



## BRIEFING PAPER

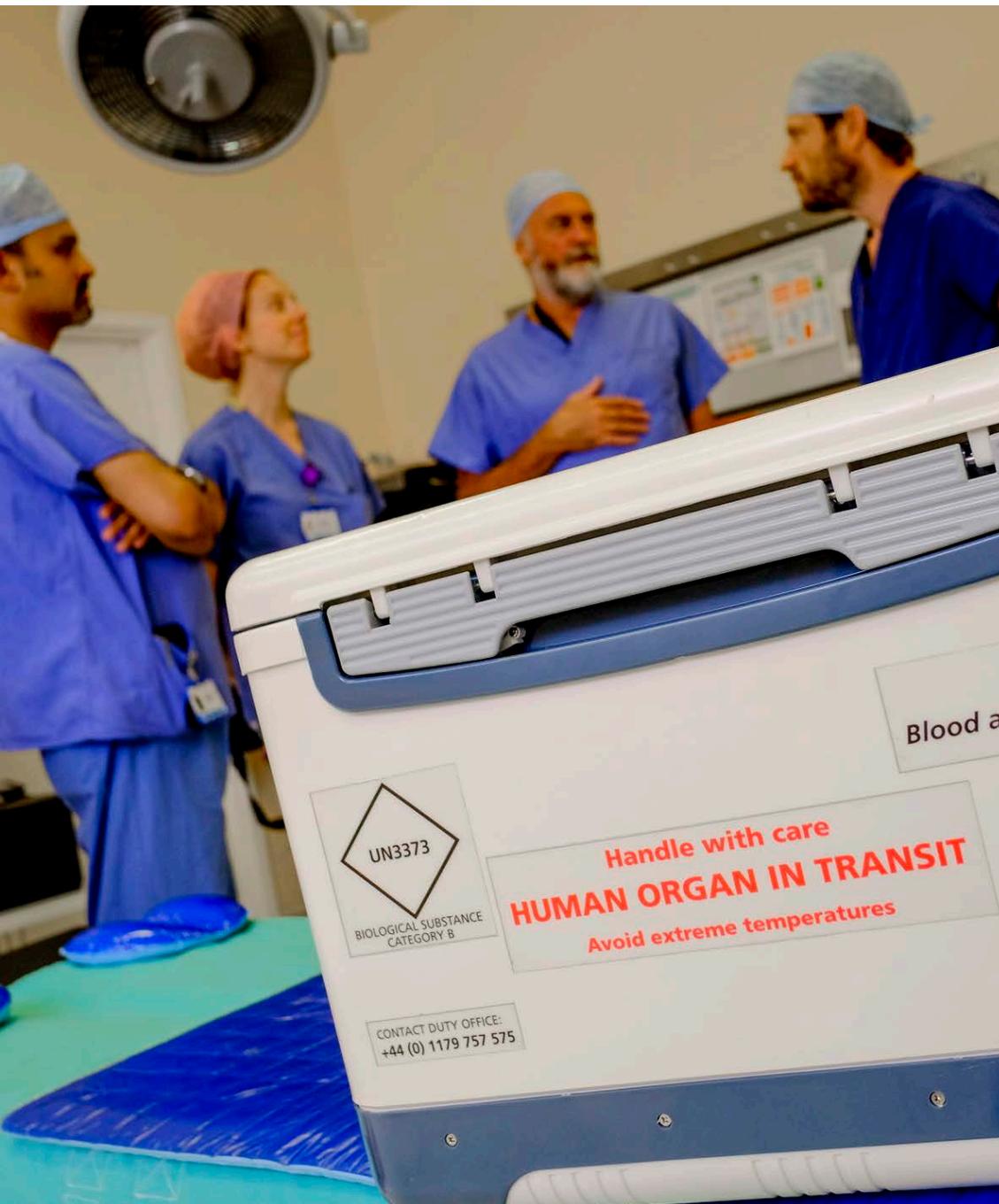
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# The Organ Donation (Deemed Consent) Bill 2017-19

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## Summary

Organ donation rates have increased significantly in the UK in the last decade, but there is still a shortage of donors and hundreds of people die whilst waiting for an organ in the UK each year. One of the proposals to address this organ shortage is a move to an opt-out organ donation consent system.

The current organ donation system in England is an opt-in system. The *Human Tissue Act 2004* sets out that a person can consent to donate their organs by expressing a view during their lifetime or by appointing a representative to consent on their behalf. If a decision on organ donation has not been made in these ways, their family will be asked to give consent. However, where the patient has not expressed a wish to donate, or their register status is not known, the latest family consent rate is only 48.5%. Where the patient's wish to donate was known at the time of potential donation, 92% of families consent to donation.

In October 2017, the Prime Minister announced that the Government would introduce an opt-out consent system for organ donation in England. In December 2017, a Government consultation was published that sought views on this change.

*The Organ Donation (Deemed Consent) Bill 2017-19* was tabled by Labour MP, Geoffrey Robinson, after coming 6th in the Private Member's Bill ballot in this parliamentary session and had its Second Reading on 23 February 2018. It was considered by a Public Bill Committee on 12 September 2018.

The Bill intends to amend the *Human Tissue Act 2004* so that where a person has not made a decision regarding organ donation during their life, or appointed a representative for this purpose, the default position will be that consent will be deemed to have been given. The measures on deemed consent within the Bill will only apply in England. The Bill is tabled for Report Stage and Third Reading on 26 October 2018.

The organ donation consent system is a devolved issue. Wales has already moved to an opt-out consent system, introduced in December 2015, and the Scottish Government have introduced legislation on this issue in the current parliamentary session.

There is significant support for a change in the law in this area, from across the political parties, the public, and health organisations who believe it will lead to an increase in donors and will save lives. However, there has also been some opposition to the proposal to change the system from those who believe the evidence does not support a move to an opt out system, and that it may have negative impacts.

This briefing provides an overview of the current law on organ donation consent, the *Organ Donation (Deemed Consent) Bill*, evidence reviews on this issue, and views.

# 1. Background

Individuals in the UK may choose to donate their organs following their death, or in some cases donate as a living organ donation. Only a small number of people each year die in circumstances that mean their organs could be considered for transplant.

Despite consistent increases in the number of people donating their organs, there is still a shortage of organs and people still die waiting for an organ transplant. NHS Blood and Transplant, the Special Health Authority responsible for coordinating organ donation and transplantation across the UK, reported that in 2016/17, 456 adults and 14 children died whilst on the transplant list, and a further 875 people were removed from the list because they were too ill for surgery.<sup>1</sup>

Individuals from a black or Asian background are more likely to suffer from illnesses where a transplant may be needed but will spend an average 6 months longer waiting for a matched donor.<sup>2</sup>

Concerns about insufficient numbers of donated organs in the UK has led to calls for further government action to increase the number of organ donors. One proposal has been to introduce a system of presumed consent to organ donation after death, also known as an opt-out system.

## 1.1 Organ donation policy in the UK

Two Government sponsored reports over the last 12 years have established current policy and work programmes on organ donation.

### Organ Donation Taskforce report 2006

The Organ Donation Taskforce (the Taskforce) was established in 2006 and chaired by Dame Elizabeth Buggins. It was comprised of specialists in the field of organ donation, and was asked by the Government to identify the obstacles to organ donation and make recommendations on measures to increase transplant rates.

The taskforce concluded that a 50% increase in deceased organ donation was possible and achievable in the UK over the next five years.<sup>3</sup> To achieve this, it made a number of recommendations, including:

- The expansion of networks of donor transplant coordinators, recruited centrally by NHSBT;
- The establishment of a new independent UK-wide donation ethics group;

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<sup>1</sup> NHS Blood & Transplant press release [Organ and tissue donation: A vital lesson that can help to save lives](#) 6 February 2018

<sup>2</sup> Government consultation [Introducing 'opt-out' consent for organ and tissue donation in England](#) 12 December 2017

<sup>3</sup> The Department of Health Organ Donation Taskforce, [Organs for Transplants: A report from the Organ Donation Taskforce](#), 2006

- That discussions about donation should be part of every end of life care when appropriate, and each hospital trust should have clinical donation champion, and a trust donation committee;
- That organ donation activity should be monitored in all hospital trusts; and
- That all clinical staff likely to be involved in treating potential donors should be given mandatory training.

The then Labour Government accepted all the taskforces recommendations, and committed £11million of funding to implement these.<sup>4</sup>

### Organ donation strategy 2013

In 2013, five years after the Organ Donation taskforce recommendations, NHS Blood and Transplant (NHSBT) reported back on the progress since the 2006 report and made further recommendations in a new organ donation strategy – *Taking Organ Donation to 2020*.

It reported that, by April 2013, there had been a 50% increase in the number of deceased donors and a 30.5% increase in transplants. However, there was still more to do and there remained a shortage of organs.

The strategy highlighted that the Government and NHS should make sure that all potential donors could donate where possible, identifying donors early, and ensuring that they can give as many organs as possible. It reported that there was still significant variation between hospitals:

If every region performed at the level of the best, it is estimated that there would be over 500 (45%) more donors than the 1,212 who actually donated organs last year.<sup>5</sup>

It highlighted poor rates of family consent to organ donation in comparison with other countries and suggested two approaches to improving this.

It should be considered normal within society for a family to be asked for consent and normal that they should give it, and there must be the best support for families going through making these decisions. Increasing public awareness is an important part of improving this as is the provision of experienced support through Specialist Nurses for organ donation (SN-OD) as soon as possible.<sup>6</sup>

The strategy noted that international evidence showed that the use of transplant coordinators achieved higher consent rates. A UK audit had demonstrated that when Specialist Nurses for Organ Donation (SN-ODs) were involved with a family at early stages, consent rates improved.

The new strategy provided the following targets for organ donation in the UK by 2020:

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<sup>4</sup> Department of Health press release [Fifty Per Cent increase in organ donation possible within five years](#), 16 January 2008

<sup>5</sup> NHSBT, [Taking Organ donation to 2020: A detailed strategy, 2013](#)

<sup>6</sup> NHSBT, [Taking Organ donation to 2020: A detailed strategy, 2013](#)

## 6 The Organ Donation (Deemed Consent) Bill 2017-19

- A consent/authorisation rate above 80% (the consent rate in 2016/17 was 62.7%)
- A deceased donor rate of 26 per million population (pmp) (the deceased donor rate in 2016/17 was 21.1 pmp in England)
- Transplant 5% more of the organs offered from consented donors; and
- A deceased donor transplant rate of 74 pmp.

More recently the Government have indicated their support for a system of 'opt-out consent' for organ donation, such as in this written statement in December 2017:

In October 2017, the Prime Minister announced the Government's intention to change the law on organ donation in England by introducing the principle of "opt-out consent", in a bid to save the lives of the 6,500 people currently waiting for an organ transplant.

Today the Government has launched a consultation to begin an open conversation about this change to opt-out organ donation, including how to encourage more conversations about personal decisions and what role families should have when their relative has consented to donate.

Currently, 80 percent of people say they would be willing to donate their organs but only 36 percent register to become an organ donor. Three people die every day in need of a suitable organ. Figures from NHS Blood and Transplant show that around 1100 families in the UK decided not to allow organ donation because they were unsure, or did not know whether their relatives would have wanted to donate an organ or not. The Government's intention is that changing the system to an opt-out model of consent will mean more viable organs become available for use in the NHS, potentially saving thousands of lives.

The consultation is open for the next three months, providing an opportunity for as many people as possible in England to give their views, including people from religious groups, patient groups, the clinical transplant community, and black, Asian and other minority communities.

It is important to ensure that moving to an opt-out system of consent will honour a person's decision on what happens to their body after death, and the consultation seeks views on how we can make sure this is the case.

The consultation also seeks views on a number of related issues, including ways in which it can be made easier for people to register their decision on organ and tissue donation. The consultation invites views on the potential impact proposals could have on certain groups who have protected characteristics in law such as disability, race, religion or belief. Questions are asked to help determine how family members should be involved in confirming decisions in future. The Government also proposes a number of exclusions and safeguards to the general rule of consent under the proposed new system. This includes the position of children, people with limited mental capacity, the armed forces and temporary residents.

The consultation is available at <https://www.gov.uk/government/consultations/introducing-opt-out-consent-for-organ-and-tissue-donation-in-england> . An

Impact Assessment has been published alongside the consultation and can be accessed in the same place as the link above on gov.uk and is also attached.

The outcome of the consultation will inform the Government's next steps and its proposals for legislation to bring the new system of consent into effect. Today the Government has launched a consultation to begin an open conversation about this change to opt-out organ donation, including how to encourage more conversations about personal decisions and what role families should have when their relative has consented to donate.

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The outcome of the consultation will inform the Government's next steps and its proposals for legislation to bring the new system of consent into effect.<sup>7</sup>

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<sup>7</sup> Written Statement: [Update on organ donation in England](#) - HCWS338 12 December 2017

## 2. Organ donation consent systems

### 2.1 Different types of organ donation consent systems

There is a wide range of different systems that could be used for organ donation consent. These were set out by the Department of Health's Organ Donation Taskforce in 2008<sup>8</sup>:

Option	Details
<b>1: A 'hard' opt out system</b>	Doctors can remove organs from every adult who dies - unless a person has registered to opt out. This applies even if relatives know that the deceased would object to donation but had failed to register during life.  Example: Austria
<b>2: A 'hard' opt out system which does not cover some groups</b>	Doctors can remove organs from every adult who dies - unless a person has registered to opt out <b>OR</b> the person belongs to a group that is defined in law as being against an opt out system.  Example: Singapore where Muslims choose to opt out as a group.
<b>3: A 'soft' opt out system</b>	<b>Option 3a: No need to consult relatives</b> Doctors can remove organs from every adult who dies - unless a person has registered to opt out <b>OR</b> the person's relatives tell doctors not to take organs. It is up to the relatives to tell the doctors because the doctors may not ask them.  Example: Belgium
	<b>Option 3b: Relatives should be consulted</b> Doctors can remove organs from every adult who dies - unless a person has registered to opt out. It is good practice for doctors to <b>ask the relatives</b> for their agreement at the time of death.  Example: Spain
<b>4: A 'soft' opt in system (current system in the UK)</b>	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. It is normal practice to let relatives know if the person has opted in and doctors can decide not to proceed if faced with opposition from relatives.
<b>5: A 'hard' opt in system'</b>	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. Relatives are not able to oppose the person's wishes.
<b>6: A choice to opt in or opt out</b>	<b>Option 6a:</b> People <b>can</b> register their choice to opt in or opt out.
	<b>Option 6b:</b> People <b>must</b> register their choice to opt in or opt out.

### 2.2 Organ donation consent systems in the UK

Policy on organ donation is devolved in the UK, as health is generally a devolved responsibility. Wales became the first country in the UK to

<sup>8</sup> Department of Health, [Organs for Transplants: A report from the Organ Donation Taskforce](#) January 2008

introduce an opt-out system for organ donation consent in 2015. An opt-in system applies in the rest of the UK

## England

Organ donation consent requirements are set out in [the Human Tissue Act 2004](#). This provides the conditions under which an individual can donate their organs for transplantation in England and Northern Ireland. In Scotland, the *Human Tissue (Scotland) Act 2006* is applicable. Both pieces of legislation came into force in 2006.

With specific regards to organ donation consent, the *Human Tissue Act 2004* sets out the following:

- Consent is required before tissue or organs are removed from a deceased person for organ donation:
  - Consent may be written but there is no requirement for it to be so, so long as it has been explicitly made;
  - An adult may appoint a representative to represent them after death. This appointment may be made orally, or in writing;
  - Consent to donate can also be given by a person who was in a qualifying relationship with the deceased before their death.
- A child (under 18 years old) may give consent for organ donation. If it has been established that the child is not competent to consent, then consent may be given by a person with parental responsibility;

Where a person has decided to refuse to donate their organs before death, the decision is binding on clinicians.

However, where an individual has consented to give their organs during their lifetime there is no obligation to take the organs and use them in this situation. For example, if a person's relative express an objection to the organs of the deceased being donated – clinicians will not proceed.<sup>9</sup>

## Wales

[The Human Transplantation \(Wales\) Act](#) came into force in Wales in December 2015. Under this law, adults who live and die in Wales will be held to have given their consent to donate their organs unless they register a wish to not be a donor (an opt-out system).

The deceased must be over 18 years of age and have lived in Wales for longer than 12 months. There is an option for the family of the deceased to provide information to show they would not have wished to consent, and those without the capacity to make this decision are excluded from the new system.

The [Organ Donation Wales](#) website has more information on the introduction of the opt-out system.

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<sup>9</sup> D. P. T. Price; [Legal framework governing deceased organ donation in the UK](#), *BJA: British Journal of Anaesthesia*, Volume 108, Issue suppl\_1, 1 January 2012, Pages i68–i72

The impact of the change to a deemed consent system in Wales is discussed further in section 5.

### Scotland

Following a public consultation on organ donation consent in 2017,<sup>10</sup> the Scottish Government committed to bring forward legislation to introduce an opt-out system of consent in the current Parliamentary session.<sup>11</sup>

The [\*Human Tissue \(Authorisation\) \(Scotland\) Bill\*](#) was introduced in the Scottish Parliament on 8 June 2018.

### Northern Ireland

A Private Members Bill introduced by Jo-Ann Dobson MLA in 2015 intended to introduce an opt-out organ donation consent system in Northern Ireland.<sup>12</sup> The Bill was referred to the Committee for Health, Social Services and Public Safety for consideration. The Committee were opposed to the clause on deemed consent within the Bill. The Bill did not progress further.

The Northern Irish Government's [\*Health \(Miscellaneous Provisions\) Act \(Northern Ireland\) 2016\*](#) includes measures on a range of subjects, including a duty on the Government to promote transplantation. In December 2017, the Northern Irish Department of Health published a consultation on the draft policy for improving organ donation rates.<sup>13</sup>

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<sup>10</sup> Scottish Government, [Organ and Tissue Donation and Transplantation: Analysis of Responses](#) 28 June 2017

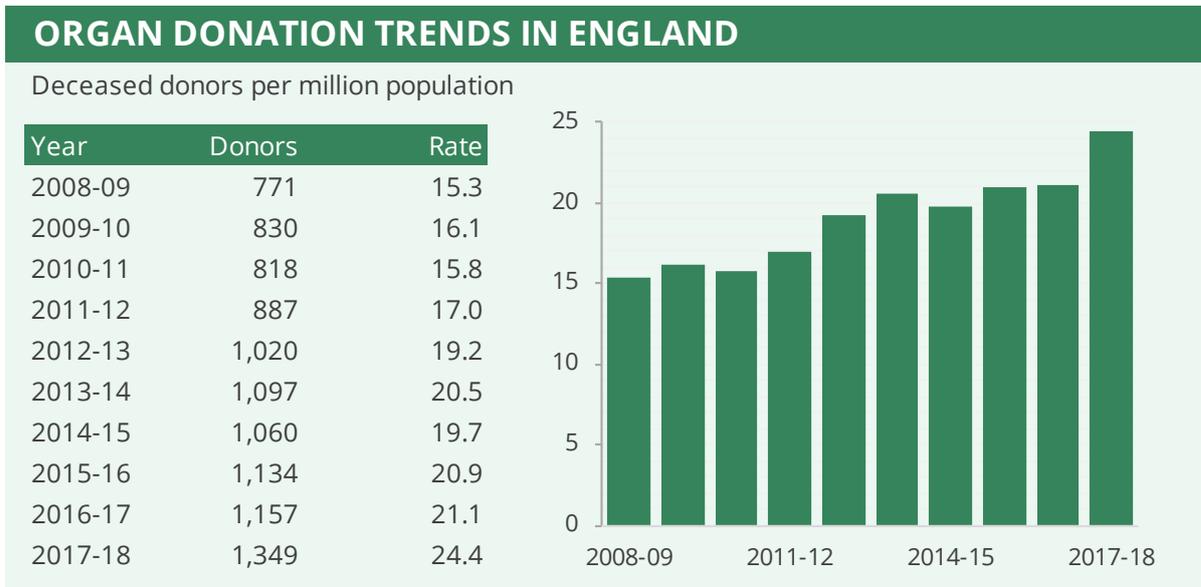
<sup>11</sup> Scottish Government, [Organ and Tissue Donation and Transplantation: Analysis of Responses](#) 28 June 2017

<sup>12</sup> Northern Ireland Assembly, [Human Transplantation Bill 2011-16 Mandate](#)

<sup>13</sup> Northern Ireland Department of Health press release, [Developing a holistic approach to organ donation – consultation launched](#), 11 December 2017

### 3. Organ donor rates

In 2017-18 there were 1,349 deceased organ donors in England – 24.4 per million population. This rate has increased from 15.3 per million population in 2008-09.<sup>14</sup>



#### 3.1 Family consent rates

As set out in section 1.1; an existing recorded decision to refuse to donate their organs before death is binding on clinicians. However, where an individual has consented to give their organs during their lifetime there is no obligation to take the organs and use them in this situation. For example, if a person's relatives express an objection to the organs of the deceased being donated, clinicians would normally not proceed.<sup>15</sup>

It should be noted that where a person has not expressed a decision in their lifetime on organ donation, the family will normally still be approached to consider donation.<sup>16</sup>

In England, just over one-third of families refuse to give consent for donation. Consent/authorisation rates have increased in recent years, as the table below shows.<sup>17</sup>

<sup>14</sup> NHS Blood and Transplant, [Transplant Activity Report 2017/18](#) and previous years

<sup>15</sup> D. P. T. Price; [Legal framework governing deceased organ donation in the UK](#), *B/A: British Journal of Anaesthesia*, Volume 108, Issue suppl\_1, 1 January 2012, Pages i68–i72

<sup>16</sup> NHS Blood & Transplant, [NHSBT press essentials on the English Opt Out Consultation](#), December 2017

<sup>17</sup> DBD = donation after brain death; DCD = donation after circulatory death. NHS Blood and Transplant, [Transplant Activity Report 2016/17](#).

DONATION CONSENT/AUTHORISATION RATES		
Total rates combining DCD and DBD cases		
	England	UK
2011-12	-	55%
2012-13	-	57%
2013-14	60%	59%
2014-15	59%	58%
2015-16	63%	62%
2016-17	63%	63%
2017-18	66%	66%

These rates vary substantially between different types of cases. Where the patient’s wish to donate was known at the time of potential donation, 92% of families consented to donation (although 90 families overruled their loved ones’ known decision to be an organ donor). However, where the patient had not expressed a wish to donate, or their register status was not known, family consent rate was much lower at 48.5%.

Consent/authorisation rates also vary depending on whether a specialist nurse in organ donation was involved in the approach to the family. In cases where a specialist nurse was involved, consent rates were 70.5%; in the minority of cases where a specialist nurse was not involved, the consent rate was 22.1%.<sup>18</sup>

The table below shows the primary reasons families gave for refusing consent for donation in 2017/18.

REASONS FOR FAMILY REFUSAL, 2017-18	
<b>22%</b>	Patient expressed wish not to donate
<b>15%</b>	Were unsure whether patient would have agreed
<b>13%</b>	Felt the process was too long
<b>11%</b>	Didn't want surgery to the body
<b>6%</b>	Felt the patient had suffered enough

<sup>18</sup> NHS Blood and Transplant, [Transplant Activity Report 2017/18](#).

## 4. A change in the law in Wales

### 4.1 The *Human Transplantation (Wales) Act 2013*

[The \*Human Transplantation \(Wales\) Act 2013\*](#) was introduced by the Welsh Government following a public consultation. A detailed background to the Bill as introduced, is provided in a [Welsh Assembly Research Service Bill Summary](#). [The Act](#) came into force in Wales in December 2015.

The new legislation introduced an opt-out system of organ donation consent - adults who live and die in Wales will be held to have given their consent to donate organs unless they register a wish to not be a donor. The deceased must be over 18 years of age and have lived in Wales for longer than 12 months. There is an option for the family of the deceased to provide information to show they would not have wished to consent, and those without the capacity to make the decision are excluded from the new system.

The new system is 'soft opt-out system.' An Inbrief article from the Welsh Assembly research service describes the role of the family:

[...]This soft opt-out system means that consent is deemed to have been given unless the deceased objected during their lifetime, but **the family will still be involved in the decision-making process**. The family will be involved in discussions both to provide information about the person's residency and medical history, as well as to say whether they knew that the deceased person had an objection to organ donation. If the deceased person did have such an objection, organ donation would not go ahead. However, an objection must be based on the known views of the deceased, rather than the views of the family. **If family members cannot be contacted, the organ donation will not go ahead.**<sup>19</sup>

[Organ Donation Wales](#) has more information on the introduction of the opt-out system.

### 4.2 Evaluation of the new system

In November 2017, the Welsh Government published a report on the evaluation of the *Human Transplantation (Wales) Act 2013*.

The evaluation report looked at several aspects of the implementation of the Act. It found that early figures on organ donation rates had not increased since the introduction of the deemed consent system, but public awareness and support for the new system was high, and family consent rates had increased.

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<sup>19</sup> National Assembly for Wales, [New organ donation system comes into force in Wales](#), 1 December 2015

It stated that more time was required to make firmer conclusions on the impact of the change in consent system. The key findings of the report were:

- Awareness of and support for the soft opt-out system of organ donation in Wales is high among the general public and NHS staff.
- However, there has been a recent drop in awareness levels among the general public suggesting that publicity of the law needs to be maintained.
- More clarity around the role of the family in the organ donation process is required. This should encourage discussion in families, which may help them support the decision of a deceased relative.
- NHS staff working within organ donation may also benefit from further training, particularly around the organ donation conversation with the family.
- Despite the high awareness and support for the new law, analysis of routine data does not show any consistent change in deceased organ donations in Wales, or more widely from Welsh residents.
- Analysis of consent data shows an increase in the percentage of families giving approval for donation. However, this is not reflected in a rise in donors overall, implying there has been lower eligibility over the period since implementation of the law.
- A longer period of time is needed to draw firmer conclusions around the impact of the change in the law. It will be important to continue to monitor public attitudes and the routine data on organ donation in Wales (and more generally across other parts of the UK for comparison).<sup>20</sup>

A study in the *Journal of Medical Ethics*, published in February 2018, assessed the Welsh legislation “in light of concerns that it would decrease procurement rates for living and deceased donation, as well as sparking an increase in family refusals”. It found that none of these concerns had come to pass, “with Wales experiencing more registered donors, fewer family refusals and more living donations”. However, it reports that “as the total number of actual donors has dropped slightly from a high level, the situation must be monitored closely.”<sup>21</sup>

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<sup>20</sup> Welsh Government, [Support for the opt-out system of organ donation in Wales is high, says new report](#), December 2017

<sup>21</sup> Albertsen A, Deemed consent: assessing the new opt-out approach to organ procurement in Wales, *Journal of Medical Ethics* 2018;**44**:314-318.

## 5. Proposals to change the organ donation consent system in the England

### 5.1 Background

The prospect of moving to an opt-out organ donor consent system has been the subject of attention in the past. In 2007, the then Chief Medical Officer, Sir Liam Donaldson expressed support for a change,<sup>22</sup> and the then Labour Government asked the Organ Donation Taskforce to consult and report on this specific issue.<sup>23</sup>

It published its report, *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce* in 2008 which did not back any change to the existing system at that time (for more information on this report, please see section 8.1).<sup>24</sup>

An opt-out consent system was also considered during 2007 and 2008 by the House of Lords European Union Committee in the context of a European Commission Communication seeking to increase the supply of donor organs within the EU. Their report, published in July 2008, did not support the introduction of presumed consent in the UK.<sup>25</sup>

There have also been a few Private Member's Bills on moving to an opt-out organ donation system. These have included the [Organ Donation \(Presumed Consent\) Bill](#) introduced by Jeremy Browne MP in 2009 which completed Second Reading but did not progress further, and a Ten Minute Rule Bill, the [Organ Donation \(Deemed Consent\) Bill 2016-17](#) introduced by Paul Flynn in January 2017.

### 5.2 UK Government Consultation on an opt-out system

In the Prime Minister's 2017 Conservative Party Conference speech she committed to change the organ donation system in England to shift "*the balance of presumption in favour of organ donation.*"<sup>26</sup> A Written Statement in December 2017 launched a consultation on introducing an opt-out consent system for organ donation.<sup>27</sup> The consultation was

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<sup>22</sup> Department of Health, [Annual report of the Chief Medical Officer 2006](#), 17 July 2007, p33

<sup>23</sup> Rt Hon Gordon Brown MP, [Organ donations help us make a difference](#), The Telegraph, 14 January 2008

<sup>24</sup> Department of Health, [The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce](#), 17 November 2008, p 5

<sup>25</sup> House of Lords European Union Committee, [Increasing the supply of donor organs within the European Union](#), 2 July 2008

<sup>26</sup> Conservatives, [Theresa May's Speech to Conservative Party Conference 2017](#)

<sup>27</sup> Written Statement: [Update on organ donation in England](#) - HCWS338 12 December 2017

open for 12 weeks, closing on 6 March 2018. The Government published its response to the consultation on 5 August 2018.<sup>28</sup>

The consultation document reported that despite widespread support for organ donation, there was a shortage of donors in England, and that consent rates were lower than the target set by the current organ donation strategy.

There is widespread public support for organ donation, with around 80% of people saying that they support organ donation 'in principle', and would be willing to donate their organs and tissue after they have died. Over the last 10 years, the number of organ donors has increased by 75% and deceased transplants have increased by 56%. There are close to 24 million people on the NHS Organ Donor Register (figures from [NHS Blood and Transplant](#)).

Despite this, there is a shortage of donors in this country, with around 6,500 people waiting for a transplant. Over half a million people die each year in the UK, but only around 5,000 people die in circumstances or from conditions that mean that their organs could be considered for transplantation.

Consent rates are also below the ambitious targets set out in the current UK strategy. Because of this shortage, 3 people die each day due to a lack of suitable organs. The situation is worse for people from black and Asian backgrounds who, due to genetic differences, are more likely to suffer from an illness that may lead to them needing a transplant. Due to the shortage of matched donors (donors with the same blood and tissue type, usually from the same ethnic group), [people from these communities will wait 6 months longer on average if they need an organ transplant](#).<sup>29</sup>

The consultation asked for views on a number of issues relating to organ donation consent including how to make it easier to register a decision on organ donation, action to ensure that families are involved in decisions, and safeguards under the proposed new system. In its consultation response, the Government set out that the key things it had heard were:

- Most people said there should be more ways to register their decision on whether they want to be an organ donor. But they also said that it's very important that this should be simple to do and that information about them should be kept safe.
- Strong support for a national media campaign to raise awareness of the changes and enable people to make an informed decision on organ donation.
- Some Jewish and Muslim respondents expressed concerns with the new arrangements. Overall, most respondents said that they did not think the change would have a negative impact.
- Mixed views on what should happen when someone has not opted out under the new system, though the largest

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<sup>28</sup> Department of Health and Social Care, [The New Approach to Organ and Tissue Donation in England: Government Response to public consultation](#), 5 August 2018

<sup>29</sup> Department of Health and Social Care, [Consultation on introducing 'opt-out' consent for organ and tissue donation in England](#), 12 December 2017

proportion of people said that donation should always go ahead.

- Most people said that a decision to donate/not donate should always be respected.
- There was broad support to exclude children under 18, people ordinarily resident in England for less than 12 months and people lacking the capacity to understand the changes.<sup>30</sup>

## Consultation responses and Government proposals

### Consent

The main change that was consulted on was a move to an 'opt-out system' – in other words that that consent would be deemed to have been given to organ donation unless the patient had opted out. The consultation document stated that:

The core change proposed by the government is on the default legal position. Subject to certain exclusions, described later in this consultation, a person will be considered to have consented to organ and tissue donation after death unless they opt out. This makes it even more important that people are aware of the changes and can simply and easily make their decision clear. [section 3.2]<sup>31</sup>

This proposal did not change following the consultation. In its response to the consultation the Government stated that "everyone in England will be considered an organ and tissue donor from spring 2020, unless they have recorded a wish not to be so or are excluded".<sup>32</sup> Those who do not wish to donate their organs and tissues will be able to record their wish on the organ donor register. The Government also set out changes to the register:

- From December 2018, there will be a more inclusive Register with the option to state that your faith is important to your organ donation decision and that your family and/or faith leader should be consulted if organ donation is a possibility on your death to ensure that any religious considerations are observed.
- There will also be greater accessibility to the Register through the new NHS app due to launch in England at the end of the year.
- As before, people will still be able to appoint somebody else to make the final decision for them after death. Children will still be able to sign up on the Register.<sup>33</sup>

The majority of respondents to the consultation (72%) said that a change in the law to an opt-out system would not affect their personal decision about organ donation.

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<sup>30</sup> Department of Health and Social Care, [Quick read: government response to consultation on organ and tissue donation](#), August 2018

<sup>31</sup> Department of Health and Social Care, [Consultation on introducing 'opt-out' consent for organ and tissue donation in England](#) 12 December 2017, section 3.2

<sup>32</sup> Department of Health and Social Care, [The New Approach to Organ and Tissue Donation in England: Government Response to public consultation](#), 5 August 2018

<sup>33</sup> Department of Health and Social Care, [The New Approach to Organ and Tissue Donation in England: Government Response to public consultation](#), 5 August 2018

### **Public awareness**

The Government emphasised in the consultation document that that any change in the consent system must be well publicised and an extensive communications campaign would be required. Respondents to the consultation were asked how people could be made aware of new rules on organ donation and a “recurring theme amongst responses was that the Government should launch a national media campaign to raise awareness and enable people to make an informed decision on organ donation”.<sup>34</sup>

The Government proposed in its response a transition period and a communication campaign, both lasting 12 months, before any new law comes into effect.<sup>35</sup>

### **Safeguards**

The consultation proposed that safeguards should be included for vulnerable groups and to ensure that any consent is reliable. Exceptions for whom the requirement for opt-in consent were proposed to be retained were children under 18; people who lack capacity; short-term visitors to England such as tourists; and people who are temporarily resident in England such as overseas workers; students and overseas armed forces personnel.<sup>36</sup>

In its response, the Government stated that it still intends to introduce these exceptions. Respondents to the consultation strongly supported exemptions for people who lack capacity (74%) and visitors to England (68%). However, opinion on exemptions for children under 18 and those resident in England for less than 12 months was more balanced with 54% in favour and 52% in favour, respectively.<sup>37</sup>

### **Family consent**

The consultation set out that currently, family members are always asked about organ donation consent despite there being no legal requirement to do so if a person has made their view known.

It asked respondents if, under the new system, families should have the final say on organ donation consent. 48% of respondents said that if a person has not opted out of organ donation, under an opt-out system, their family should not be able to make the final decision, while 25% said they should and 27% said they should sometimes.<sup>38</sup> 68% of respondents said a family should not be able to make a decision about donation if it is different to the decision made by the deceased person when they were alive.

The Government response stated that a discussion about donation will always take place under the new system between the family, clinicians

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<sup>34</sup> Ibid

<sup>35</sup> Ibid

<sup>36</sup> Department of Health and Social Care, [Consultation on introducing ‘opt-out’ consent for organ and tissue donation in England](#) 12 December 2017, section 4.8

<sup>37</sup> Department of Health and Social Care, [The New Approach to Organ and Tissue Donation in England: Government Response to public consultation](#), 5 August 2018

<sup>38</sup> Ibid

and specialist nurses, regardless of the deceased persons decision or lack thereof:

A personal discussion between the family, the specialist nurse and clinicians at the bedside before donation goes ahead, to reflect faith, cultural considerations and the views of the family. The family will always be given the opportunity to provide information to show that their loved one would not have wanted to donate their organs - if this is the case - or that their recorded decision, whether to donate or to not donate, is not the most recent.<sup>39</sup>

### **Faith training and guidance**

The Government also reported that a number of respondents highlighted concerns with regards to their religious beliefs and organ donation. It said that it would make it possible for people to set out in the register that their faith is important to them and that guidance and training for healthcare professionals would be provided in this area:

We will make it possible for people signing up to the Register to state that their faith is important to them and that their family and/or faith leader should be consulted in the discussions with nurses and doctors about the religious and cultural customs that need to be observed.

The faith training that is already available for specialist nurses on organ donation will be updated and extended to other healthcare staff working on organ donation.

We will be working on guidance for healthcare professionals setting out how the new arrangements will work in practice and detailing how religious and cultural considerations will form part of discussions with the family.<sup>40</sup>

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<sup>39</sup> Ibid

<sup>40</sup> Department of Health and Social Care, [Quick read: government response to consultation on organ and tissue donation](#), August 2018

## 6. The Organ Donation (Deemed Consent) Bill 2017-2019

The [Organ Donation \(Deemed Consent\) Bill 2017-2019](#) was introduced by Geoffrey Robinson MP, after being drawn 6th in the Private Member's Bill ballot 2017. It is not a Government Bill, but the Department of Health and Social Care has supported the drafting of it.

It received its Commons First Reading on 19 July 2017, and its Second Reading on 23 February 2018.

The Bill was considered by a Public Bill Committee on 12 September 2018.<sup>41</sup>

The Bill is tabled for Report Stage and Third Reading on 26 October 2018.

### 6.1 Content of the Bill

This section provides an overview on the content of the Bill as introduced. The [explanatory notes](#) to the Bill provide more detail on this. Changes made to the Bill in Public Bill Committee are highlighted in section 6.3 below.

The principle changes apply only to England.

#### Clause 1: Changing the consent system

Clause 1 seeks to amend Section 3 of the *Human Tissue Act 2004* to change the consent requirements for organ donation.

##### Consent

Section 3(6) of the *Human Tissue Act 2004* sets out what appropriate consent means for activities under the Act:

- a person has made a decision on consent;
- the deceased has appointed a representative to make this decision; or
- If neither of these apply, a person in a qualifying relationship to the deceased has consented.

Clause 1 intends to add a further paragraph to this subsection, to allow for deemed consent. This means that in cases where a person has not made an explicit decision on organ donation, and has not appointed a representative, consent will be deemed.

A further proposed change to Section 3 includes the insertion of a new subsection, 6A, which sets out all the transplantation activities will be subject to deemed consent.

##### Exceptions

New Subsection, 6B, states that consent of the person would be deemed "unless a person who stood in a qualifying relationship to the

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<sup>41</sup> Public Bill Committee, [Organ donation \(deemed consent\) Bill](#), 12 September 2018,

*person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned would not have consented.”*

A further proposed subsection in Clause 1 provides for exceptions to the application of deemed consent. Individuals who would not have their consent deemed are:

- Where the deceased has not ordinarily been resident in England for a period of at least 12 months before their death; and
- Where the deceased lacked capacity to understand the effect of deemed consent in the Bill.

## **Clause 2: Consequential amendments**

Clause 2 seeks to establish that organ removed in England under deemed consent may be stored and used anywhere in the UK. This is already allowed in Scotland and Wales, but the Bill will ensure this is also the case in Northern Ireland.

### **Guidance**

Clause 2 requires that the Human Tissue Authority give practical guidance on the circumstances under which consent will be deemed, alongside its existing responsibility with regards to guidance on consent.

It also requires that the Human Tissue Authority give practical guidance on the information to be provided by a person in a qualifying relationship in order to show that the deceased would not have consented.

## **Clause 3: Extent and Commencement**

Clause 3 sets out that the Bill extends to England, Wales and Northern Ireland only. However, the measures relating to deemed consent will only apply in England.

It proposes that the majority of the Bill would come into force on a day set out in Regulations by the Secretary of State.

## **6.2 Second Reading**

During the Second Reading debate Geoffrey Robinson MP stated that the Bill had widespread support across the House:

I have seldom seen such unanimous support across the House, with the 11 Members who have sponsored the Bill representing seven political parties in this House.<sup>42</sup>

He also said that the Bill had the personal support of the Prime Minister and the Leader of the Opposition.

He explained his rationale for introducing an opt-out system for organ donation:

Why are we actively looking towards implementing an opt-out solution at this stage? In England, for example, the situation is disappointing. We have some of the lowest rates of consent for organ donation in western Europe. Low family rates of consent

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<sup>42</sup> HC Deb 23 February 2018 c445

have been one of the major barriers to the donor rate increasing. In effect, that prevents one third of available organs from being used. They go straight to the grave or to the crematorium. None of us likes to think about the worst happening, and it is challenging to have conversations with family and loved ones about one's wishes after death. However, one of the Bill's principle aims must be to encourage open discussions among families, so that an individual's real wishes are known to their nearest and dearest. I think it reasonable to say that in the majority of cases, given the outcome of the consultation and what we know from the polls, people would wish to donate their organs after their death.<sup>43</sup>

He sought to allay concerns that some may have about the Bill, emphasising that 'soft' opt-out provisions will be included:

[T]here will be those who take a different view. Perhaps even one or two in the Chamber feel that way and will make their feelings known in the debate. In no way do I wish them to feel that they have been railroaded into decisions that they do not wish to take. Therefore, I emphasise to those who feel that they cannot lend their support or have doubts about the Bill at this stage that soft opt-out provisions will be built into it.<sup>44</sup>

While there was widespread support for the Bill across the House some Members raised some specific concerns about the Bill including the ability of certain religious groups, such as the Jewish community, to be able to act in accordance with religious teachings, and the ability of families to withdraw consent.<sup>45</sup>

Jackie Doyle-Price MP, Parliamentary Under-Secretary of State at the Department of Health and Social Care, responded to the debate for the Government and stated that the Government fully supports the Bill. She explained that the Government's "best estimate" was that the change to an opt-in system would lead to an additional 100 donors a year, which could lead to 200 more lives saved.<sup>46</sup>

### 6.3 Committee Stage

The Bill was considered by a Public Bill Committee in one sitting on 12 September 2018 when some Government amendments were made.

[The Bill as amended in Public Bill Committee](#) has been published on the Bill webpage.

Report stage is scheduled for 26 October 2018.

#### Membership of the Public Bill Committee

The Public Bill Committee consisted of the following Members:

Chair: Phil Wilson

Bim Afolami (Con)

Tonia Antoniazzi (Lab)

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<sup>43</sup> HC Deb 23 February 2018 c446

<sup>44</sup> Ibid

<sup>45</sup> HC Deb 23 February 2018 c446, c449

<sup>46</sup> HC Deb 23 February 2018 c485

Jackie Doyle-Price (Parliamentary Under-Secretary of State for Health and Social Care)

Julie Elliott (Lab)

Caroline Flint (Lab)

Kevin Foster (Con)

Dame Cheryl Gillan (Con)

Peter Heaton-Jones (Con)

Eddie Hughes (Con)

Dan Jarvis (Lab)

Mr Khalid Mahmood (Lab)

Stephen Metcalfe (Con)

Mr Geoffrey Robinson (Lab)

Jim Shannon (DUP)

Eleanor Smith (Lab)

Maggie Throup (Con)

## Committee debate

There were 7 amendments tabled jointly in the names of Geoffrey Robinson and Jackie Doyle-Price. All of the amendments were agreed to and added to the Bill.

**Amendments 1-3** replaced the term “relevant material” with “permitted material” in a number of places within the Bill. Geoffrey Robinson set out that the purpose of this change in the term used was to ensure that any consent for transplantation under the Bill would only apply to organs usually used in organ transplantation and would not apply to forms of novel transplantation, such as of faces and limbs.

He said that it was:

...imperative that the amendments are made to the Bill to ensure that consent is considered to be in place only for organs and tissues that are in line with the public’s perception of donation. I am sure we all understand the need for that.<sup>47</sup>

**Amendment 4** amends Clause 1 to provide a definition of “permitted material.” It sets out that “permitted material” means “relevant material” except where the Secretary of State has set out in regulations that certain types of “relevant material” are not included.

Relevant material is defined under section 53 of the *Human Tissue Act 2004* as “material, other than gametes, which consists of or includes human cells.”<sup>48</sup>

Amendment 4 creates regulation-making powers for the Secretary of State to set out what organs will not be “permitted materials” under

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<sup>47</sup> [PBC 12 September 2018 c4](#)

<sup>48</sup> The Human Tissue Act 2004 also sets out that relevant material does not include hair or nails from a living person, or embryos outside of the human body.

the Bill. **Amendment 6** provides that the regulations made would be subject to the affirmative procedure.

**Amendment 7** changes the long title of the Bill to show that it makes amendments to the *Human Tissue Act 2004*.

Jackie Doyle-Price described the amendments to the Bill. She said that they:

...constitute a tidying-up exercise that essentially make it clear that we are talking about organ transplantation. Their effect would be to remove novel transplants—such as hand and uterine transplants—from the scope of the Bill. The medical advances that allow such transplants are amazing, but in order that the law keeps pace with those developments, we need to make those exemptions and state that we really are only talking about organs. Amendment 7 amends the long title of the Bill to better describe what the Bill will do.<sup>49</sup>

There was support for the Bill throughout the debate in Committee and it was highlighted that the Bill had cross party support.<sup>50</sup> However, some Members stated that beyond the changes in the Bill, further action was needed to ensure that organ donation rates increased, for example, increased public information and time for the implementation of the measures in the Bill. Jackie Doyle-Price set out the future plans for the implementation of the Bill and further actions to be taken:

We expect a rise in the number of organ transplants as a consequence of this legislation, because more organs will be available. We could estimate that, and it could be anything from one to 700, but even one extra life is enough for me. However, I am confident that it will be much more than that. We will also have to put in place the register and the mechanics around it and publicise the changes. Following the Bill's passage to becoming an Act—touch wood—we are looking at an implementation period of a year before everything is completely nailed down, enshrined and operational.

There has been lots of talk about the role of families. Ultimately, families will clearly wish to have a role in the welfare of a person who lacks the capacity to make a decision after deciding to be a donor. We need a system that takes families with us on this. We are sensitive to people's faiths and beliefs, and that will all be considered as part of the wraparound care that we will put in place. We will obviously undertake further discussions with the Welsh Government to see how far we can learn from their experiences. By the time the Bill's passage is complete, we will essentially have the same legal structure across Wales, England and Scotland.<sup>51</sup>

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<sup>49</sup> [PBC 12 September 2018 c12](#)

<sup>50</sup> [PBC 12 September 2018 c5](#)

<sup>51</sup> [PBC 12 September 2018 c12](#)

## 7. The evidence on moving to a deemed consent system

There have been a number of reviews of the evidence on moving to an opt-out system of consent for organ donation. This section provides an overview of the findings of these reviews.

### 7.1 Department of Health Organ donation taskforce report 2008

In 2008, the Department of Health Organ Donation Taskforce was asked to look at the evidence on moving to an opt-out system in England. This work included:

- The commissioning of a systematic review of international literature on presumed consent systems;
- The setting up of 6 working groups: clinical, communications, cultural, ethics, legal and practical;
- The commissioning of an initial analysis of costs; and
- A range of work to assess the views of the public and stakeholders.

The Taskforce's report and recommendations were published in November 2008. On balance, it concluded that:

...moving to an opt out system at this time may deliver real benefits but carries a significant risk of making the current situation worse.<sup>52</sup>

#### Box 1: Systematic review of research

A systematic review looking at the impact of an opt-out system of consent on organ donation rates was undertaken as part of the taskforce's work by a team at the University of York.<sup>53</sup>

This concluded that whilst there was an association between higher donation rates and an opt-out system, it was not possible to say that an opt-out consent system alone would lead to an increase in rates. Several other factors are likely to play a part in affecting organ donation rates, such as organisation and infrastructure of the organ donation service, public awareness and investment in health care:

The available evidence suggests that presumed consent is associated with increased organ donation rates, even when other factors are accounted for. However, it cannot be inferred from this that the introduction of presumed consent legislation per se will lead to an increase in organ donation rates. The availability of potential donors, the underpinning infrastructure for transplantation, wealth and investment in health care, and underlying public attitudes may all have a role.

This review cannot be fully informative with respect to policy. It focuses on a particular aspect of the evidence and does not address all the relevant issues. To fully inform policy the findings of this systematic review need to be considered in the context of the current UK infrastructure for

<sup>52</sup> Department of Health Organ donation Taskforce, [The potential impact of an opt out system for organ donation in the UK: An independent report from the Organ Donation Taskforce](#), 2008

<sup>53</sup> Rithalia Amber, McDaid Catriona, Suekarran Sara, Myers Lindsey, Sowden Amanda. [Impact of presumed consent for organ donation on donation rates: a systematic review](#) BMJ 2009; 338 :a3162

organ donation, the possible impact on donation rates of introducing the recommendations from the UK Organ Donation Taskforce, the moral and ethical issues of presumed consent, and how the public may respond.

The evidence in this review was primarily in relation to country-level indicators such as gross domestic product and deaths from road traffic accidents. Further work is required to investigate factors at the personal level that may modify donor rates such as how families are approached to discuss donation of a relative's organs. A review of qualitative research addressing these issues would be useful, and further primary research may also be necessary.

Policy evaluation using a before and after design should collect information relating to context, to ensure that potentially important factors other than the intervention itself are given proper consideration.

The taskforce noted that on the face of it there were several factors to support a change to an opt-out system:

- There was significant public support for a move to an opt-out system, so long as there were safeguards in place;
- the systematic review of evidence in this area (See box 1) showed an association between an opt-out system and higher donation rates, but did state that the organ donation system alone does not explain variation in the rates;
- the working groups had not identified any fundamental legal/ethical barriers to establishing an opt-out system.

However, it also identified potential risks associated with a change to an opt-out system. For example:

- health professionals had expressed concerns about possible negative impacts on clinical practice and on the trust relationship between patients, their families and healthcare professionals;
- some members of the public supported the principle of informed consent and felt that an opt-out consent system did not fit with this; and
- Some recipients of organs felt that it was important to know that the organs they had been given were given freely.

The report provides an overview of the taskforce's considerations and conclusions:

Taskforce members had a wide range of views at the outset. however, after examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. most compelling of all, we found no

convincing evidence that it would deliver significant increases in the number of donated organs.<sup>54</sup>

## Welsh Government review

The Welsh Government published a review of the international evidence on consent system in December 2012. This included the four studies used in the systematic review undertaken in 2008, but also included consideration of two further 2012 studies.

The review found that opt-out systems for organ donation were associated with increased organ donation rates and an increased reported willingness to donate. However, it reported that it "*cannot be inferred that this association means that presumed consent causes increased organ donation.*"<sup>55</sup> Other factors could also impact on donation rates, such as increased mortality in circumstances where organs can be donated, health expenditure, and greater transplant capacity.

The review also highlighted recent surveys that showed significant support for the introduction of an opt-out consent system. In two surveys of Welsh adults, 49% and 63% of respondents were in favour of a change to an opt-out system.<sup>56</sup>

The third strand of the review looked at experimental studies looking at how a presumed consent system might impact on organ donation rates. These suggested that when the default position is to be an organ donor, there may be higher rates of family consent. The report urged caution when interpreting the findings of this research and how it could be extrapolated to real life.

The review concluded that:

In combination, these three strands of evidence provide a convincing basis for the introduction of an opt-out system in Wales. However, there can be no guarantees that this legislative change will result in increased organ donation rates.<sup>57</sup>

## Department of Health impact assessment

The Department of Health and Social Care published a detailed impact assessment alongside the consultation on introducing an opt-out system in England.<sup>58</sup>

This provides the following conclusions on a number of questions:

### **Would opt-out change the organ donation consent rate?**

The evidence is inconclusive. While it seems that moving to an opt-out system is unlikely to decrease the consent rate, there is no unambiguous evidence that opt-out by itself increases consent rates. There is evidence that in some cases, when opt-out is implemented alongside other pro-organ donation policies,

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<sup>54</sup> Department of Health Organ donation Taskforce, [The potential impact of an opt out system for organ donation in the UK: An independent report from the Organ Donation Taskforce](#), 2008

<sup>55</sup> Welsh Government, [Opt-out systems of organ donation: International evidence review](#), 3 December 2012

<sup>56</sup> Ibid.

<sup>57</sup> Ibid.

<sup>58</sup> Department of Health, [Consultation on an opt-out system of organ and tissue donation: Impact Assessment](#), 6 November 2017

consent rates increase. However, the available evidence does not allow the individual contribution of changing the system of organ and tissue donation to opt-out to be identified. There is currently insufficient evidence from the experience of opt-out in Wales to conclude whether it has had a positive impact on consent rates.

**Would a higher consent rate lead to more transplants?**

While there is currently no reason to believe that the organs of the newly consenting donors would be less likely than average to be medically fit for transplant, there remains an issue of the health system's capacity to transplant any additional organs. This issue will be examined in the public consultation.

**Would implementing an opt-out policy be a good use of health system resources?** The analysis in this IA suggests that if moving to an opt-out system shifted consent rates from the current level of 62.4% to 63.5%, and that if this in turn led to a proportionate increase in organ transplants, then the policy would be good value for money. However, any additional transplants will result in an increased cost to the health system and given uncertainties about the impact of opt-out on consent rates, we are not currently in a position to say whether the required increase in consent rate would occur in practice.

**How sensitive are the estimates to changes in assumptions?**

The estimates are very sensitive to any change in the assumption about the increase in consent rate following implementation of an opt-out system. Unfortunately, the consent rate is by far the most uncertain parameter in the analysis.<sup>59</sup>

The document also provides the Chief Scientific Adviser's conclusions on the existing reviews of evidence in this area:

Looking at these reviews, the Chief Scientific Adviser advised that it is possible to say, with moderate certainty, that when introduced as part of a wider communication and logistical package, opt-out systems can be associated with higher donation rates. He has drawn three conclusions from the data:

- Opt-out systems do not reduce organ donation (high certainty), which is relevant as some have expressed concerns that such systems could anger people and cause them to withdraw consent which may have been given otherwise.
- There is reasonable evidence from before-and-after studies that, when introduced as part of a wider package, opt-out systems are associated in some cases with higher organ donation. What fraction of this increase is attributable to the opt-out is difficult to say as they are not introduced in isolation.
- There is an association between opt-out and higher rates in geographical studies, but they should be interpreted with caution as this may be reverse causation - societies where donation is more acceptable may be more likely to accept opt-out.<sup>60</sup>

The Impact Assessment models three scenarios for the potential impact of a move to an opt-out consent system on donor numbers and transplants: a best estimate which results in an increase in consent rate

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<sup>59</sup> Ibid.

<sup>60</sup> Ibid.

to 70%, a lower estimate where consent rates do not change, and an upper estimate where the consent rate achieved is 85%, similar to that currently in Spain.

A table sets out the estimated impact of these three scenarios on transplant numbers<sup>61</sup>:

Scenario	No. of additional transplants per year				
	Kidney	Liver	Heart	Lung	Total
Lower estimate	0	0	0	0	0
Best estimate	228	93	20	18	360
Upper estimate	680	277	59	54	1,070

## 7.2 International examples

England's deceased organ donation rates fall short of some countries, like Spain and Croatia, which have opt-out donation policies. However, England's rates are higher than other opt-out countries such as Sweden and Poland. Rates in England are also lower than in the USA, which has an opt-in policy.<sup>62</sup>

ORGAN DONATION RATES: INTERNATIONAL COMPARISONS			
Selected countries, 2017			
Country		Policy	Deceased donors per million
Spain		Opt-out	46.9
Portugal		Opt-out	34.0
Croatia		Opt-out	33.0
USA		Opt-in	32.0
Italy		Opt-out	28.2
France		Opt-out	26.8
<b>England</b>		Opt-in	<b>24.4</b>
Norway		Opt-out	22.1
Ireland		Opt-in	21.8
Australia		Opt-in	20.7
Sweden		Opt-out	19.0
Denmark		Opt-in	17.5
Poland		Opt-out	14.6
Germany		Opt-in	14.6

<sup>61</sup> Ibid. The Impact Assessment provides more information on the methodology used for this modelling and assumptions made for the analysis.

<sup>62</sup> [IRODAT database](#)

## 8. Views on a change to a deemed consent system for organ donation

Supporters for a move to a deemed consent system state that they believe it will lead to an increase in donors and will save lives.

However, there has been some opposition to the proposal to change the system. Some of those against a change suggest that the evidence does not support a move to an opt out system, and concerns have been raised that it may have negative impacts. This section includes some of examples of these.

### 8.1 Political parties

#### Conservatives

In her Conservative Party conference speech in 2017, the Prime Minister said that there were limits to how many people could be helped by transplant through the number of people who came forward. She highlighted the number of people waiting, and those that had died whilst on the transplant list. She said that

... to address this challenge that affects all communities in our country, we will change that system. Shifting the balance of presumption in favour of organ donation. Working on behalf of the most vulnerable.<sup>63</sup>

The Mirror's ongoing campaign on introducing an opt-out system, Change the law for life, has highlighted the story of a 9 year old boy called Max Johnson who has recently had a heart transplant. The newspaper has reported that the Prime Minister wrote a letter to Max saying that the new law would be named after him:

Mrs May told him: "When I read your inspirational story, I knew I had to act to change the organ-donation rules to an opt-out system. I also read that you thought it would be fun to name the change in the rules after you.

"I think that is a brilliant idea, so, while it will have to have a bit of a boring title when it goes through Parliament, I and my Government will call it Max's Law."<sup>64</sup>

The Government made clear that it supports the *Organ Donation (Deemed Consent) Bill 2017* during the second reading debate on the Bill.

#### Labour Party

In his Party Conference speech in 2017, the Labour leader, Jeremy Corbyn committed to introducing an opt-out organ donation consent system in England.

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<sup>63</sup> Prime Minister's speech, [Renewing the British Dream](#), 2 October 2017

<sup>64</sup> Jeremy Armstrong, [Donor law will be called 'Max's Law' in honour of little boy whose bravery helped change Britain](#), Mirror, 11 October 2017

In February 2018, it was by the Birmingham Mail that Jeremy Corbyn had written to Labour MPs calling on them to support the *Organ Donation (Deemed Consent) Bill 2017* at its Second Reading on 23 February. It is reported that the letter also clarified that the Bill will be subject to a free vote for Labour Members.<sup>65</sup>

## Scottish National Party

The Scottish National Party support an opt-out consent system for organ donation and provides information [on its website](#) about the introduction of an opt-out organ donation system in Scotland.<sup>66</sup>

## Liberal Democrats

In September 2017, the Liberal Democrat party leader, Vince Cable, confirmed that it was Liberal Democrat policy to change the law to an opt-out organ donation system.<sup>67</sup>

## Other parties

It has not been possible to find a statement as to whether the Democratic Unionist Party support a change in the law on organ donation consent system. However, the party's health spokesperson, Jim Shannon, has said that he personally supports the introduction of an opt-out system.<sup>68</sup>

Plaid Cymru supported the introduction of a change in the law on organ donation consent in Wales through the *Human Transplantation (Wales) Act 2013*.<sup>69</sup>

It is Green Party policy to support a move to a presumed consent system for organ donation.<sup>70</sup>

## 8.2 Stakeholders

This section provides some key stakeholder responses to the introduction of an opt-out organ donation system.

A number of stakeholders, including health charities, patient groups and transplant bodies have expressed support for a change in the law to introduce an opt-out consent system. However, some concerns have been expressed by other groups, such as the Nuffield Council on Bioethics, and some transplant clinicians.

NHSBT is a special health authority responsible for coordinating organ donation and transplants across the UK. It welcomed the Government consultation on moving to an opt-out consent system, and said it supports any initiative which leads to more organ donors and more lives

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<sup>65</sup> Jonathan Walker, [Jeremy Corbyn urges Labour MPs to back 'opt-out' organ donation law to save lives](#), Birmingham Mail, 13 February 2018

<sup>66</sup> SNP, [Does the SNP support a soft opt out system for organ donation?](#)

<sup>67</sup> [Sir Vince Cable: Nearly 500 people died last year waiting for donors ... that's why I am backing Mirror's campaign](#), The Mirror, September 2017

<sup>68</sup> [HC Deb 13 July 2017 c204WH](#)

<sup>69</sup> Welsh Assembly Research Service, [Bill summary: Human Transplantation \(Wales\) Bill](#), January 2013

<sup>70</sup> Green Party, [Health Policy](#) (updated August 2017)

being saved. In a February 2018 document, NHSBT set out its position on an opt-out consent system:

**What is NHS Blood and Transplant's position on the consultation? Are you in favour of opt out?**

We welcome the Government's commitment to the lifesaving power of organ donation, which is demonstrated by their desire to hold a consultation into an opt out system. We support any initiative which leads to more organ donors and more lives being saved. We hope it will ensure that everyone makes a decision about organ donation, and that their decision is respected.

We hope people will take time to think about organ donation, make a decision about what they want, and if they want to donate, to sign up to the NHS Organ Donor Register and discuss their decision with their family so that their intention to give the gift of life after death is fully understood. We also hope people will join the national conversation about organ donation the consultation brings.<sup>71</sup>

The British Medical Association (BMA) has actively campaigned across the UK on introducing an opt-out system for organ donation consent for many years. It believes a move to an opt-out system "is the best option for the UK to reduce the shortage of organs and save lives." It also highlights that surveys have shown that two thirds of people in the UK support a change to a soft opt-out system.<sup>72</sup>

A [February 2018 news story](#) provides more information:

BMA medical ethics committee chair John Chisholm said:  
'Although organ transplantation has seen amazing medical achievements it has not yet reached its full life-saving and life-transforming potential.

'These figures show that in the current system, a large number of people who wish to donate their organs are not signing up to the register. Vital opportunities to save people's lives are being missed.

'Around 10,000 people in the UK are in need of an organ transplant, with 1,000 people dying each year while still on the waiting list. As a doctor it is difficult to see your patients dying and suffering when their lives could be saved or dramatically improved by a transplant.

'Since soft opt-out was adopted in Wales, 160 organs have been transplanted, almost a quarter of which were down to the new system.

'The BMA is calling for all UK Governments to follow suit and adopt a soft opt-out system. If we have an opportunity to address the chronic shortage of organs and save the lives of patients across the UK, surely we should be taking it.'<sup>73</sup>

The independent ethics body, the Nuffield Council on Bioethics, have expressed concerns about the evidence on an opt-out organ donation consent system; it has said that the Government shouldn't be making a

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<sup>71</sup> NHSBT, [NHSBT press essentials on the English Opt Out Consultation](#), February 2018

<sup>72</sup> British Medical Association press release, [Support for opt-out donor rules](#), 28 February 2017

<sup>73</sup> British Medical Association press release, [Support for opt-out donor rules](#), 28 February 2017

change until there is evidence that it works.<sup>74</sup> In response to the Government's consultation response and decision to introduce an opt-out system, Katharine Wright, Assistant Director of the Nuffield Council on Bioethics said that the Council was concerned that "promises being made by the Government about what it can achieve may be misleading." It called for a Government commitment to improving public information and education:

The Nuffield Council on Bioethics strongly supports organ donation where this meets with the wishes of the donor. At the moment, there is no evidence to indicate that introducing opt-out will, on its own, increase organ donation rates. No one really knows what the effect of it will be, and we are concerned that the promises being made by the Government about what it can achieve may be misleading. But evidence does show that more public awareness, more investment in staff training, more specialist nurses and ensuring that all families are central to the donation process would do more to help those in need of an organ.

For an opt-out system to operate ethically, people need to be fully informed so they can make an active choice about whether or not to donate. So it is vital that the Government commits to improving public information and education – not just at the point when the system changes but on an ongoing basis. Families must remain at the heart of the process, and be properly supported. Critically, any changes to the system must operate in a way that will not risk undermining what we already have: public trust in our donation and transplant system.<sup>75</sup>

The National BAME Transplant Alliance (NBTA) is a coalition of organisations seeking to promote organ donation and stem cell donation in BAME people. They have expressed support for a move to an opt-out organ donation system:

Orin Lewis, Chief Executive of Afro-Caribbean Leukaemia Trust & Co-Chair of National BAME Transplant Alliance said:

"As a parent of a young man who sadly passed away from Multiple Organ Failure, I gladly welcome the Prime Minister's decision to instigate a much needed public Consultation on the relative positive and negative merits of England having an Opt Out Donation policy. Looking forward I am expecting a wide spectrum of heated but ultimately constructive views and opinions from key stakeholders across the public domain, with the end goal of ultimately saving many more lives across the wide diversity of patients in England needing an organ transplant."<sup>76</sup>

Transplant clinicians have spoken in favour of a change in the law to introduce an opt-out system.<sup>77 78</sup> However, there has also been some

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<sup>74</sup> Nuffield Council on Bioethics press release, [UPDATED: Ethics think tank expresses concern over premature move to an opt-out organ donation system in England](#), 12 December 2017

<sup>75</sup> Nuffield Council on Bioethics, [Response to Government's plans for an 'opt-out' system for organ donation](#), August 2018

<sup>76</sup> NBTA, [NBTA welcomes 'opt-out' consultation](#), December 2017

<sup>77</sup> [Doctors praise plan for organ donor presumed consent in England](#), The Guardian, October 2017

<sup>78</sup> [Top doctors urge MPs to "save hundreds of lives each year" with change to organ donor laws](#), The Mirror, 16 February 2018

opposition. A notable example is Professor Chris Rudge, the former National Clinical Director for Transplantation. In an editorial in the British Journal of General Practice, he said that there was a lack of evidence that a change in the law leads to a sustained increase in organ donation:

The need for more organs for transplantation is pressing, but there seems to be little merit in pursuing a change in the law that appears to revert to the utilitarian approach that is now discredited and is unproven, controversial, expensive, ethically questionable, and possibly risky.<sup>79</sup>

Many health charities have expressed support for a change to an opt-out system for organ donation consent. This has included, the British Liver Trust,<sup>80</sup> Kidney Care UK,<sup>81</sup> and Fight for Sight<sup>82</sup>. Prior to the Second Reading debate of the *Organ Donation (Deemed Consent) Bill*, the Chief Executive of the British Heart Foundation, Simon Gillespie, said that the change cannot come soon enough for patients:

“Across the UK there is a desperate shortage of organ donors, meaning people needlessly die as they wait for organs to become available.

“Introducing a soft-opt out system in England will mean that more people will get the life saving transplant they desperately need.

“The Government’s commitment to a soft-opt out system is a commitment to ending the agonising pain felt by families who risk losing a loved one while they wait for a donor.

“This change can’t come soon enough for patients.”<sup>83</sup>

NHSBT report that the major religions in the UK support the idea of organ donation and transplantation.<sup>84</sup> They also provide more detailed information on the views on organ donation from a number of faiths.

The Government’s consultation on introducing and opt out consent system for organ donation highlights the ongoing work engaging faith communities on the issue of organ donation. However, it also noted that concerns have been expressed about presumed consent systems from people of certain faiths in the past:

The Organ Donation Taskforce considered the attitudes of different faith and belief groups towards an opt-out system of consent. This work highlighted significant reservations from people of certain faiths about the impact of moving to an opt-out system of consent, particularly for people less comfortable with the prospect of the change. These concerns included:

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<sup>79</sup> Chris J Rudge, Editorial: Organ donation: opting in or opting out? Br J Gen Pract 2018; 68 (667): 62-63.

<sup>80</sup> British Liver Trust press release, [New ‘opt-out’ system for organ donation in England announced by ministers](#), August 2018

<sup>81</sup> Kidney Care UK, [Third reading of Organ Donation Bill on 26 October](#), October 2018

<sup>82</sup> Fight for Sight press release, [Fight for Sight response to the organ donation opt-out system proposal](#), 12 December 2017

<sup>83</sup> British Heart Foundation press release, [Government announces consultation on organ donation opt-out system](#), 4 October 2017

<sup>84</sup> NHSBT, [What does my religion say?](#)

- the definition of death as brain stem death being incompatible with the beliefs of some faith groups
- the need to allow for personal choice and the importance of donation under conditions of informed consent
- difficulty in establishing whether a person who has not opted out has made an informed decision to donate
- unease and negative perceptions about a shift in the balance of power between individuals and the state
- With these concerns in mind, changing the default of consent could therefore increase the risk of more people deciding to opt out, where they would otherwise be happy to support donation under the current opt-in system.<sup>85</sup>

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<sup>85</sup> Department of Health, [Consultation on an opt-out system of organ and tissue donation: Impact Assessment](#), 6 November 2017

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