

NHS BLOOD & TRANSPLANT
RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP
RESEARCH CONSENT/AUTHORISATION RATES

SUMMARY

INTRODUCTION

- 1 This paper summarises how generic research consent/authorisation rates have changed over the last ten years in the UK.
- 2 Families can give generic consent/authorisation for research use of any organs that are found to be unsuitable for transplantation. They are only asked this question if consent/authorisation for transplantation has been ascertained. No organ specific questions are asked regarding research consent/authorisation.

DATA AND METHODS

- 3 Research consent/authorisation rates were analysed for actual organ donors (where at least one organ was retrieved for the purposes of transplantation) in the UK from 1 January 2012 to 31 December 2021.
- 4 When considering organ specific consent/authorisation rates, donors with contraindications for specific organs were excluded where the data is available on the UK Transplant Registry.

CONCLUSION

- 5 The overall UK consent/authorisation rate for research was 86% in 2012 and has risen to 93% in 2021. Consent/ authorisation rates in 2021 have varied by nation from England at 92% to Northern Ireland and Wales at 97%.

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INTRODUCTION

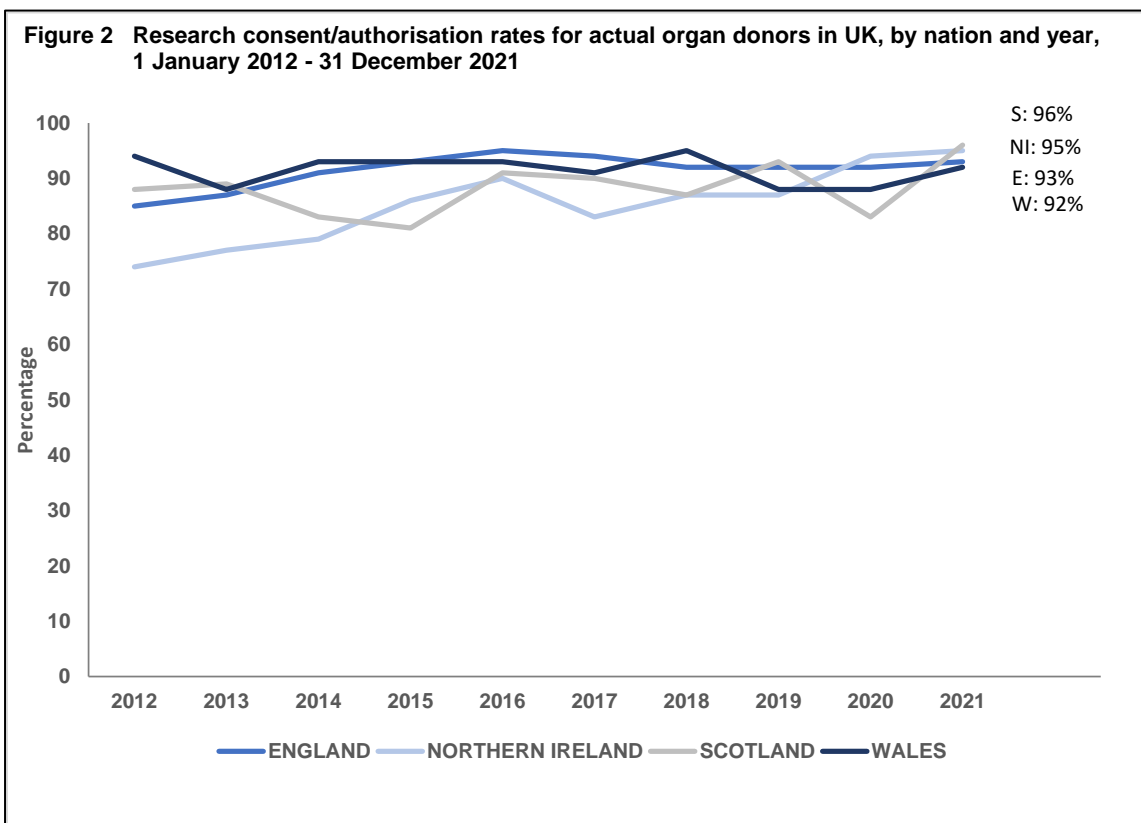
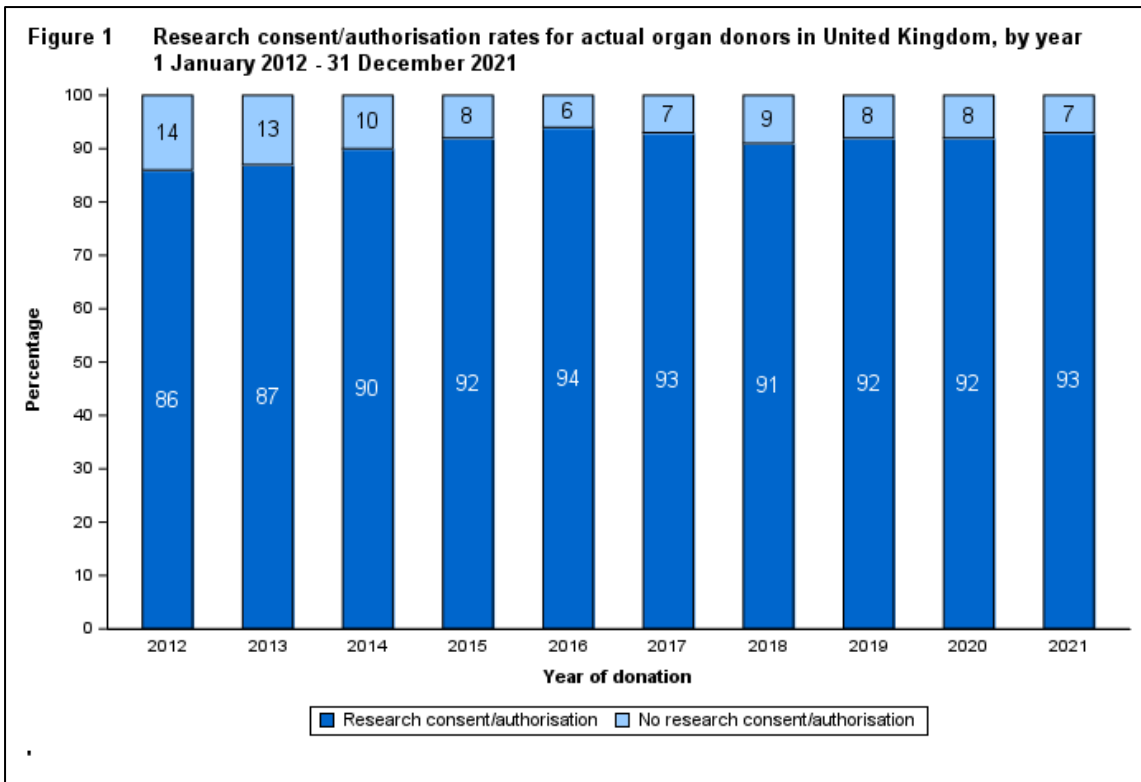
- 1 This paper summarises how generic research consent/authorisation rates have changed over the last ten years in the UK.
- 2 Families can give generic consent/authorisation for research use of any organs that are found to be unsuitable for transplantation. They are only asked this question if consent/authorisation for transplantation has been ascertained. No organ specific questions are asked regarding research consent/authorisation.

DATA AND METHODS

- 3 Research consent/authorisation rates were analysed for actual organ donors (where at least one organ was retrieved for the purposes of transplantation) in the UK from 1 January 2012 to 31 December 2021.
- 4 When considering individual organ research consent/authorisation rates, donors with the following organ-specific contraindications for transplantation were excluded:
 - Intestinal: all DCD donors, DBD donors aged ≥ 56 years or weighing ≥ 80 kg excluded
 - Pancreas and islets: DBD donors aged ≥ 65 years, DCD donors aged ≥ 56 years, all donors with BMI > 40 kg/m², all donors with past history of diabetes excluded
 - Heart: DBD and DCD donors aged ≥ 65 years or died of myocardial infarction excluded.
 - Lung: DBD donors aged ≥ 70 years and who were a past smoker, or DBD donors aged ≥ 75 years and were not a past smoker, DCD donors aged ≥ 65 years and were a past smoker, or DCD donors aged ≥ 75 years and were not a past smoker.

RESULTS

- 5 **Figure 1** illustrates that overall UK research consent/authorisation rates for solid organ donors increased from 86% in 2012 and has fluctuated above 90% since 2014. The UK generic consent/authorisation rate in 2021 was 93%. This shows that a large majority of donors that donate at least one solid organ also have consent/authorisation for research.
- 6 **Figure 2** breaks down research consent/authorisation rates for actual organ donors by nation and year. Consent/authorisation rates in 2021 have varied by nation from Wales at 92% to Scotland at 96%. Rates for Scotland, Northern Ireland and Wales fluctuate more than for England as there are fewer donors.



- 7 **Figures 3 and 4** show consent/authorisation rates broken down by organ and tissue, respectively. These rates are shown for actual solid organ donors from January to December 2021 for which overall generic consent/authorisation for research had been ascertained. When the SNOD reaches the research section of the consent form, the consent for untransplantable organs to be used in research is a blanket consent for all organs previously consented for transplant with one consent rate (97%).
- 8 A list of organ-specific donor contraindications is provided in the **Appendix**. Where the associated data were available, donors with organ-specific contraindications have been excluded from **Figure 3**. However, many cases could not be identified using UK Transplant Registry data hence consent/authorisation rates may appear lower.
- 9 **Figure 3** shows that kidneys (92%) and liver (89%) gained the highest rates of consent/authorisation for actual donors with consent/authorisation for research.

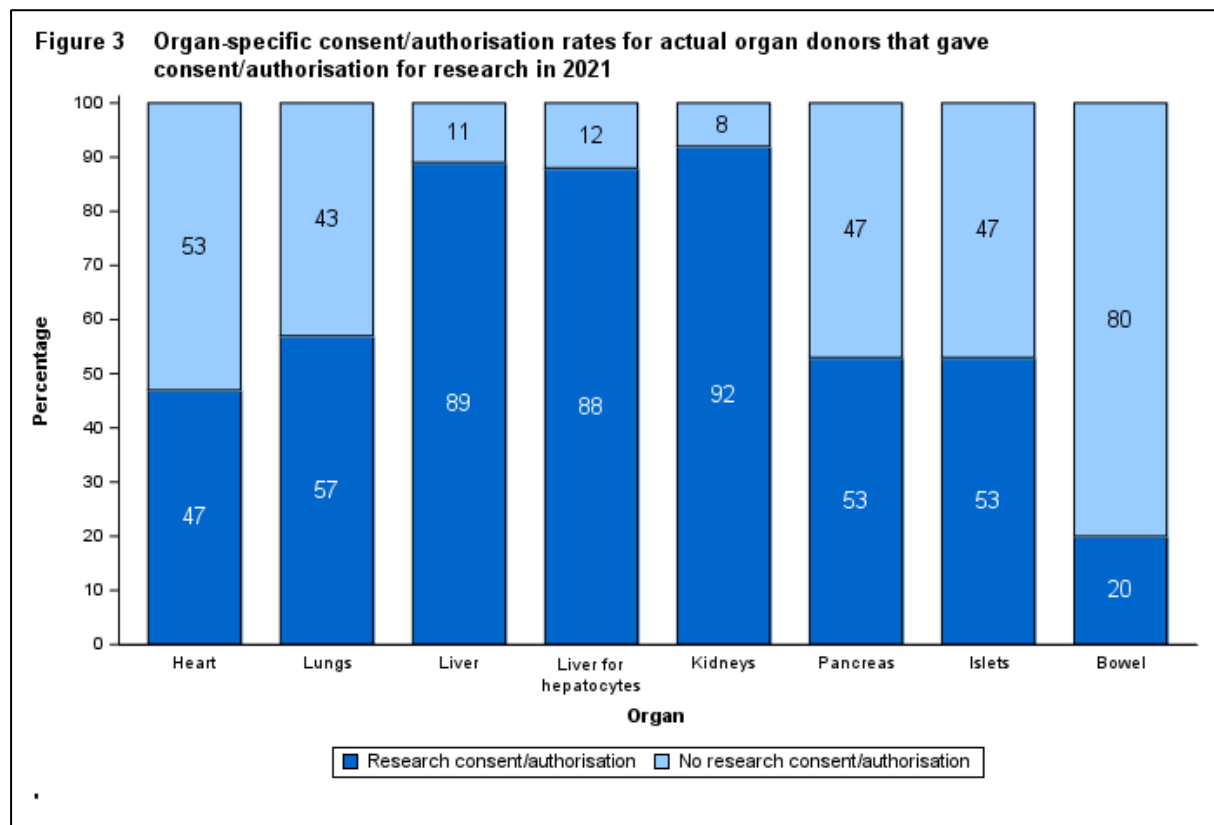
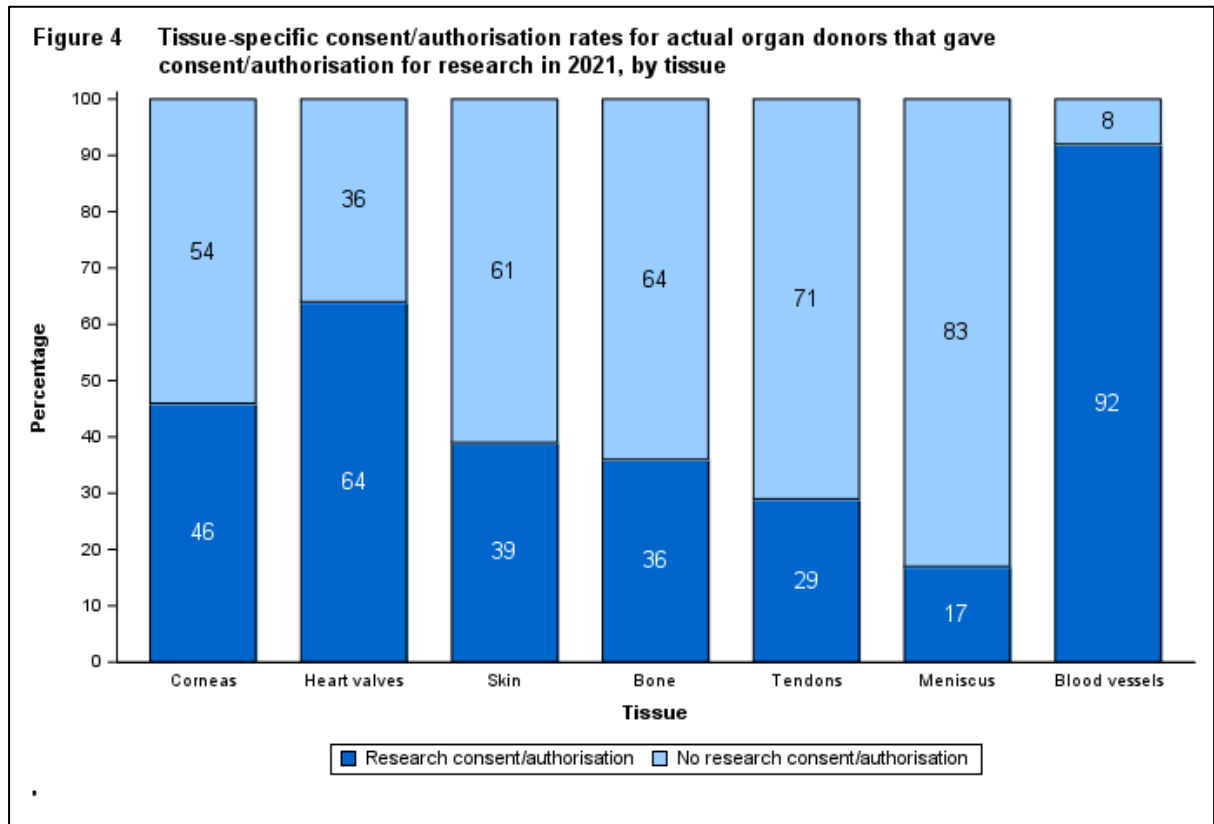


Figure 4 illustrates that tissues generally have lower consent/authorisation rates than solid organs. Please note that this cohort excludes tissue-only donors.



CONCLUSION

10 The overall UK consent/authorisation rate for research was 86% in 2012 and has risen to 93% in 2021. Consent/authorisation rates in 2021 have varied by nation from Wales at 92% to Scotland at 96%.

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APPENDIX – Contraindications to organ donation as at October 2019

Organ/contraindications	Excluded from Figure 3 (Y/N)
Liver	
Acute hepatitis of viral, drug or other known aetiology	N
Serum AST or ALT >10000 IU/L (if of liver origin)	N
Cirrhosis	N
Portal vein thrombosis	N
Metabolic diseases that would be of harm to the recipient and not treatable (such as haemophilia A and B, inborn errors of metabolism such as axaluria, tyrosinaemia)	N
Idiopathic Thrombocytopenia (ITP) (relative contraindication)	N
Bowel	
DCD donors	Y
DBD donor age ≥56 years of age (on or after their 56th birthday) or weight of 80kg or more	Y
Underlying chronic intestinal disease	N
Intra-abdominal sepsis	N
For abdominal wall/fascia donation: Extensive surgical scars/damage to the abdominal wall/fascia	N
Pancreas	
Insulin dependent diabetes (excluding ICU associated insulin requirement)	Y ¹
Non-insulin dependent diabetes (Type 2)	Y ¹
Any history of pancreatic malignancy	N
Donor BMI >40kg/m ²	Y
DBD donor age ≥66 years of age (prior to 1/10/2020)	Y
DBD donor age ≥61 years of age (from 1/10/2020)	
DCD donor age ≥56 years of age	Y
Heart	
<i>Urgent:</i>	
Age of 65 years or more (on or after their 65th birthday)	Y ²
<i>Non-urgent:</i>	
Documented coronary artery disease (e.g. confirmed history of MI, CABG or percutaneous stenting)	Y ³
Median sternotomy for cardiac surgery	N
LVEF ≤30% on more than one occasion	N
Massive inotropic or pressor support, but only if adequate circulating volume has been confirmed by monitoring	N
Myocarditis	N
Lyme disease	N

NOTES

¹ Data collected indicates past diabetes and not the type of diabetes

² Included for all heart donors

³ Only available where cause of death is myocardial infarction (MI)

APPENDIX – Contraindications to organ donation as at October 2019

Organ/contraindications	Excluded from Figure 3 (Y/N)
Lungs	
DCD donor aged ≥65 years (on or after their 65th birthday) unless donor is a lifetime non-smoker, or has not smoked for 10 years or more, in which case donor age ≥75 years (on or after their 75th birthday)	Y ⁴
DBD donor aged ≥70 years (on or after their 70th birthday) unless donor is a lifetime non-smoker, or has not smoked for 10 years or more, in which case donor age ≥75 years (on or after their 75th birthday)	Y ⁴
Previous intra-thoracic malignancy	N
Significant, chronic destructive or suppurative lung disease (those with controlled asthma are suitable donors)	N
Chest X-ray evidence of major pulmonary consolidation	N
Influenza with demonstrable lower respiratory tract infection	N
DCD Exclusion Criteria	
Patients aged >75 unless they are dying of a neurological condition	N
Patients aged 70-75 unless they are of either a neurological condition or respiratory disease	N
Patients aged >70 dependent on RRT	N
Patients aged >70 with CKD 3b or greater	N
Patients aged >40 with a current clinical diagnosis of multi organ failure ***	Y ⁵
Patients with a current clinical diagnosis of Septicaemia or Sepsis with severe multi organ dysfunction ***	Y ⁶
Patients with previous cancer in the last 5 years (except Primary CNS cancer, localised prostate, thyroid, in-situ cervical cancer or non-melanotic skin cancers)	N
***If a potentially transplantable organ is unaffected by MOF or Sepsis the patient should not be excluded and organ offering should be undertaken as per age related offering guidance	

NOTES

⁴ Data collected only indicates past smoker

⁵ Only have cause of death not diagnosis

⁶ Only have cause of death not diagnosis and septicaemia not sepsis