly increased the number of organs available for research as the percentage of organs retrieved but not transplanted that did not have consent/authorisation for research was 9.1%, 10.5 and 7.3% in 2013, 2014 and 2015 respectively. This decreased in 2017 (using data up until 31 August 2017) to 6.5%.

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**APPENDIX**

Consent/authorisation prior to 6 January 2016

CONSENT/AUTHORISATION

<b>Donors in England/Wales/Northern Ireland</b>		<b>NHS/academic research</b>	Commercial research	Education/training relating to HH or PA
Transplant	Clinical audit			
No = 1 Yes = 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Donors in Scotland</b>		<b>Ethically approved research</b>	Education/training	Quality assurance
Transplant	Clinical audit			
No = 1 Yes = 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Consent/authorisation from 7 April 2016

**Consent / Authorisation**

SN-OD who obtained consent/authorisation

**Donors in England/Wales/Northern Ireland**

There is also an opportunity to support transplantation/healthcare through the removal of samples, for example blood, urine, and /or tissue samples from specific organs which can then be used in approved research projects. Do the family consent to this? No = 1  
Yes = 2

On occasion, organs/tissues the family have agreed to donate may be found to be unsuitable for transplant. However, these organs/tissues can be used in research (or other Scheduled Purposes) to gain a better understanding on how we can improve healthcare in the future. Do the family consent to this? No = 1  
Yes = 2

Organs/tissues/materials may also be donated and used to improve future healthcare. Do the family consent to the removal of specific organs/tissues/samples for research or other Scheduled Purposes? No = 1  
Yes = 2

If YES please provide details in the Additional Information box No = 1  
Yes = 2  
NOT DISCUSSED THEREFORE AUTHORISATION NOT OBTAINED -3

**Donors in Scotland**

Have the next of kin authorised that specified organs and/or samples derived from specific organs:

May be stored and used for ethically approved research?

May be removed and stored for the purposes of specific ethically approved research projects described in the additional information box below?

May be stored and used for education/training?

May be stored and used for quality assurance / performance assessment?

May be stored and used for audit of clinical services?

Have the next of kin authorised that following either completion or education / training / quality assessment / research or if found unsuitable for clinical use all organs and/or samples derived from specific organs or tissue will be disposed of in a safe and lawful way?

Additional Information:

Has Coroner/Procurator Fiscal given consent for donation? No = 1  
Yes = 2  If YES, type (see code W)