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 or 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 current family consent rate is only 46.7%. Where the patient’s wish to donate was known at the time of potential donation, 91% 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 Geoffrey Robinson MP after coming 6th in the Private Member’s Bill ballot in this parliamentary session and is tabled for Second Reading on 23 February 2018. The Bill intends to amend the Human Tissue Act 2004 to mean 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 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 committed to introducing 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.\(^1\)

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.\(^2\)

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.\(^3\) 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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\(^1\) NHS Blood & Transplant press release Organ and tissue donation A vital lesson that can help to save lives 6 February 2018

\(^2\) Government consultation Introducing ‘opt-out’ consent for organ and tissue donation in England 12 December 2017

\(^3\) 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 £11 million of funding to implement these.4

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.5

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.6

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:

4 Department of Health press release Fifty Per Cent increase in organ donation possible within five years , 16 January 2008
5 NHSBT, Taking Organ donation to 2020: A detailed strategy, 2013
6 NHSBT, Taking Organ donation to 2020: A detailed strategy, 2013
• 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.

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.7

7 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:

<table>
<thead>
<tr>
<th>Option</th>
<th>Details</th>
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| 1: A 'hard' opt out system | 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 |
| 2: A 'hard' opt out system which does not cover some groups | Doctors can remove organs from every adult who dies - unless a person has registered to opt out OR 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. |
| 3: A 'soft' opt out system | Option 3a: No need to consult relatives  
Doctors can remove organs from every adult who dies - unless a person has registered to opt out OR 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  
Option 3b: Relatives should be consulted  
Doctors can remove organs from every adult who dies - unless a person has registered to opt out. It is good practice for doctors to ask the relatives for their agreement at the time of death.  
Example: Spain |
| 4: A 'soft' opt in system (current system in the UK) | 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. |
| 5: A 'hard' opt in system | 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. |
| 6: A choice to opt in or opt out | Option 6a: People can register their choice to opt in or opt out.  
Option 6b: People must 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
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.9

**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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9  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, the Scottish Government have committed to bring forward legislation to introduce an opt-out system of consent in the current Parliamentary session.

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. 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.

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10 Scottish Government, *Organ and Tissue Donation and Transplantation: Analysis of Responses* 28 June 2017
11 Scottish Government, *Organ and Tissue Donation and Transplantation: Analysis of Responses* 28 June 2017
12 Northern Ireland Assembly, *Human Transplantation Bill 2011-16 Mandate*
13 Northern Ireland Department of Health press release, *Developing a holistic approach to organ donation – consultation launched*, 11 December 2017
3. Organ donor rates

As shown in the chart and table below, in 2016-17 there were 1,157 deceased organ donors in England – 21.1 per million population. This rate has increased from 15.3 per million population in 2008-09.14

![Organ Donation Trends in England](image)

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.15

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.16

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.17

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14 NHS Blood and Transplant, Transplant Activity Report 2016/17 and previous years
15 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
16 NHS Blood & Transplant, NHSBT press essentials on the English Opt Out Consultation, December 2017
These rates vary substantially between different types of cases. Where the patient’s wish to donate was known at the time of potential donation, 91% of families consented to donation (although 100 families overruled their loved ones’ known decision to be an organ donor in 2016/17). However, where the patient had not expressed a wish to donate, or their register status was not known, the family consent rate was much lower at 46.7%.

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 is involved, consent rates are 68.6%; in the minority of cases where a specialist nurse is not involved, the consent rate is 27.5%.18

The table below shows the primary reasons families gave for refusing consent for donation in 2016/17.

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4. Proposals to change the organ donation consent system in the England

4.1 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, and the then Labour Government asked the Organ Donation Taskforce to consult and report on this specific issue.

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).

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 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.

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.

4.2 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 to shift “the balance of presumption in favour of organ donation.” A Written Statement in December 2017 launched a consultation on introducing an opt-out consent system for organ donation. The consultation is open for 12 weeks, it will close on 6 March 2018.

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19 Department of Health, *Annual report of the Chief Medical Officer 2006*, 17 July 2007, p33
20 Rt Hon Gordon Brown MP, *Organ donations help us make a difference*, The Telegraph, 14 January 2008
23 Conservatives, *Theresa May’s Speech to Conservative Party Conference 2017*
24 Written Statement: *Update on organ donation in England* - HCWS338 12 December 2017
The consultation document reports that despite widespread support for organ donation, there is a shortage of donors in England, and that consent rates are 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.25

The consultation asks for views on a number of issues relating to organ donation consent:

- Proposals to make it easier for people to register their decision on organ and tissue donation. This is to ensure decisions people make about organ donation are honoured after their death.
- Proposals to change the law so that people would be considered willing to be an organ donor unless they decide to opt out. We invite views on the potential impact on certain groups, for example, people who have protected characteristics in law such as disability, race, religion or belief.
- How family members should be involved in confirming decisions in future.
- Proposals for changes, exemptions and safeguards for certain groups of people under the new system.

The consultation is considering consent for organ and tissue donation after death only. The government is not proposing any changes to the current rules and processes regarding living donors.26

Consent

25 Department of Health and Social care, Consultation on introducing ‘opt-out’ consent for organ and tissue donation in England, 12 December 2017

26 Department of Health and Social care, Consultation on introducing ‘opt-out’ consent for organ and tissue donation in England, 12 December 2017
The main change that is being consulted on is a move to an ‘opt-out system’ – in other words that consent would be deemed to have been given to organ donation unless the patient has opted out. The consultation document states 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.

This would apply only where a decision had not been recorded. The consultation document describes the current process for recording a decision, and states that this will not change:

Currently in England, there is an ‘opt-in’ basis for consent for organ donation. This means that donation will only ever proceed if a person had given their express consent for organ donation – either by registering on the NHS Organ Donor Register or making their decision known to their family.

If the person’s decision is not known, their family is approached for consent to proceed with a donation. People who are happy to be organ donors, but who do not make their decision known, risk this decision not being honoured after their death.

At present, people can decide through the NHS Organ Donor Register to opt in, to opt out, or to appoint a representative to make a decision after death. People who are happy to be organ donors, but who do not make their decision known, risk this decision not being honoured after their death.

The consultation stresses that it must be made easier to record a decision and keep it up to date:

A new opt-out system of consent would have to make it much easier to record a decision, to change it if necessary and to keep it up to date. The government has plans for every patient in England to be able to access their own medical records and complete a number of different services online, which includes decisions on organ donation.

Public awareness

The government also emphasises that that any change in the consent system must be well publicised, an extensive communications campaign would be required:

To implement the new system of consent successfully and support increased rates of organ donation, the government considers that an extensive communications campaign would be required both before and after legislation comes into effect.

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27 Consultation on introducing ‘opt-out’ consent for organ and tissue donation in England 12 December 2017, section 3.2
28 Ibid, section 3.1
29 Ibid, section 3.2
30 Ibid, section 3.4
Safeguards

The consultation proposes 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 are proposed to be retained are 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.  

Family consent

The consultation sets 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 asks respondents if, under the new system, families should have the final say on organ donation consent.
5. A change in the law in Wales

5.1 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.  

Organ Donation Wales has more information on the introduction of the opt-out system.

5.2 Evaluation of the new system


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.

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 are included below:

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32 National Assembly for Wales, New organ donation system comes into force in Wales, 1 December 2015
• 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). ³³

³³ Welsh Government, *Support for the opt-out system of organ donation in Wales is high, says new report*, December 2017
6. The Organ Donation (Deemed Consent) Bill 2017

The Organ Donation (Deemed Consent) Bill 2017 has been 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 is tabled for its Second Reading on 23 February 2018.

6.1 Content of the Bill

This section provides an overview on the content of the Bill. The explanatory notes to the Bill provide more detail on this.

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 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 intends to require 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.
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 will provide 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.34

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.35

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

34 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
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.36

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.”37 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.38

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.39

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.40

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,

36 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
38 Ibid.
39 Ibid.
40 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.41

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.42

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

41 Ibid.
42 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:

<table>
<thead>
<tr>
<th>Scenario</th>
<th>No. of additional transplants per year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kidney</td>
</tr>
<tr>
<td>Lower estimate</td>
<td>0</td>
</tr>
<tr>
<td>Best estimate</td>
<td>228</td>
</tr>
<tr>
<td>Upper estimate</td>
<td>680</td>
</tr>
</tbody>
</table>

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 Ireland. Rates in England are also lower than in the USA, which has an opt-in policy.

There are several other factors that will impact on a country’s organ donation rates, these may include transplant services, public opinion on organ donation, and the number of people who die in circumstances where organ donation may be possible.

Spain

Spain consistently has the highest rates of organ donation and consent rates internationally. In 2016, its organ donation rate was 43.4 per million population, compared with 21.1 in the UK.

Spain introduced an opt-out organ donation system in 1979. However, it is reported that the significant increase in organ donation rates followed organisational and infrastructure changes introduced in 1989 – often described as the ‘Spanish system.’ These changes included

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43 Ibid. The Impact Assessment provides more information on the methodology used for this modelling and assumptions made for the analysis.
44 IRODAT database
increased number and role of transplant coordinators, improved training and increased public awareness of organ donation.45

Spain does not have an opt-out register for those who do not wish to donate their organs and families are always asked for consent.46

In response to a Parliamentary Question about an opt-out organ donation system, the Parliamentary Under-Secretary of State for Health, Jackie Doyle-Price noted the system in Spain and highlighted the importance of the wraparound care that goes alongside a new consent system:

[…]the system that we are looking to introduce has much in common with that in Spain. The issue is not so much about the register moving towards an opt-out system, but the wraparound care that goes with it, such as the specialist nurses who speak with relatives when they are going through the trauma of losing a loved one, and the public debate that raises awareness. Taken together, they are what will lead to more organs becoming available.47

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45 BMA, Building on Progress: Where next for organ donation policy in the UK? 2012
46 Fabre John, Murphy Paul, Matesanz Rafael. Presumed consent: a distraction in the quest for increasing rates of organ donation; BMJ 2010; 341:c4973
47 HC Deb 19 December 2017 | Vol 633 c892
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.

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. 48

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.” 49

There has been no statement as to whether the Government will support the Organ Donation (Deemed Consent) Bill 2017 but the Department of Health and Social Care have prepared the Bill and Explanatory Notes with Mr Robinson.

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.

48 Prime Minister’s speech, Renewing the British Dream, 2 October 2017
49 Jeremy Armstrong, Donor law will be called ‘Max’s Law’ in honour of little boy whose bravery helped change Britain, Mirror, 11 October 2017
It has been reported in the last week by the Birmingham Mail that Jeremy Corbyn wrote 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 clarifies that the Bill will be subject to a free vote for Labour Members.  

Scottish National Party

The Scottish National Party provide information on its website about the introduction of an opt-out organ donation system in Scotland.

Liberal Democrats

In September 2017, the Liberal Democrat party leader, Vince Cable, confirmed that it is Liberal Democrat policy to change the law to an opt-out organ donation system.

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.

Plaid Cymru supported the introduction of a change in the law on organ donation consent in Wales through the Human Transplantation (Wales) Act 2013.

8.2 Stakeholders

This section is not comprehensive but provides some key stakeholder responses to the introduction of an opt-out organ donation system.

A number of stakeholder, 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 has 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 being saved. In a February 2018 document, NHSBT sets 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?

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50 Jonathan Walker, *Jeremy Corbyn urges Labour MPs to back ‘opt-out’ organ donation law to save lives*, Birmingham Mail, 13 February 2018
51 SNP, *Does the SNP support a soft opt out system for organ donation?*
52 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
53 HC Deb 13 July 2017 c204WH
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.55

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.56

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.47

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 change until there is evidence that it works:

Hugh Whittall, Director of the Council, said: “We are concerned that the Government consultation goes straight into

55 NHSBT, NHSBT press essentials on the English Opt Out Consultation, February 2018
56 British Medical Association press release, Support for opt-out donor rules, 28 February 2017
57 British Medical Association press release, Support for opt-out donor rules, 28 February 2017
asking how an opt-out system should be introduced, rather than if it should.

“We all want to maximise organ donation in a way that is in keeping with people’s wishes. The issue is what is the best way to do this, and we need first to understand the evidence and the implications of the options.

“The Government should not be making this change until there is evidence that it works, and until we are confident that it won’t undermine people’s trust in the system in the long-term. That evidence is simply not there yet, though we do know some things that do work. Key amongst those is raising public awareness, encouraging family discussion, and better support and communication between specialist nurses and bereaved families.

“Even in systems where an ‘opt-out’ approach has been adopted (such as Spain), it is generally recognised that these are the elements that have made a difference, rather than the legal basis of the donation.

“We welcome the Government’s call for discussion with family members about donors’ wishes. However, we should be basing our legislative decisions on evidence. A decision to change the law without first evaluating evidence could have serious consequences for organ donation.”

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.”

Transplant clinicians have spoken in favour of a change in the law to introduce an opt-out system. However, there has also been some opposition. A notable example is Professor Chris Rudge, the former National Clinical Director for Transplantation. In a recent 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:

58 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
59 NBTA, NBTA welcomes ‘opt-out’ consultation, December 2017
60 Doctors praise plan for organ donor presumed consent in England, The Guardian, October 2017
61 Top doctors urge MPs to “save hundreds of lives each year” with change to organ donor laws, The Mirror, 16 February 2018
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.62

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,63 Kidney Care UK64 and Fight for Sight65. The Chief Executive of the British Heart Foundation, Simon Gillespie, has 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.” 66

The British Heart Foundation has conducted a recent survey of people’s views on this issue. It reported in February 2018 that, of a poll of 2000 people, nearly 75% of people were in favour of an opt-out consent system.67

NHSBT report that the major religions in the UK support the idea of organ donation and transplantation.68 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 notes 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:

63  British Liver Trust press release, Theresa May vows to change law on organ donations, 4 October 2017
64  Kidney Care UK, Organ donation opt-out plans launched, December 2017
65  Fight for Sight press release, Fight for Sight response to the organ donation opt-out system proposal, 12 December 2017
66  British Heart Foundation press release, Government announces consultation on organ donation opt-out system, 4 October 2017
67  BHF, Over three quarters of people in England say they would support changing the law for organ donation, 21 February 2018
68  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.69

69 Department of Health, *Consultation on an opt-out system of organ and tissue donation: Impact Assessment*, 6 November 2017
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