



Department  
of Health &  
Social Care

# The New Approach to Organ and Tissue Donation in England

Government Response to public consultation

5 August 2018

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# Ministerial Foreword

Organ donation is a precious gift that improves and saves the lives of thousands of people each year. Over 40,000 people are alive in England today thanks to the selflessness of individuals and their families who are willing to donate their organs. Whilst this is a great achievement, there is still a desperate shortage of organs, with around 5,100 people in England waiting for a transplant at the end of March 2018.

Last October, the Prime Minister made a bold commitment to change the current system to shift the balance of presumption in favour of organ donation, to help more people in England to receive a much needed organ transplant.

When our consultation launched in December, I said that we wanted to spark public debate, to get people thinking about organ donation and to encourage families to start having these vital conversations. We received an unprecedented 17,000 responses, making it the biggest consultation my Department has ever run, which is a testament to how significant this issue is to so many people. I am delighted to say that all of these views have been carefully listened to as we have worked to develop our proposals for a new system for organ and tissue donation in England.

We know that the vast majority of people say that they would be willing to donate their organs after they die, but a far smaller proportion of people have actually recorded a wish to be an organ donor. As a result, where someone has not expressed a wish to donate, only 50% of families give their consent for donation to proceed. We want to change this and encourage as many people as possible to make a decision and make it known - whether it is to donate their organs or not.

That is why, ahead of our communication campaign in 2019, we will deliver a new route to the Organ Donor Register ('the Register') in the new NHS app. This will give people in England greater choice on how they record their preferences.

Meanwhile, the Government intends to change the law on consent for organ donation so that in future if someone dies and they have not recorded an express decision, the default position will be that consent to donate will be 'deemed'. This means that consent will be considered to be in place. This type of system is known as 'deemed consent' and has also been referred to as 'opt-out'.

The new system will better reflect what we know already, that the vast majority of the public in England support making their organs available to help others in need.

No matter what, there will always be a personal discussion with the family at the bedside, and special consideration will be given to a person's faith and the views of their loved ones. We appreciate the significant pressures that families are under at the time when these decisions are being made, and we will support healthcare professionals to ensure that families are always sensitively and compassionately involved in discussions.

Although the new default position will be that donation goes ahead unless someone has recorded a wish to not donate, clinicians will never proceed if the family objects strongly. That is why we want everyone to make their wishes known to their family to ensure that preferences in life are honoured after death.

As you read this, there are thousands of people up and down the country waiting for that one life-changing phone call to tell them that an organ has been found. It is my priority that we give all of these people a better chance of receiving a transplant, and if we are going to do this then we cannot afford to be complacent. The first step is to increase the number of people who

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register a wish to donate their organs and for the Register to reflect what we know from surveys - that 80% of people in England are willing to, or would consider donating some or all of their organs.

**Jackie Doyle-Price MP**

# Executive summary

## The vision

Organ and tissue donation is the gift of life to others - 25 million people in the UK have already recorded their wish to donate their organs after they die to help others in need and 82% of the public agree with the idea of organ donation. Organ donation is an altruistic act that should be celebrated – it can transform the life of another human being who is very likely to be seriously ill while waiting for an organ. Sadly, some people do not get the transplants they need and we must do more to ensure we prevent this where possible.

The last three years have seen record numbers of organ donors resulting in record numbers of transplants. This is tremendous progress. In 2017/18, there were over 3,000<sup>1</sup> transplants in England, and as a result, people receiving these organs will now be facing a better future. We want to see this number continue to rise, so that more people can be helped.

Organ donation has an important value not just for the recipient of the healthy organ but also for the family of the donor at a very difficult time. Many families take comfort in knowing that the donation of their loved one's organs has helped to save others.

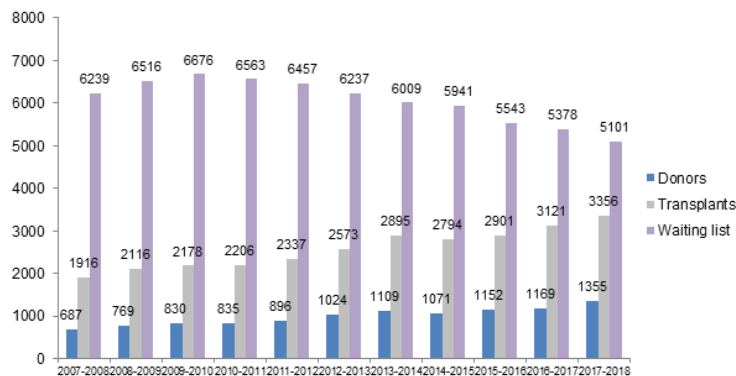
However, although 80% of people in England are willing to, or would consider donating some or all of their organs, only 37% have recorded their decision on the Organ Donor Register ('the Register'). This gap is crucial because when a patient's wish to donate is not known at the time of potential donation, the decision falls to the family in distressing circumstances, and in many cases they do not give consent.

The Government's vision is therefore to encourage as many people as possible to think about organ donation and to tell us their preferences, whether yes or no, and to shift the balance of presumption in favour of organ donation in cases where the deceased has not registered a preference. This will save lives that are currently lost due to lack of available organs. It will also allow family members to feel confident that they are acting in accordance with their loved one's wishes.

## The challenge

Over 40,000 people are known to be alive in England today thanks to organ donation and transplantation. Unfortunately, however, this country still has a severe shortage of organs available for transplant. As can be seen below, the number of people who are waiting for a transplant is a lot higher than the number of deceased donors. Every day, thousands of people wait for the phone call from the hospital that could transform their life.

Figure 1 - Number of deceased donors and transplants in England, 1 April 2007 - 31 March 2018, and patients on the active transplant list at 31 March 2018



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For example, in England in 2017/18 there were 1,269 deceased kidney donors but at 31 March 2018 there were 4,298 people on the waiting list for a kidney transplant, meaning that less than a third of these people were able to receive the kidney they need.<sup>2</sup> Those who receive a transplant will typically have been on the waiting list for at least two years. People are often removed from the waiting list if they are too ill to receive a transplant. In the UK in 2017/18, 755 people were removed and 411 patients died while on the waiting list.

The current shortage of organs is even more severe for people from black and Asian communities. People from these communities are more likely to develop conditions such as high blood pressure, diabetes and certain forms of hepatitis than white people, and this makes them more likely to need a transplant. In the UK in 2017/18, there were 1,487 black and Asian patients on the kidney transplant waiting list, but only 49 deceased kidney donors from a black or Asian background.<sup>3</sup> Although many black and Asian patients can receive a transplant from a white donor, the best match will often come from a donor from the same background.

Of the 1,355 deceased organ donors in England in 2017/18, only 49% were registered on the Organ Donor Register. Last year, where a patient's wish to donate was known at the time of potential donation, 93% of families in England gave their consent (although 80 families still overruled their loved one's known decision to be an organ donor). However, where a patient had not expressed a wish to donate, only 50% of families gave their consent for donation to proceed. We want this to change and to change the culture around organ donation in this country in the longer term.

## A New Approach to Organ and Tissue Donation in England from 2020

Last October, the Prime Minister announced plans to increase organ donation by shifting the balance of presumption in favour of organ donation.

The first important step will be to encourage everyone to see it as their responsibility to register a decision, so that if organ donation is a possibility on a person's death, their family can feel confident that they are acting in their loved one's best interests. We know that some families later regret their decision to decline organ donation as they realise that this was a missed opportunity to save the lives of others and to create a legacy for their loved one.

Recording a decision in life will help the discussions between the specialist nurses and families as the starting point would be how to support their relative's known decision about organ donation rather than trying to figure out what their loved one would have wanted at an already distressing time for the family. We want to raise awareness of these important issues and support the public to make informed decisions.

We want more people to tell us their preferences regardless of what these might be - whether to donate or to not donate. We want families to be aware of their loved one's wishes, so that they can feel confident that they are acting in their best interests.

The Government will be taking steps to make it as easy as possible for people to record their wishes. By the time we launch our communication campaign in 2019, everyone in England will be able to record their wishes through our new NHS app and also highlight to us if their faith is important to their decision. Looking forwards, we will be developing this route so that people will be able to use the app to check and amend their registration details.

Meanwhile, we intend to change the law so that from spring 2020, everybody will be considered as a potential organ donor unless they have expressed on the Register that they do not wish to donate their organs (known as 'deemed consent' or 'opt-out'), or are in one of the excluded groups. We know that the vast majority of people support organ donation, so it is right that we

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change the law to better reflect this and ultimately give more people the chance of receiving a life-saving transplant.

We need people to let us know their wishes. We want to make it easier for families to support organ donation when faced with such difficult circumstances and the best way to achieve this is to encourage everyone to record a decision and let their friends and family know their wishes.

Given that 80% of people in England are willing to, or would consider donating some or all of their organs, our ambition is to see many more donations as a result. If we all work together, we could see 700 extra transplants a year, transforming 700 lives.

Last July, Geoffrey Robinson MP was successful in a ballot in Parliament which allowed him to put forward legislation proposing how the new system will work in England. The Government ran a three month public consultation setting out proposals for the new arrangements. This document sets out what we heard from members of the public and organisations, and outlines how we will be changing the system.

Under the new way of doing things, we will be offering the following:

- A 12 month transition period between the new law being passed and the arrangements coming into effect, with an indicative start date for the new arrangements of spring 2020, giving people time to understand how the change will affect them and discuss with friends and family.
- A 12 month communication campaign to raise awareness of the changes, with information about the different options available to record a decision before the new arrangements begin.
- Ahead of this campaign, a new route to the Organ Donor Register through the NHS app will transform the way people can make their wishes known. Every adult in England will be able to record their preferences on organ donation either online, over the phone or via the app. Further integration between the NHS app and the Register from 2019, to allow users to check and update their registration details.
- 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 discuss how donation can proceed, whilst ensuring that any religious obligations are observed (this option will not capture ethnicity or religion).
- Safeguards to make the system fair for everyone - to exclude children below 18, people who lack the mental capacity to understand the changes and make an informed decision, and people who have lived ordinarily in England for less than 12 months immediately before their death.
- NHS Blood and Transplant and faith leaders will work together to develop faith-specific donor cards setting out special arrangements according to their beliefs which will need to be accommodated as part of the donation process.
- 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.

A snapshot of the differences between the existing system and proposed new system is at Appendix I.



# 1. Background to the consultation

## Introduction

In her announcement in October 2017, the Prime Minister made it clear that the Government would act to address the shortage of organs available for transplant in England by altering the system to shift the balance of presumption in favour of organ donation.

Following this pledge, in December 2017, the Government launched a 12-week consultation on proposals to introduce a new approach to organ and tissue donation in England to deal with the shortage of organs and tissues available for transplantation, known as 'deemed consent' or 'opt-out'. The consultation sought views from members of the public and professional organisations on how changes to the organ donation system in England could be implemented and whether there were other steps that could be taken.

In particular, the consultation asked important questions on:

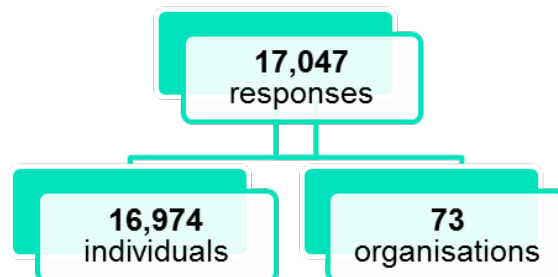
- ways to make it easier for people to register their decision on organ and tissue donation;
- the potential impact proposals could have on people from certain religious groups or ethnic backgrounds;
- how to ensure that moving to an 'opt-out' system will honour a person's decision on what happens to their body after death;
- how family members should be involved in confirming decisions in future; and
- appropriate exclusions and safeguards to the general rule of consent under the proposed new system.

We recognise that organ donation is a deeply personal and emotive issue, and we accept that there will always be people who feel they cannot support organ donation. Alongside our public consultation over the past few months, we have engaged with a range of stakeholders who have helped us in considering a number of important issues about how organ donation affects them.

## The public consultation

The consultation ran from 12 December 2017 to 6 March 2018, and we received 17,047 responses. This volume is a demonstration of the significant public engagement with the proposals that were put forward.

Figure 2 - breakdown of respondents by individual/organisation



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Figure 3A - breakdown of respondents by religion

No religion	Christian	Prefer not to say	Jewish	Muslim	Hindu	Buddhist	Pagan	Other	Sikh
7,582	6,840	1,224	639	348	101	88	60	58	34

Figure 3B - breakdown of respondents by ethnicity

White	Prefer not to say	Asian	Mixed	Black	Other
14,791	1,318	417	224	184	40

Figure 3C - breakdown of respondents by age

35-44	25-34	45-54	55-64	65 or above	18-24	Under 18
7,582	6,840	1,224	639	348	101	88

Figure 3D - breakdown of respondents by geography

SE	London	NW	SW	Yorkshire & Humber	West Mds.	East Mds.	East	NE	Scotland	N Ireland	Wales
3,038	2,528	2,022	1,810	1,374	1,332	1,190	1,185	993	503	185	131

We used a range of different means to encourage as many people as possible to engage in this important conversation, publicising the consultation through press notices on TV, radio and in print media. We also promoted the consultation on social media and worked with a number of organ donation-related organisations to highlight the Government's consultation via their respective platforms.

## Focus groups

To complement the consultation process, NHS Blood and Transplant commissioned **Ipsos MORI** to run focus groups and test the new proposals.<sup>4</sup> 26 focus groups were organised across England with a number of black and Asian groups, faith groups, parents of children under 18 and people who had only been living in England for a short time. Key themes in these discussions were:

- general recognition that organ donation saves lives;
- lack of clarity on where some religions stand on organ donation;
- lack of awareness and misconceptions about how organ donation works and the transplantation process;

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- an expectation that if someone has made a decision about organ donation, their decision should be honoured and not overridden by their family, provided that the person was in a fit state, was aware of the new arrangements and had made an informed decision. However, there were exceptions to this position, with some groups arguing that the family should have a greater role where an individual had not recorded a decision; and
- views that some people should be excluded from the new arrangements - children under 16 or 18, those lacking the capacity to understand the new arrangements, and people who have lived in England for less than 12 months.

## Ministerial faith event

The Minister for Mental Health and Inequalities at the Department of Health and Social Care attended various events and panel discussions with different communities to discuss the proposals, and engaged with Parliament through the All-Parliamentary Group on Heart Disease.

On 9 May 2018, the Minister hosted an event with faith leaders to discuss barriers to organ donation, explore what more can be done to engage with the different faith groups on organ donation, and look at how government and faith leaders can work better together. Some of the key themes coming out of the event were:

- more needs to be done to build trust between the Government and black, Asian and minority ethnic (BAME) communities;
- safeguards within the system are vital to any change. The public will need to be reassured that if they decide not to donate, their organs will not be removed;
- people need unbiased information so that they are able to take properly informed decisions;
- faith leaders can play an important role in educating their communities, but it should be recognised that faith groups are not homogeneous and there will be diversity of opinion and beliefs within a single religion. It would be useful if faith leaders could provide clarity on the position of their faith towards organ donation, where there is no clear consensus;
- there is good work going on at a local level but these initiatives are under-resourced. It is considered important that those leading on this work are involved in designing solutions; and
- more resources and better co-ordination is required in order to change attitudes towards organ donation amongst BAME communities. Personal accounts from transplant recipients and donor families were seen to be extremely powerful tools for generating support.

## Campaign to increase black and Asian organ donors

We are aware of the need to improve the chances of black and Asian patients waiting for organ transplants, and that is why as a first step we have launched a campaign focussed on increasing black and Asian organ donors. Our ambition is to encourage families to talk about organ donation in their everyday life and therefore make organ donation a natural part of end of life care.

## Analysing the responses

The consultation asked nine questions, covering issues such as ways to record a decision on organ donation, how to raise awareness of the new arrangements, the potential impact of the

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new arrangements on people from certain faiths and ethnic backgrounds, the role of the family and who should be exempt from the new arrangements.

The responses provided invaluable insight into the views of members of the public and organisations regarding the proposals. The responses were analysed by the Organ Donation policy team at the Department of Health and Social Care with support from the analytical team. Digital tools were also used to combine the qualitative and quantitative data and allow more in-depth analysis of key themes.

## 2. Summary of consultation responses

This chapter provides a summary of our analysis of the questions asked in the consultation. In chapter 3, we set out how we will address the issues raised and wider changes to make the new system work.

### Question 1: Do you think people should have more ways to record a decision about organ and tissue donation?

**Yes - 89%**

**No - 11%**

In the consultation, we explained the current system of consent for organ and tissue donation in England. We said that currently, in order for someone to become a donor, they need to give their express consent – either by registering themselves as a donor on the Organ Donor Register ('the Register') or by making their decision known to their family. If someone has not made their wishes clear during their lifetime, and organ donation is a possibility on their death, then the decision falls to those closest to them.

The Register currently allows people to record a decision to donate, not to donate, or to appoint a representative to make a decision for them after their death. People are also able to amend their decision at any time if they have changed their mind.

We said that it would still be possible to record these decisions on the Register in the future and asked whether there should be more ways to record a decision about organ and tissue donation, so that the Government is able to capture as many decisions as possible.

Altogether, 16,700 people answered this question and around 4,350 used the free-text box to provide further comment. **A large majority of respondents (89%) said that there should be more ways to record an organ donation decision, including when people are doing other things, such as registering with a GP.** Respondents commonly argued that there should be as many opportunities as possible to register, but **the process must be kept simple.** Many highlighted the need to maintain a **central database to record the information, to avoid conflicting data.** Other respondents said that the opportunity to register a decision should be presented in different healthcare settings, arguing that staff should be given appropriate training to be able to sensitively hold a conversation on organ donation.

Only a small proportion (11%) said that you should only be able to record your decision directly onto the Register online or on the phone. A common theme was that people should be provided with complete and unbiased information so that they can make an informed and considered decision in their own time. Some highlighted the risk of an organ donation decision becoming 'too casual' if approached as a side-note to other practices. Many respondents noted that introducing different systems could lead to conflicting data and inefficiencies. Some argued that recording a decision via one's GP does not guarantee an accurate recording.

Other notable themes:

- methods must be inclusive and cater for those who do not use a computer, are illiterate or do not speak English;
- awareness-raising is vital to empower people to make an informed choice. There must be an effective media campaign and healthcare professionals should broach the subject with patients;

- it is important that people discuss their organ donation decision with their family. Some suggested possible ways to record acknowledgement of decision by the next of kin;
- government administrative procedures (for example applying for a passport), were cited as useful ways to register decisions;
- the system must not be intrusive or put pressure on members of the public, who should not be asked about donation repeatedly;
- people should be regularly prompted at GP appointments to check that their decision is still current; and
- concerns that GPs or other NHS staff would treat someone differently if they had knowledge of their organ donation decision.

## Question 2: What do you think are the advantages or disadvantages of including personal information on someone's organ donation decision?

In the consultation, we argued that it could be beneficial to record additional information on a person's organ donation decision, whilst stressing that any developments in this area would need to be balanced to keep processes for recording a decision as simple as possible.

Some 12,000 people provided comments in response to this question. This was not a closed (yes/no) question and therefore it is not possible to provide statistics. There was a fairly even split between: (i) those in favour of including more personal information; (ii) those against including more personal information; and (iii) those who listed both advantages and disadvantages to being able to add more data.

The most common suggestions regarding additional information that could be recorded were medical information and preferences on which organs to donate, the latter of which is already captured when someone signs up to be a donor on the Register. A number of other pieces of information were suggested, including someone's reason for their decision, whether or not someone has discussed their decision with their family, lifestyle factors and ethnicity.

**There was no clear consensus about whether or not more personal information should be recorded on someone's organ donation decision.**

Where cited, **advantages** included:

- help to ensure the wishes of the donor are respected;
- help to clarify the person's intentions;
- help to ensure that people are making a fully informed and considered choice;
- prevent relatives from overriding the wishes of registered donors;
- assist relatives in understanding the person's wishes;
- assist healthcare professionals in securing matches;
- help to speed up the donation/matching process; and
- help to ensure religious/personal wishes are respected.

Where cited, **disadvantages** included:

- additional complexity of requiring personal information might deter some from registering;
- data security and confidentiality concerns – risk that information might be lost or misused;
- concerns about data becoming out of date;
- collecting personal information is unnecessary and overly intrusive;

- recording individual wishes might lead to people making stipulations around the types of recipients they'd be willing for their organs to be offered to; and
- adds to complexity and costs of administering the system.

### Question 3: How can we make people more aware of the new rules on organ donation?

We invited respondents to share their views on how the Government might make people more aware of the new rules on organ donation.

Approximately 15,000 people responded to this question. As above, this was not a closed (yes/no) question and therefore no statistics have been produced. **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.**

Respondents commonly noted that any information offered must be simple and easy to digest.

While a significant proportion of respondents advocated the use of TV and social media, many highlighted the issue of informing hard-to-reach groups – such as those whose first language isn't English, the homeless, people with learning difficulties and the elderly – and argued that the Government must employ a range of different formats to ensure a wide coverage. Others said that it was vital to engage those groups likely to be most sceptical about a change, with some noting the potential role of community and faith leaders.

The most common platforms suggested were:

- posters/leaflets in different healthcare settings;
- letters to every household;
- TV and radio;
- newspapers;
- social media;
- education in schools and universities; and
- religious institutions.

### Question 4: If the law changes, would this affect your decision about organ donation?

**Yes, I will opt in - 13%**

**No - 72%**

**Yes, I will opt out - 15%**

16,730 people answered this question. **A large majority of respondents (72%) said that the proposed change in the law would make no difference to their decision about organ donation.** 13% said that the change would make them opt in, while 15% of respondents said that they would opt out. There was however a strong representation from both the Muslim and Jewish communities that the changes would be more likely to encourage them to record a decision that they do not want to donate their organs after death, with 60% and 63% respectively answering to this effect.



## Question 5: If the law changes, people would be considered willing to be an organ donor unless they have opted out. Do you think this change could have a negative impact on people from some religious groups or ethnic backgrounds?

**Yes - 32%**

**Don't know - 24%**

**No - 44%**

Almost 16,700 people answered this question, with some 12,000 respondents using the free-text box to provide further comment. **The largest proportion of respondents (44%) said that they did not think the change could have a negative impact, largely because those who are opposed to organ donation will be able to record on the Register that they do not want to donate.** 24% said that they were not sure.

**33% of respondents said that the change could have a negative impact on people from certain religious groups or ethnic backgrounds. The most common argument amongst these respondents was that some people's religious beliefs might prohibit organ donation.** Others reiterated the importance of choice, arguing that deemed consent contravenes the idea of free will.

Many Jewish and Muslim respondents felt that the changes could have a negative impact on those from certain faith groups or ethnic backgrounds, with 85% and 79% respectively answering to this effect. Muslim respondents commonly cited the lack of consensus amongst religious scholars over the compatibility of their religious views and organ donation as being problematic, arguing that there is a need for better engagement with Islamic communities on the issue. Some Jewish respondents specified perceived incompatibilities with their religious views, for example the belief that the body must remain intact after death. Respondents from both of these groups noted that it would be helpful for faith leaders to dispel misconceptions and clarify whether or not organ donation can be reconciled with adherence to their respective religious law.

## Question 6: If the law changes and someone has died, and they have not opted out of organ donation, should their family be able to make the final decision?

**Yes - 25%**

**Sometimes - 27%**

**No - 48%**

We asked if the family should be able to make the final decision on organ donation under the new system, when someone has died and they have not recorded a decision.

Almost 13,400 people answered either 'Yes', 'No' or 'Sometimes' in response to this question. A further 3,400 people gave their answer as 'Other', with approximately 3,000 of these using the free-text box to provide further comment.

**The greatest proportion of respondents (48%) said that donation should always go ahead if someone has not opted out.** These respondents typically argued that a decision not to actively record a decision that you do not want to donate must be treated as a positive decision



to donate, and since individual autonomy must be upheld, the family should not be able to contravene this.

**There was some support (25%) for the family always having the final say in the absence of an express decision, with very strong support from Jewish and Muslim respondents (76% of all Jewish respondents and 70% of all Muslim respondents answered to this effect). For all other religious groups this remained the least common answer.**

Respondents who said the family should always have the final say argued that the deceased's wishes are unclear when no express decision has been recorded and the family knows best what their loved one would have wanted. Others contested what they perceived to be the state assuming ownership of the deceased's body, remarking that the family is responsible for a loved one's body after death.

**There was some support (27%) for the family sometimes having the final say in the absence of an express decision.** These respondents commonly argued that it was necessary to have some **exceptions** to the rule under deemed consent, to account for circumstances such as where there are doubts over the mental capacity of the deceased or where the family has information to show that the deceased would have objected. Others advocated softer restrictions, arguing that organ donation should not go ahead if the family is strongly against it and would be left distressed.

### Question 7: Do you think someone's family should be able to decide if their organs are donated, if it is different to the decision they made when they were alive?

**Yes - 6%**

**Sometimes - 28%**

**No - 66%**

The consultation explained that although over 90% of families agree to donation if they know it was what their loved one wanted, around 100 families each year in the UK do not support a decision to consent as recorded on the Register and, as a result, donation does not proceed. Respondents were asked if someone's family should be able to decide if organs are donated, even if it is different to the decision made by the potential donor when they were alive.

16,600 people responded to this question, with some 11,600 respondents using the free-text box to provide further comment. **The majority of respondents (66%) said that an express decision on organ donation should always be respected.** The most common reason cited was the sanctity of individual autonomy, with respondents arguing that a person should feel confident that a decision made in their lifetime will be honoured after they die.

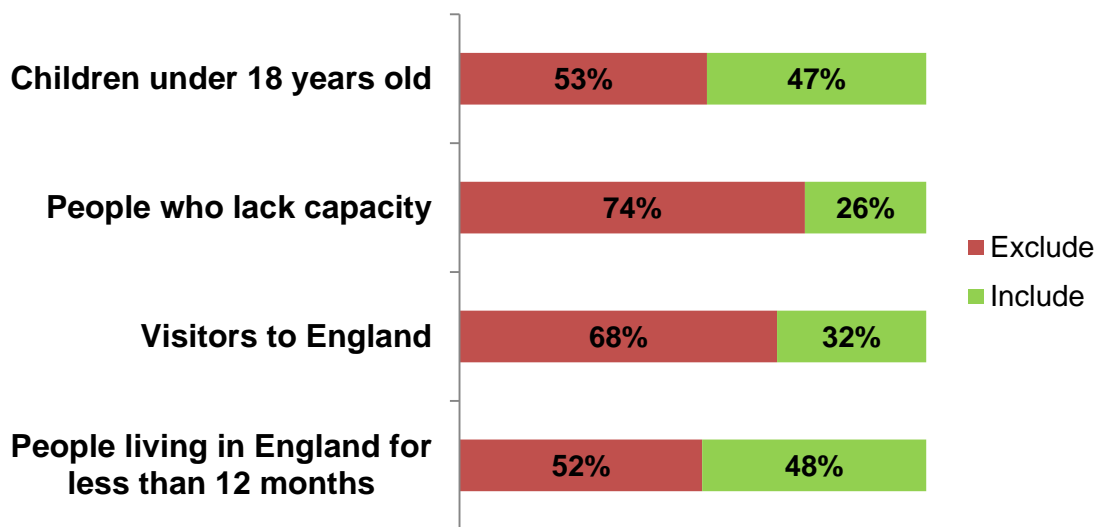
**There was very little support (6%) for giving families the right to overturn an express decision, with some support from Jewish and Muslim respondents (20% of all Jewish respondents and 23% of all Muslim respondents answered to this effect).** The majority of those who argued for a family override did so on account of their belief that the welfare of the bereaved must take precedence, while others said that the family is best placed to know what their loved one would have wanted under the particular circumstances surrounding their death. **Some Jewish and Muslim respondents argued that the family should be able to reverse an express decision for religious reasons.**

**There was some support (28%) for sometimes allowing the family to overturn an express decision on organ donation.** Many respondents offered similar reasoning to the above, while

others remarked that the family should always be consulted in case they have new information that contradicts an individual's recorded decision.

## Question 8: Which of the following should not be included in the proposed new rules about organ donation?

- children under 18 years old
- people who lack capacity
- visitors to England
- people living in England for less than 12 months (for example, students from overseas, armed forces personnel)



The consultation outlined that the Government considers there to be some groups for whom express consent for organ donation should continue to be required under the new system. Respondents were asked if they agreed with the groups of individuals that the Government proposes to exclude from the new arrangements.

16,700 people answered this question and around 4,800 of these used the free-text box to provide further comment. **While it was generally accepted that tourists (68%) and people who lack capacity (74%) should be excluded, there was less agreement on whether or not children under 18 (53%) and people living in England for less than 12 months (52%) should be excluded.**

Some respondents suggested that the age threshold should be lowered, with a number of responses suggesting that children aged 16 and over should be included since this is the legal age for other important life events, such as marriage. Others argued that the suggested residency period of 12 months for including people in the changes should be reduced. **A number of Muslim and Jewish respondents advocated that members of certain religious groups should be excluded completely from the changes.**

## **Question 9: Please tell us about any opinions or evidence you have about opting out of organ donation.**

Approximately 10,500 people responded to this question. Our analysis of responses did not uncover any new issues that had not already been covered in previous responses.

Respondents frequently used this question to either set out support for the new arrangements, sometimes detailing their personal experience of organ donation (either directly as a transplant recipient or member of a donor family, or as a medical professional), or to set out their concerns about the new approach.

## **Legislating for the new arrangements**

Taking the results of the consultation together, our next step will be to consider how the outcome of the consultation is reflected in the future legislation.

## 3. The New Approach to Organ Donation

### The current system for Organ and Tissue Donation in England

- Those who wish to donate their organs after death register as organ donors on the Organ Donor Register ('the Register').
- People can appoint someone (a friend or family member, for example) to make a decision on their behalf after they die.
- People can amend their decision at any time via the Register.
- If someone has not recorded a decision during their lifetime and organ donation is a possibility on their death, the decision falls to those closest to them.
- Children can record a decision on the Register (although in practice parents must give consent to donation after a child's death).
- People can state which organs they want to donate.
- For organ donation to be possible, someone needs to be in a critical care unit. If somebody is registered as an organ donor, healthcare professionals will decide on which organs are suitable for donation.
- There is always a discussion with the family to discuss the possibility of organ donation, regardless of whether someone has recorded a decision on the Register.
- Even if someone has registered as a donor, there are a number of cases each year where the family will refuse to give permission for donation to go ahead.

### Proposed new system from 2020

**To increase the number of organs and tissues available for transplant, 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.**

- Those who do not wish to donate their organs and tissues will be able to record their wish on the Register.
- Those who do wish to donate will still be able to express their wish on the Register and select the organs they are willing to donate. People will continue to be able to change or amend their decision at any time.
- 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.
- Some people will be excluded from the changes to the law:

## The New Approach to Organ and Tissue Donation in England

- children under 18;
  - people who lack mental capacity to understand the new arrangements and take the necessary action; and
  - people who have not been ordinarily resident in England for at least 12 months immediately before their death.
- Nurses will continue to have a conversation with the family to discuss their loved one's wishes, during which the family will be able to provide information if they know that their loved one would or would not have wanted to donate their organs. Even if there is a recorded decision on the Register, those close to the potential donor will still be able to provide information if they know that what has been recorded is not the deceased's latest wish. Faith and the views of the family will form part of these discussions.
  - There will be a year-long communication campaign to give people time to familiarise themselves with the changes. And we will be working to integrate the new NHS app and the Register to allow users more flexibility to add and check their registration details.

## What will be changing?

### The role of the Organ Donor Register ('the Register')

Currently, people who wish to donate their organs and tissues add their name on the Register to register as a donor or appoint someone (a friend, family member or faith leader, for example) to make the final decision for them after their death. People who sign up to be an organ donor are also able to select which organs they wish to donate.

These options will still be available in the future. However, we want to make the system simpler and better in order to encourage as many people as possible to make their wishes known:

- We will be making the Register more accessible by introducing a new pathway through the NHS app for England due to launch at the end of the year. This means that by the time we launch our communication campaign in 2019, every adult in England will be able to set out if they wish to be an organ donor or not, via the app. Those who have already recorded a decision on the Register will not have to take any action unless they change their mind and wish to amend their decision.
- During the consultation process and from our further engagement with stakeholders, we heard that some people have concerns about the impact of our proposals on their religion. This is why from December 2018, there will be a new option on the Register to allow people to state that their faith is important to their organ donation decision and that their family and/or faith leader should be consulted if organ donation is a possibility for them, to discuss how donation can proceed whilst ensuring that any religious obligations are observed. This information will be visible to the specialist nurses and will be considered as part of the conversations with the family, to ensure that any religious and cultural aspects are firmly taken into consideration. This option will not capture ethnicity or religion.

The responses to the consultation highlighted lack of awareness of the existing ways to register, so more needs to be done to raise awareness of these methods.

We will continue to make the system of recording a decision more user-friendly to have ready by the time we launch our communication campaign. We will be working with NHS Digital and NHS Blood and Transplant to see how the Register and the new NHS England app can be integrated to allow users more flexibility to check and update their registration details .

## People will be given time to make the right decision for them

Our ambition is that the changes we are planning will make it easier to record a decision about organ donation. The 12 month transition period - which is a key part of our proposals - is to allow time for discussions with friends and family and gradually change the culture about how we discuss organ donation in England.

We want everyone to consider what the new policy means for them, discuss organ and tissue donation with their friends and family and decide whether they wish to be a donor, and then record their decision. This will be important as from spring 2020, when someone has not recorded a decision on the Register to say that they do not wish to donate their organs, unless they are excluded, they will be considered as having no objection to organ donation. However, if organ donation is a possibility on someone's death, there will always be a personal conversation with the family to understand what their loved one's wishes were.

The Government understands that the changes to how organs and tissues will be donated in the future mark a fundamental shift from what is happening currently in England.

Therefore, during the transition period the Government will launch a year-long communication campaign to raise awareness – likely in the spring of 2019. This will be a comprehensive campaign using multiple channels to achieve a wide coverage across England. The Government wants to reach as much of the population as possible, to make people aware of how the change in the law will impact on them and to get people thinking about their organ donation decision.

By the time this campaign is launched, the NHS app will be up and running so that people will be able to record their decision on organ donation with even greater ease.

## Honouring the wishes of the deceased and the role of the family

Around 66% of respondents to the public consultation said that they would not want their family to override a decision that they have made when they were alive to donate their organs and tissues after death. A number of strong statements were made against families being able to override a recorded decision, with respondents arguing that if families continued to be able to do this, nothing would change and being able to do this undermines the idea of having a Register and recording your wishes on it.

Under the new system, families will still be supported by the specialist nurses in personal discussions about organ donation at the bedside with the emphasis on honouring their loved one's wishes. The family will maintain a key role, not least because families provide important information to nurses and clinicians about their loved one's medical and behavioural history which allows clinicians to assess whether donation could be an option. Doctors also have duty of care to the family of the deceased and will not want to cause further upset at such a difficult time for the family.

- Where the deceased has not recorded a decision on the Register, their close family and friends will play an important role in providing information to the specialist nurse if they believe that the deceased would not have wanted to donate their organs and tissues. This may be, for example, building on discussions that they have had with the deceased about donation, or their knowledge of the deceased and their generosity or attitude more generally in life.
- Where there is a recorded decision on the Register to either donate or to not donate, if the family believe that the deceased's recorded decision is not the most recent one and they had changed their mind since they recorded a decision on the Register, the family will be able to provide the relevant information to the specialist nurse.



- As highlighted above, from December 2018 those who wish to donate will be able to state that their faith is important to their organ donation decision and that their family and/or faith leader should be consulted if organ donation is a possibility for them, to discuss how donation can proceed whilst ensuring that any religious obligations are observed.

### Faith training and guidance for specialist nurses and clinicians

In addition to being able to record on the Register that someone's faith is important to them and that the family and/or religious leader should be consulted, as part of training nurses and clinicians on the new system, we will be strengthening the current arrangements:

- 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. This will ensure that they are fully aware of the different religious and cultural beliefs, including the role of the family which will need to be taken into account as part of discussions at the bedside.
- We will be working on implementation guidance for healthcare professionals setting out how the new arrangements will work in practice. This will be in the form of a Code of Practice which will be issued and monitored by the Human Tissue Authority following public consultation. This will also set out how religious and cultural considerations will form part of discussions with the family.

### Digital faith-specific donor cards

Through our consultation, we heard that religious beliefs or not knowing how religious scholars feel about organ donation is a concern to many. Building on the Ministerial faith event of 9 May, the Government will be working with NHS Blood and Transplant and faith leaders to find solutions to overcome barriers which currently stop people of different faiths engaging with organ donation. This will include working with faith leaders to develop the content of digital faith-specific donor cards, which can be downloaded and shared on social media and/or shared with friends and family, to help people ensure that their friends and family know about their decision. This will mean that the family will be better able to advise the specialist nurses for organ donation about their loved one's decision, if faced with such circumstances.

The cards will largely act as a tool to raise awareness amongst friends and family, but we envisage that they might also contain useful information about organ donation, including the special arrangements which might be required for people of different faiths as part of the transplantation process.

### Safeguards to ensure the system is fair

The Government believes that certain exceptions should be made to the general rule that everyone will be considered willing to donate their organs after their death unless they have recorded a decision to not donate.

People who lack mental capacity, children under 18, people ordinarily resident in England for less than 12 months immediately before their death, are less likely to be aware of the system, understand the changes and make an informed decision. As such, these groups will be excluded from the new arrangements. Building on how the system works in Wales, the Code of Practice which will be developed by the Human Tissue Authority will set out how the new arrangements will work in practice, including the discussions between the specialist nurses and the family, to establish how long someone has been ordinarily resident in England.

### Children under 18 years old

As mentioned in chapter 2, 53% of those who responded to the question about who should be excluded from the new arrangements supported excluding children below 18. There were exceptions to this, with some suggesting that the cut-off point should be at different ages, ranging from 16, 17 or over 18.

The Government agrees that the new arrangements may be too complex for children below 18 to understand and decide what action they need to take, and for this reason children below 18 will not be part of the new arrangements. This means that unlike adults, for children below 18, there will not be a presumption in favour of organ donation if they have not opted out. Indeed, the age of 18 is widely recognised as the age at which one becomes an adult, and gains full citizenship rights.

### People who lack capacity

The consultation identified a strong sentiment that people who do not have the mental capacity to understand the changes and take the relevant action should be excluded. The Government agrees with this position. Currently, any person can record a wish to donate their organs without their mental capacity being assessed. This will not change, but those who lack the capacity to understand the effect of the new arrangements will not have their consent 'deemed' on their death, if they have not recorded an express decision.

### People who have been living in England for less than 12 months

We also agree with the view that people who had not been ordinarily resident in England for at least 12 months before their death (for example tourists and short-term visitors) should be excluded from the new arrangements. This is because they are less likely to be aware of the changes, understand how they impact on them and the action they need to take. Therefore to be included in the new arrangements, someone will need to have been an ordinary resident in England for at least 12 months immediately before their death.

## What will remain the same?

The new arrangements from 2020 will not be changing:

- the medical treatment patients receive, including end of life care and time of death;
- the way death is confirmed;
- living donation is not included in the new arrangements;
- novel transplants will not be covered by the new arrangements ('novel' transplants are the more controversial transplants such as face, limbs etc. The new law will only cover the most common types of transplants, for example, kidney, liver and heart);
- how organ and tissues are allocated;
- donated organs and tissues will continue to be used for no purposes other than transplantation and, if this is not possible, for research;
- the clinical decision for, and processes associated with, transplants; and
- people will still be able to use the Register to record their wishes, whether this is to donate, to not donate or appoint a representative to make the decision for them after death.



## 4. Conclusion

Though great progress has been made in recent years, 3 people still die each day due to a lack of suitable organs and there are around 5,100 people waiting for an organ transplant in England that could save or transform their life.

Our ability to help those in need of transplants is limited by the number of organ donors that come forward. We know that the vast majority of people in this country support organ donation in principle, but only about one third have signed up to be an organ donor.

The Government aims to change the law to shift the balance of presumption in favour of organ donation. But, to save more lives, we need more people to take the positive step to register their decision to donate, so that if they die in circumstances where donation is a possibility, their organs can be made available to help those so desperately in need.

It is crucial that everyone takes a decision on organ donation - whether that is to donate or to not donate - registers their decision on the Register and makes their decision known to their family and friends. In this way, families can be certain that they are acting according to their loved one's wishes.

We intend to make the system more inclusive to ensure that people with religious considerations can note beforehand that their faith is important to their views and that they want their family and/or their religious leader to have input into the the discussions with the nurses and doctors, so that their religious obligations are observed. There will also be updated training for healthcare professionals involved in organ donation to increase awareness of faith considerations on organ donation.

Meanwhile, the new NHS app will play a vital role in making the Register more accessible for people living in England, so that it becomes easier than ever to record a decision on organ donation. We will be working to make the system of recording a decision more user-friendly, to allow users more flexibility to check and update their registration details.

# Appendix I - Snapshot of the proposed new system

## Organ Donation in 2018

- You can register by adding your name on the Organ Donor Register ('the Register') if you wish to donate your organs.
- You can also add your name on the Register if you do not wish to donate your organs.
- You can appoint someone else to make the decision on your behalf.
- If there is no recorded decision for you, your family will be asked to make a decision.
- Children can register a decision and parents/guardians give consent.
- From December 2018, you will be able to state on the Register that your faith is important to you and that your family and/or religious leader should be consulted about this if organ donation is a possibility for you, to discuss how donation can proceed whilst ensuring that religious obligations are observed.
- From end of 2018, you will be able to access the Register through the new NHS app in England.

## Organ Donation in 2019/20

### ***No change***

- Communication campaign to make people aware of the new changes from 2020.
- A two-way integration system between the Register and the new NHS England app to allow users more flexibility to check and update their registration details.

## How we propose to change organ donation from 2020

- You will still be able to express on the Register if you wish to donate your organs. If you have registered to donate, you may want to double-check that you are happy with your decision and talk to your friends and family.
- You will still be able to express on the Register if you do not wish to donate your organs.
- You will still be able to appoint someone else to make the decision whether to donate your organs or not after death.
- If you do not do any of the above, the default position from 2020 will be that you will be an organ donor after death unless you are excluded.

### Role of friends and family

- If you have made a decision to donate *or* to not donate, those close to you will be asked if this was your most recent decision. They will be able to override your decision on your behalf if they have information that you had changed your mind since making your decision.
- If you record a decision to donate your organs, you will be able to state that your faith is important to you and request that your family/religious leader be involved in the discussions if organ donation is a possibility on your death, to discuss how donation can proceed whilst ensuring that religious obligations are observed.
- If you have appointed someone else to make a decision for you, this individual will be asked to make a decision on your behalf on your death.
- **If you do not do any of the above, the default position from 2020 will be that you will be an organ donor after your death unless you are excluded. Your family will however be able to provide information if they know that you would not have wanted to donate.**

### How we will be supporting discussions with families

- More formal guidance and updated training for specialist nurses, doctors and healthcare professionals to ensure that faith is covered in the discussions with the family.
- New option on the Register to state that your faith is important to you and your family and/or faith leader should be approached to identify how organ donation can go ahead whilst also meeting your faith obligations.
- A new Code of Practice for healthcare professionals setting out how the new arrangements will work in practice.
- Faith-specific donor cards available to download, to raise awareness of your decision with your friends and family.

### Who will not be affected by the changes?

- Children below 18 will still be required to record a decision if they wish to donate/not to donate and their parents or guardians will need to give their consent.
- People who have not been ordinarily resident in England for at least 12 months (for example tourists and short-term visitors) immediately before their death will not be affected by the changes.
- Those who lack the capacity to understand the changes and take appropriate action will not be included in the new policy.

<sup>1</sup> NHS Blood and Transplant, Organ Donation and Transplantation Report 2017/18

<sup>2</sup> NHS Blood and Transplant, Organ Donation and Transplantation Report 2017/18

<sup>3</sup> NHS Blood and Transplant, Organ Donation and Transplantation Data for Black, Asian and Minority Ethnic (BAME) Communities Report 2017/8

<sup>4</sup> Ipsos MORI, Focus group consultation: Opt-out system for Organ Donation, March 2018