

<p><i>Title: Consultation on an opt-out system of organ and tissue donation</i></p> <p><b>IA No:</b></p> <p><b>Lead department or agency:</b> Department of Health</p> <p><b>Other departments or agencies:</b></p>	<b>Impact Assessment (IA)</b>		
	<b>Date: 6 November 2017</b>		
	<b>Stage: Consultation</b>		
	<b>Source of intervention: Domestic</b>		
	<b>Type of measure: Other</b>		
<b>Contact for enquiries:</b>			

<b>Summary: Intervention and Options</b>	<b>RPC Opinion: Not Applicable</b>
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Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out? Measure qualifies as
	£0m	£0m	No   NA

**What is the problem under consideration? Why is government intervention necessary?**

There is a lack of organs for transplantation and in 2016/17 more than 390 people in England died while on transplant waiting lists. In around 40% of potential donations the family does not support donation and consent is refused. It is believed that by moving to an opt-out system of donation consent rates will increase leading to more organs being available for transplantation. Government intervention is required to make the necessary change to the legislation covering organ and tissue donation.

**What are the policy objectives and the intended effects?**

The reforms should: Be value for money for taxpayers, in terms of economy, efficiency and effectiveness; and increase the annual number and quality of organs transplanted so that everyone requiring a transplant stands the best chance of receiving one.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

Option 0: Carry on without reforming the existing system of organ and tissue donation.  
Option 1: Change to an opt-out system of organ and tissue donation similar to that currently implemented in Wales.

As this is a consultation IA there is no preferred option.

**Will the policy be reviewed? It will be reviewed. If applicable, set review date: 12/2019**

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	<b>Micro No</b>	<b>&lt; 20 No</b>	<b>Small No</b>	<b>Medium No</b>	<b>Large No</b>
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b> N/A	<b>Non-traded:</b> N/A	

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible Minister:

Date:

# Summary: Analysis & Evidence

Policy Option 0

Description: Do Nothing

## FULL ECONOMIC ASSESSMENT

Price Base N/A	PV Base N/A	Time Period N/A	<b>Net Benefit (Present Value (PV)) (£m)</b>		
			<b>Low: Optional</b>	<b>High: Optional</b>	<b>Best Estimate: 0</b>

<b>COSTS (£m)</b>	<b>Total Transition (Constant Price) Years</b>		<b>Average Annual (excl. Transition) (Constant Price)</b>	<b>Total Cost (Present Value)</b>
<b>Low</b>	Optional		Optional	<b>Optional</b>
<b>High</b>	Optional		Optional	<b>Optional</b>
<b>Best Estimate</b>	0		0	<b>0</b>

### Description and scale of key monetised costs by 'main affected groups'

This is the do nothing option. Incremental costs are zero.

### Other key non-monetised costs by 'main affected groups'

This is the do nothing option. Incremental costs are zero.

<b>BENEFITS (£m)</b>	<b>Total Transition (Constant Price) Years</b>		<b>Average Annual (excl. Transition) (Constant Price)</b>	<b>Total Benefit (Present Value)</b>
<b>Low</b>	Optional		Optional	<b>Optional</b>
<b>High</b>	Optional		Optional	<b>Optional</b>
<b>Best Estimate</b>	0		0	<b>0</b>

### Description and scale of key monetised benefits by 'main affected groups'

This is the do nothing option. Benefits are set to zero.

### Other key non-monetised benefits by 'main affected groups'

This is the do nothing option. Benefits are set to zero.

Key assumptions/sensitivities/risks

None

Discount rate (%)

N/A

## BUSINESS ASSESSMENT (Option 1)

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>In scope of OITO?</b>	<b>Measure qualifies as</b>
<b>Costs: 0</b>	<b>Benefits: 0</b>	<b>Net: 0</b>	No	NA

# Summary: Analysis & Evidence

# Policy Options 1

**Description:** Move to an opt-out system of organ and tissue donation.

## FULL ECONOMIC ASSESSMENT

Price Base 2016/17	PV Base 2016/17	Time Period 100 years	<b>Net Benefit (Present Value (PV)) (£m)</b>		
			<b>Low: -1,100</b>	<b>High: 13,400</b>	<b>Best Estimate: 6,600</b>

<b>COSTS (£m)</b>	<b>Total Transition Years</b>		<b>Average Annual (excl. Transition)</b>	<b>Total Cost (Present Value)</b>
<b>Low</b>	60	3	20	<b>1,100</b>
<b>High</b>	60		100	<b>4,300</b>
<b>Best Estimate</b>	60		50	<b>2,300</b>

### Description and scale of key monetised costs by 'main affected groups'

The transition costs: a) a £13m NHSBT spend on communications over the first 3 years; and b) a £2m one-off cost for managing the spike in opt-out registrations on the organ donor register (ODR). The average annual cost: a) an annual one-off cost for any additional transplants and the ongoing medical costs of transplant recipients; b) savings realised by individuals on the waiting list being transplanted; c) an annual £5m NHSBT spend on communications; and d) an ongoing annual cost of £0.2m to run the ODR.

### Other key non-monetised costs by 'main affected groups'

The above costs do not include: a) any primary care or indirect costs/savings to the health service (e.g. hospital length of stay); and b) costs/savings associated with the wider societal impact (e.g. transplant recipients returning to work).

<b>BENEFITS (£m)</b>	<b>Total Transition Years</b>		<b>Average Annual (excl. Transition)</b>	<b>Total Benefit (Present Value)</b>
<b>Low</b>	0	3	0	<b>0</b>
<b>High</b>	9		400	<b>17,600</b>
<b>Best Estimate</b>	3		200	<b>8,800</b>

### Description and scale of key monetised benefits by 'main affected groups'

The societal value of the QALYs accrued from transplant recipients compared to if they had remained on the transplant waiting lists.

### Other key non-monetised benefits by 'main affected groups'

There are potentially further benefits: a) due to tissue grafts and particular types of organ transplants that were not included in the analysis as, based on expert opinion, they were assumed to be relatively small; and b) due to the wider societal impact of the reform (e.g. improved quality of life of family members).

Key assumptions/sensitivities/risks	<b>Discount rate (%)</b>	1.5
Under Option 1 the consent rate will increase by 0%, 12%, and 36% under the low, best, and high estimates respectively. While these values are based on recommendations from NHSBT, the size of any increase is highly uncertain and the estimated NPV is extremely sensitive to this increase.		
Key assumptions in these estimates are:		
<ul style="list-style-type: none"> <li>Both NHSBT and NHS England have the capacity to deal with any additional donors that might arise from this reform so will not incur any additional cost – this is far from certain.</li> <li>That following the reform there will be no change to the annual number of high value living kidney and liver transplants – there is some literature that suggests a decrease following a change to an opt-out system.</li> </ul>		

## BUSINESS ASSESSMENT

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>In scope of OIOO?</b>	<b>Measure qualifies as</b>
<b>Costs: 0</b>	<b>Benefits: 0</b>	<b>Net: 0</b>	No	NA

## Summary

The government is interested in ways of increasing human organ transplantation in England. One way of achieving this may be to change the default position whereby individuals have to actively opt-in to organ and tissue donation to one in which individuals have to actively opt-out. It is believed that this change would lead to higher levels of consent and that this would in turn lead to more transplants. The Government intends to change the rules on organ donation to a system with a general position that people are considered to consent to being organ donors unless they expressly say that they do not agree. The Government wants to make it easier for people to give their consent in order to increase organ donation so more lives can be saved. Following a change in the law, people will be able to “opt-out” of being an organ donor instead of having to “opt in” to become one. The Government’s intention is that this change will mean the system better reflects the position of the majority of people who would be happy to donate their organs and tissue. The purpose of this consultation is to consider how the changes should be implemented and whether there are other steps that should be taken. While any additional transplants would represent an increased cost, it is estimated that these transplants would generate more net social benefits than if the money (including any costs associated with implementing the opt-out policy) were to be spent elsewhere in the health system.

This IA examines the evidence behind these assumptions.

**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, 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.

## Introduction

1. In 2016/17 there were 1,177 deceased organ donors and 3,155 transplants in England, the highest ever rates<sup>1</sup>. Whilst encouraging, there are only a limited number of deaths following which organ donation may be possible. In around 40% of these cases, the family does not support organ donation and consent is refused<sup>2</sup>. The most common reasons for families to decline are because they know the relative did not want to donate or because they are unsure of their relative's wishes and are likely to feel it is safer to say no. In some cases, families will refuse to support a relative's known decision to be a donor.
2. Lack of consent is one of a range of factors that determine whether potential donations go ahead. Others include a donor being considered medically unsuitable or, where consent is given, the organs proving to be medically unsuitable or if there is a prolonged time between withdrawal of treatment and the person dying.
3. This is a consultation impact assessment. It is intended to inform a 13 week public consultation being held in December 2017.

## Rationale for intervention

4. In 2016/17 395 people in England died while on the active transplant waiting list and a further 732 people were removed from the list, mainly due to ill health<sup>3</sup>. There are currently around 5,400 people waiting for a transplant.
5. Changing the law on consent may have the potential to address some of the reasons why families do not agree to donation and so increase the number of organs available for transplant. England has an opt-in system of organ and tissue donation, which means deceased donation generally requires express consent from the person while they were alive or a family member if he or she had not made their wishes known. People can consent to donation by joining the organ donor register (ODR) and telling their family that they want to be a donor.
6. Other countries have an opt-out system where a person has presumed to have consented to donation unless he or she has explicitly stated that they do not want to be a donor. This is commonly referred to as presumed consent. The various systems differ in their detail but are generally described as either 'hard' or 'soft' depending, broadly, on how prescriptive the procedure is for recording the wish to opt-out and the degree to which families are consulted as part of the decision making process.

## Policy objectives

7. The reforms should:
  - Ensure the framework for consent addresses reasons why people do not currently agree to donation, while also providing a means to opt-out;
  - Be value for money for taxpayers, in terms of economy, efficiency and effectiveness;
  - Increase the annual number and quality of organs transplanted so that everyone requiring a transplant stands the best chance of receiving one.

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<sup>1</sup> Organ Donation and Transplantation Activity Data: ENGLAND available from <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/>

<sup>2</sup> Organ Donation and Transplantation Annual Activity Report 2016/17 available from <https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/>

<sup>3</sup> Data for England provided by NHSBT

# Policy Options

## Do nothing

8. Under this option, the current opt-in system of organ and tissue donation would be maintained.

## Opt-out policy

9. Some countries with opt-out legislation have better donation rates than England and some worse. The Department of Health, in collaboration with the Devolved Administrations set up the Organ Donation Taskforce to carry out a comprehensive review of organ donation in the UK. The report “Organs for Transplants” was published in January 2008. The Taskforce looked at the potential impact for organ donation and commissioned a systematic literature review from the University of York to assess the impact of organ donation rates in other countries<sup>4</sup>. The Welsh Government (WG) commissioned an update of this review in 2012, to support its decision making on opt-out, which concluded that the international evidence suggests an association exists between presumed consent legislation and increased organ donation rates but that it cannot be inferred that this association means that presumed consent causes increased organ donation<sup>5</sup>. The 2012 report also looked at a small body of experimental literature concluding that it provides evidence for a mechanism through which presumed consent might increase organ donation, through the influence of the default position. It also advises of a limit to the extent to which its findings could be applied to real life situations.

10. 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.

11. Data on the impact of the legislation in Wales are beginning to emerge. The overall consent rate in Wales has increased from 54% in 2013/14 (the year prior to the new scheme) to 64% in 2016/17. The small number of potential donors in Wales means that it is too soon to judge the impact on donor rates with any statistical confidence. Wales has also experienced a lower level of people opting-out than they initially estimated. It is too early to say how much of this increase is attributable to the Welsh opt-out policy as opposed to the other measures, particularly a communications campaign, that were introduced at or around the same time.

12. The Government is consulting on moving from an opt-in system of organ and tissue donation to an opt-out system in England. The consultation is considering how government can increase rates of organ donation, particularly from Black, Asian and minority ethnic communities, how the issue of

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[http://webarchive.nationalarchives.gov.uk/20130124044543/http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_090295.pdf](http://webarchive.nationalarchives.gov.uk/20130124044543/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090295.pdf)

<sup>5</sup> <http://gov.wales/statistics-and-research/opt-out-systems-of-organ-donation/?lang=en>

consent should change and be managed within the NHS, the role of technology in helping people to make their preferences known and how “opt-out” could work in practice, including safeguards and support for families.

13. Introducing an opt-out system would require primary legislation to change the law on consent as set out in the Human Tissue Act 2004. This is the same legislation that used to apply in Wales before it changed to an opt-out system. Opt-out systems differ in their detail depending on how prescriptive they are and the degree families are consulted in decision making. The consultation is seeking views on different potential options. For the purposes of this assessment, we have considered the provisions in the law in Wales whereby:
- people can still register consent to donation by adding their name to the ODR
  - those who do not will be presumed to have consented unless they have expressly opted-out (e.g. on the ODR)
  - there will be some exemptions to this presumption:
    - i. if the family can provide evidence that the deceased was opposed to giving consent
    - ii. for non-residents
    - iii. for those under age 18
    - iv. for adults without capacity

## Costs and Benefits of Policy

14. The costs and benefits of moving to an opt-out system of organ and tissue donation are compared to those that would be accrued if the current opt-in system was maintained – the counterfactual. To do this the total ongoing resource use and health state for individuals who receive an organ transplant and those still on the transplant waiting lists under the proposed policy is compared to that in the counterfactual.
15. For the purposes of modelling the costs and benefits, it has been assumed that England will adopt the same opt-out system of organ and tissue donations as has been implemented in Wales.
16. Based on the experience in Wales, which included a long lead in time and an extensive communications campaign to alert people to the change in law and how to opt-out, the new system is modelled based on a three year introductory period:
- Year 1: Consultation, initial communications, and legislation;
  - Year 2: Preparation of the new opt-out system and further communications;
  - Year 3: Launch of the new system (at the start of the year) alongside continuing high level communications;
  - Year 4 (onwards): Ongoing maintenance of system and communications.

### Transition costs

17. Moving to an opt-out system of organ and tissue donation will require significant initial costs covering communications and the infrastructure associated with the organ donor register (ODR). There are also potentially capacity costs incurred by both NHSBT and NHS England in order to cope with any increase in deceased donor numbers.
18. Following the change in Wales, the capability already exists for the ODR to record opt-out registrations. In the current process, each new registration requires support (including a validation letter, call centre support, social media moderation, etc) at a cost of £0.56 per registration<sup>6</sup>. In Wales,

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<sup>6</sup> Cost provided by NHSBT

in the financial year prior to the new law coming into force, there was an initial spike of 165k<sup>7</sup> opt-out registrations representing approximately 5% of the Welsh population. If we believe that a similar proportion of the population in England will opt-out, than this could mean potentially 3m additional opt-out registrations in the year prior to any new law taking effect. This would represent a cost of approximately £1.6m, which we have rounded to £2m to cover any associated additional staffing required to deal with the initial spike in registrations.

19. However, in the professional judgement of NHSBT, the current ODR service is not capable of safely handling the high volumes associated with changes in England. Instead, NHSBT proposes to re-engineer the process to create a digital “self-service” system that is safer and will support the change at lower cost. As full costings for such a system are not available we have used the costs of the current system for modelling purposes.

20. The UK *“Taking Organ Transplantation to 2020”* Strategy (2013) set an ambitious target to achieve world class consent rates to donation after death of over 80% by 2020. In 2016/17 the consent rate was 63% behind the Strategy's target of 70%. If the targeted consent rate of 80% can be achieved this would have resulted in about 320 additional deceased donors<sup>8</sup>. As both NHSBT and NHS England are committed to this strategy we assume that they would already have enough capacity to deal with any increase in deceased donor numbers associated with a change to an opt-out system and so do not include the cost here. It should be noted that there is a significant risk associated with this assumption as it is unclear if the transplant infrastructure will not be able to cope with a significant increase in the number of transplants without further funding. This will need to be investigated further as part of the consultation.

## **On-going fixed costs**

21. Following these initial costs, NHSBT have also budgeted for an ongoing annual communication campaign to cover hard to reach donors as well as annual maintenance costs associated with the ODR.

22. To inform the public about the change to the organ and tissue donation system a communications campaign will be required. The introduction of the opt-out system in Wales was supported by an extensive campaign, with ongoing communications as people reach the age of 18 when the law will affect them. NHSBT has provided an initial assessment of the campaign recommended to support any change in England to raise public awareness and maximise the potential for a cultural shift in behaviour and attitudes. The estimated budget is £13m over a three year period, with an ongoing campaign with harder to reach communities at around £5m a year.

23. After the introduction of an opt-out system in Wales there was a 17% increase in the number of new registrations on the ODR each year (including both opt-in and opt-out registrations)<sup>9</sup>. Currently there are approximately 950k<sup>10</sup> new annual registrations in England and so, if we assume a similar increase to that in Wales, following the legislation coming into force we would expect an additional 170k registrations each year at a cost of £92k (see transition costs above). NHSBT have also advised us that there would be an ongoing annual cost of approximately £100k to cover additional staffing associated with a move to an opt-out system. We have therefore assumed a total ongoing

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<sup>7</sup> Organ Donation and Transplantation Activity Data: WALES available from <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/>

<sup>8</sup> 1,177 deceased donors in 2016/17 scaled by a factor of  $(80\% / 63\% - 1) = 27\%$  to give ~ 318 additional deceased donors

<sup>9</sup> See 7.

<sup>10</sup> Organ Donation and Transplantation Activity Data: ENGLAND available from <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/>

cost of £200k following implementation of an opt-out system of organ and tissue donation, although this may be lower if a digital solution is supported.

## Variable costs and benefits

### *Types of transplant*

24. There are three types of donor involved in organ and tissue donation: donor after cardiac death (DCD); donor after brain death (DBD); and living donors. Deceased donors are able to donate one or more of: kidneys, heart, liver, lungs, pancreas, small bowel, corneas, and tissue (heart valves, skin, bone, tendons, and eyes). Living donors can donate: one kidney, some of their liver, and tissue (bone and amniotic membrane).
25. For this analysis only deceased donors have been considered although the policy may impact the number of living donors (see risks below).
26. Of the organs that can be transplanted we will only consider single-organ kidney, heart, liver, and lung transplants as these make up 94% of all organs transplanted<sup>11</sup> and account for the majority of resource use.
27. While potential donors can register to donate tissues as well as organs, the tissue donation process, with the exception of heart valves, is separate from that of organs with the potential pool of tissue donors being much wider and tissue retrieval occurring on different timescales. NHSBT have advised us that while an increase in donors will benefit the tissue services any impact will be much lower than that for organs and so we have not included tissues in the analysis.

### *Number of additional organs*

28. The number of additional donors under an opt-out system of organ and tissue donation has been calculated based on a model produced by NHSBT. The annual number of donors is given as the product of: the number of deceased individuals who could potentially donate; the rate at which these individuals are approached to request donation; the rate of consent to donation; and the proportion of these authorised donors that go on to become actual donors.
29. In our analysis we have assumed that:
- the number of potential donors remains unchanged over time at 1,245 DBD and 3,655 DCD;
  - the rate at which potential donors are approached remains unchanged over time at 91.8% for DBD and 42.2% for DCD;
  - the proportion of authorised donors (those that have given consent) that go on to become actual donors remains unchanged as 88.8% DBD and 53.4% for DCD;
  - the relative distribution of the demographics (age, sex, ethnicity, etc) in the donor population do not change over time; and
  - the relative proportion of potential DBD to DCD donors remains unchanged for any change in consent rate.
30. To estimate the number of additional donors under an opt-out system we consider three scenarios for the overall consent rate (combining DCD and DBD rates) based on advice from NHSBT:
- Best estimate, in which the overall consent rate increases from the 2016/17 value of 62% to 70%;
  - Lower estimate, in which the overall consent rate remains unchanged; and

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<sup>11</sup> See 10

- Upper estimate, in which the overall consent rate increases to 85% in line with that observed in Spain (considered the gold standard in organ and tissue donations).

**31.** Applying these rates gives the following estimated change in number of donors if we move from an opt-in to opt-out system of organ and tissue donation:

<b>Scenario</b>	<b>Consent rate</b>	<b>Additional donors per year</b>	<b>% Change</b>
Lower estimate	62%	0	0%
Best estimate	70%	142	12%
Upper estimate	85%	422	36%

#### *Impact of additional donors*

**32.** Any additional deceased organ donors are likely to have a significant impact on the English health system in terms of:

- Increased transplantation costs for kidney, liver, heart, and lung;
- Increased maintenance therapy costs following these transplantations over the lifetime of the transplanted individuals;
- Savings due to reduced renal dialysis and other medical management costs of transplanted individuals;
- Savings due to the cumulative reduction in the size of the transplant waiting list meaning fewer individuals will be waiting for transplants each year; and
- An increase in life expectancy and a better quality of life for transplanted individuals.

**33.** To estimate the costs and benefits that any additional deceased donors would provide, the number of transplants that would arise due to these donors needs to be calculated. Based on 2016/17 transplant activity data for England<sup>12</sup> there were 1,877 kidney, 764 liver, 163 heart, and 150 lung transplants<sup>13</sup>. While organs can be imported from overseas the annual numbers are relatively small and so have been ignored in this analysis<sup>14</sup>. The number of additional transplants is then calculated by scaling the annual number of transplants by the estimated increase in the number of deceased donors.

**34.** Based on these values we would expect the following number of additional transplants under each scenario:

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

#### *Methodology*

**35.** To model the impact of these additional transplants each year we have assumed that they are transplanted to individuals on the relevant transplant waiting lists. This means that not only will more individuals get organ transplants in any given year but also the size of the waiting lists will decrease leading to shorter waiting times for all the individuals still on the list and those joining in the future.

<sup>12</sup> See 10

<sup>13</sup> These numbers are for recipients on the English transplant waiting list and with postcodes resident in England, Channel Island and Isle of Man

<sup>14</sup> See Appendix of "Organ Donation and Transplantation: Annual activity report" available from <https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/>

36. It has been assumed that individuals on the waiting lists are equally likely to match with any additional organs and that organs are only transplanted if there is a matched recipient (i.e. if there are no individuals left on the waiting list then no further transplants are carried out).
37. To model the number of transplanted individuals and the size of the transplant waiting lists each year we have made the following assumptions:
- the number of new registrants to the waiting list each year remains unchanged over time;
  - the annual number of living donors remains unchanged over time (including for any change in deceased donor consent rate); and
  - the rate at which individuals either die while on the waiting list or are removed from the list remains unchanged over time.
38. The governing equations for the number of transplanted individuals and the size of the transplant waiting lists can be seen in appendix 1. Using these equations we are able to calculate the annual numbers under both the counterfactual and with any additional transplants following a change in policy to an opt-out system of organ and tissue donation.
39. Transplanted individuals are modelled over a maximum lifetime of 50 years and a time horizon of 100 years used to calculate total costs and benefits (as it is only at this point that the difference between the counterfactual and proposed policy reaches a steady state).

#### *Costs and benefits of additional transplants*

40. To calculate the costs and benefits that any additional transplants would accrue, data on the costs, survival times and mean age of transplant, and health utility of individuals who have been transplanted and those still on the transplant waiting list were sourced from the literature and NHS reference costs. Details of the values used, as well as the values used for modelling the waiting lists, and their sources can be seen in appendix 2.
41. For the cohort of individuals on the transplant waiting list it is assumed that the health state and annual cost of medical management remains constant each year until they are either transplanted or removed from the list (due to death or any other reason).
42. For the transplanted cohort there is a one-off transplantation cost followed by annual maintenance therapy each year. It is assumed that immediately following transplantation the individual's health state will increase and then remain constant. To account for the higher resource usage in the first year following transplantation, the maintenance therapy is split into two parts: the first year following transplantation; and the second and all subsequent years.
43. By using HRG codes for transplants any additional costs associated with medical complications during organ transplantation are included.
44. The number of transplanted individuals who either die or experience organ failure each year is modelled using the exponential rate derived from the associated median survival time and the population death rate extrapolated from the mean age of transplant - whichever is greater.
45. Due to the lack of other robust data, the maintenance therapy costs following a transplant for all types of transplanted organ are assumed to be the same as for kidney and the annual medical management costs following a heart transplant are assumed to be the same as for a liver transplant.

46. Costs and benefits (QALY gains) due to the proposed policy are calculated using the difference in the number of transplanted individuals and those still on the waiting list under the modelled additional transplants and the counterfactual and multiplying this by the average resource use and health utility.

47. In addition to the health system costs associated with the transplanted individual and those on the waiting lists there are also costs incurred by NHSBT in managing the donation process (such as extracting the organs from the deceased donors and obtaining consent from the deceased's family). These costs are set at £44,210 per additional deceased donor<sup>15</sup>.

#### *Organ failure and pre-emptive transplants*

48. Once an individual has been transplanted there is a chance that the transplanted organ will fail due to rejection. As acute transplant rejection rarely leads to failure, only organ failure due to chronic rejection is considered here. In the model, the rate of organ failure following transplantation is accounted for by the "survival" probabilities of the transplant recipients.

49. Due to its slow progression and the high level of medical monitoring of transplanted individuals, it is assumed that any chronic rejection will be picked up before catastrophic failure occurs. Individuals diagnosed as suffering chronic rejection will then re-join the relevant transplant waiting list and have their treatment adjusted accordingly. In the model, the re-joining of the waiting list of such individuals is accounted for in the annual number of new registrants.

50. Pre-emptive kidney transplants (those performed while an individual's kidneys are still functional and prior to starting dialysis) are not considered in the analysis as in the majority of cases the donated kidney comes from a living donor.

#### *Omitted costs and benefits*

51. Because of a lack of data, primary care and indirect costs to the health system (such as increased length of stay or infections) have been excluded from the analysis. It is assumed that as transplanted individuals are comparatively healthier such costs will be lower than if they remained on the waiting lists and that this will offset any increased resource usage due to greater life-expectancy. This is a simplification and should be kept in mind when interpreting the outputs of this model.

52. Any potential increased health system costs associated with the death of an individual (either transplanted or on the waiting list) have also been omitted from the analysis. It is assumed that as transplant recipients live longer on average than those on the waiting lists any costs will occur further into the future and so have a lower present value making increased transplantation more cost-effective.

53. Time constraints have also meant that we have excluded any wider impacts to society as a whole (for example transplanted individuals being able to return to work).

#### *Steady state result*

54. The steady state difference<sup>16</sup> in costs and QALY gains for each type of transplant under the best estimate and the associated value and opportunity cost to the English health system can then be calculated. The cost incurred by NHSBT has been apportioned equally across each transplanted organ while the ongoing fixed costs have been excluded. All values are in year and so undiscounted with negative figures in red:

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<sup>15</sup> Cost provided by NHSBT

<sup>16</sup> The difference in in-year costs and QALY gains accrued once the proposed policy has been in place for 100 years compared to the counterfactual.

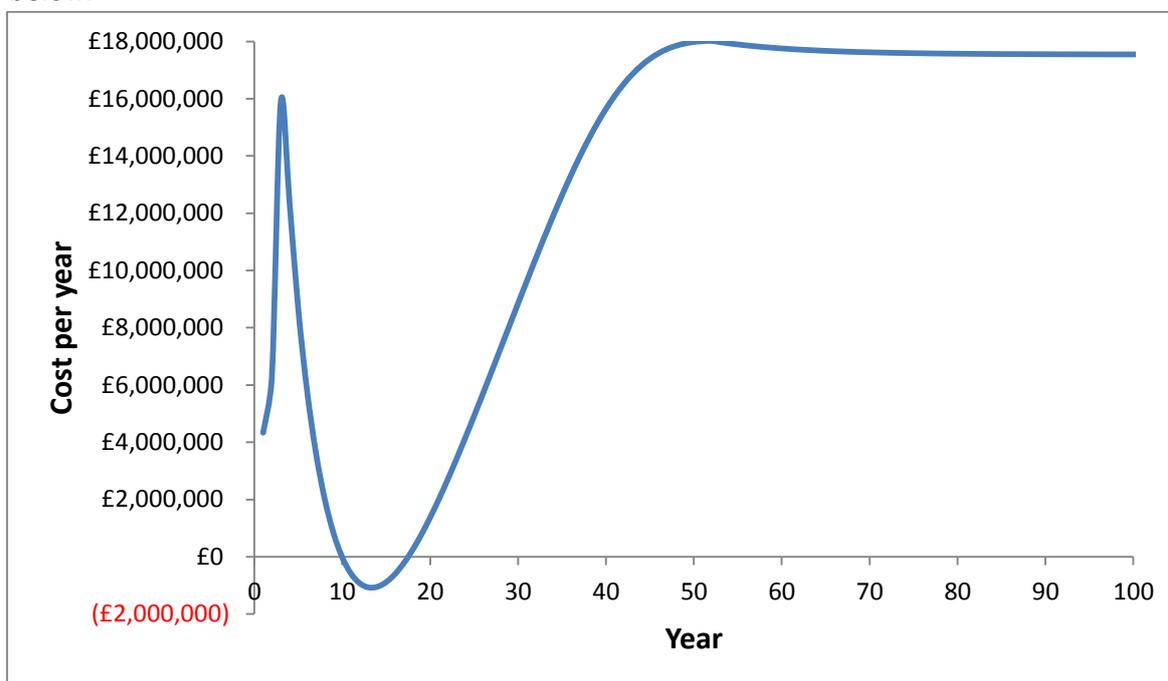
Transplant type	Cost (£k) [a]	QALY gain [b]	Opportunity cost (£k) [c = a * £60k / £15k]	Net Value (£k) [b * £60k - c]
Kidney	-£10,304	2,391	-£41,217	£184,672
Liver	£17,640	1,305	£70,559	£7,721
Heart	£3,594	234	£14,378	-£333
Lung	£1,412	85	£5,648	-£520
<b>Total</b>	<b>£12,343</b>	<b>4,015</b>	<b>£49,371</b>	<b>£191,541</b>

55. As can be seen, all additional organ transplants provide QALY gains to the health system under the steady state. For the additional heart, lung, and to a lesser extent liver transplants the proportion of the total net value they represent is small and given the inherent uncertainty in the model it would be difficult to say whether these types of transplants are cost-effective or not if considered in isolation. The kidney transplants, however, provide extremely high net value as not only do they give a large QALY gain but are also cost saving and represent 96% of the total value given by the additional deceased donors each year.

56. If we include the annual ongoing fixed costs of £5.2m for the communication package (£5m) and ODR maintenance (£0.2m) this gives a steady state cost of £17.5m that generates £240.9m worth of value and represents a £70.2m opportunity cost giving a net value of £170.7m.

#### Cost structure

57. While the steady state costs are illustrative of the final value of the proposed policy they ignore the complicated cost structure that occurs following implementation. A graph of this structure can be seen below:



58. The initial peak of £15.9m at 3 years occurs as the proposed policy comes into effect and there are 361 additional transplants. Between 3 years and 13 years the annual cost falls as the rate at which the waiting lists decrease (producing savings) is greater than the rate at which the number of transplanted individuals increase (incurring costs). This leads to a cost saving of £1.0m per year in years 13 and 14. After 13 years the waiting lists start to stabilise and so the rate of increase in costs due to the additional transplanted individuals becomes dominant. This continues until the in-year costs reach a maximum of £18.0m after 50 years before reverting to the steady state cost of £17.5m

when the costs due to transplanted individuals reach equilibrium (the number of transplanted individuals lost each year equals the number of annual transplants).

### Net Present Value

59. Using a discount factor of 1.5% and a time horizon of 100 years gives the following discounted benefits (discounted QALY gain \* £60k), discounted opportunity cost (discounted costs \* £60k / £15k), and NPV for moving to the proposed opt-out system of organ and tissue donation in England:

Scenario	Consent rate	Discounted benefits (£m)	Discounted opportunity cost (£m)	NPV (£m)
Lower estimate	62%	0	1,098	-1,098
Best estimate	70%	8,820	2,251	6,569
Upper estimate	85%	17,647	4,252	13,395

60. Our best estimation is that the policy of moving to an opt-out system of organ and tissue donation represents good value for money to the health system if a consent rate of 70% can be achieved. Our upper estimate (consent rate comparable to Spain) has an even greater positive NPV, while our lower estimate (no increase in consent rate or donors) has a negative NPV. In order to realise this value the health system would need to spend an additional £17.5m (Lower: £5.2m; Upper: £41.9m) each year once the steady state was reached (see above).

### Scenario analysis

61. Due to the uncertainty around the potential increase in consent rate following implementation of the proposed opt-system a scenario analysis has been performed to calculate the consent rate required for the estimated NPV to equal the opportunity cost. Implementing the opt-out system will represent value for money if it increases the consent rate to more than 63.5% from its current level of 62.4%. We are currently unable to comment on how likely this increase in consent rate would be observed in practice but the required increase is small.

## Sensitivity analysis

62. Sensitivity analysis has been performed on all input variables in the model. The baseline values used under the best estimate are varied across a range of 10% from a minimum value 5% below the baseline to a maximum value 5% above the baseline. The difference in NPV is then calculated between the maximum and minimum inputs. The full results of the sensitivity analysis ordered by the relative impact they have on the modelled NPV can be seen in appendix 3 and some key values are reproduced below:

Variable	Minimum NPV (£m)	Maximum NPV (£m)	Change (£m)	Relative change
Modelled consent rate	3,036	10,102	7,066	108%
Kidney WL: Cost per year	5,973	7,165	1,192	18%
Kidney Tx: QoI	6,152	6,987	835	13%
Annual deceased donors	6,186	6,952	767	12%
Kidney Tx: Cost of follow up (y2+)	6,935	6,203	-732	11%
Kidney WL: Death/removal	6,944	6,224	-720	11%
Kidney WL: QoI	6,730	6,408	-323	5%
Liver Tx: QoI	6,409	6,729	320	5%
Liver Tx: Cost of follow up (y2+)	6,705	6,433	-272	4%
NHSBT cost per donor	6,633	6,505	-128	2%
Liver WL: Cost per year	6,515	6,623	108	2%

Ongoing communications spend	6,619	6,519	-100	2%
Initial communications spend	6,572	6,567	-5	0%
Ongoing ODR spend	6,571	6,567	-4	0%
Initial ODR spend	6,570	6,569	-1	0%

Note: WL – Waiting List; Tx – Transplant; Qol – Quality of life (health state)

- 63.** The input variable with the greatest impact was the modelled consent rate where a 10% change led to a 108% change in NPV. As the value for the consent rate following implementation of an opt-out system is highly uncertain the NPV value for the best estimate should also be considered uncertain and the range between the lower and upper estimates used in deciding whether to implement the policy.
- 64.** The model is also particularly sensitive to the value for the annual number of deceased donors and the parameters used to calculate the costs and benefits of kidney transplants.
- 65.** While the annual number of deceased donors does fluctuate annually, it has increased year-on-year for the last 10 years while the consent rate has remained relatively constant. As the annual number of deceased donors is positively correlated, any increase would result in a higher NPV. As the annual number of deceased donors is assumed to be constant, this implies that the modelled best and upper estimates are probably an underestimate of the true value that would be generated by moving to an opt-out system if this year-on-year increase holds.
- 66.** The parameters used to calculate the costs and benefits of kidney transplants were taken from the literature or derived from reference costs or empirical data and are considered constant over the lifetime of a transplanted individual. While there may be some uncertainty and/or variability around these values it is unlikely to be very high or biased in a particular direction and so will not significantly change the findings of this analysis. One uncertainty not considered in the model is that as most complications will occur early on following a transplant the first year health utility state will on average be slightly lower than that over the life time of the transplant. This effect will be explored for inclusion in the final IA.
- 67.** As would be expected, the estimated NPV is more sensitive to the variables associated with modelling the value of kidney and liver donations than those associated with heart or lung transplants as these make up a greater proportion of the value from each donor.
- 68.** It should be noted that variables that did not have a significant impact on the NPV include the annual number of new registrants on any of the organ waiting lists and the transition and ongoing costs of implementing the proposed policy.

## Risks, assumptions and affordability

### *Living donors*

- 69.** The analysis only considers the impact of an opt-out system on the number of deceased donors and does not include any modelling of living donors. As living donors mainly donate kidneys which are extremely valuable and cost saving any decrease in this number could be significant. There is some research that suggests that moving to an opt-out system might depress living donor numbers but the impact is unclear. We will seek further evidence on this during the public consultation.

### *Potential of limited increase*

70. While NHSBT have estimated that moving to an opt-out system of organ donation will increase consent rate and so the number of donors the validity of this estimate is questionable. Several European countries with opt-out systems have lower donor rates than the UK and, while we are still awaiting the full results, initial data from Wales does not support a statistically significant change to their donor rates following a change to an opt-out system. We will seek further evidence of this during the public consultation.

### *Limitation of model*

71. The model used in this analysis is based on one previously developed by DH in 2006 which has been updated and had further alterations made to it in line with a 2011 NICE costing report on organ transplantation. This model is extremely high level and does not consider a lot of the subtleties around transplant pathways. It is possible that all the cost savings estimated might in reality be offset by some additional costs that have not been modelled. We will further develop the model after the consultation.

### *Capacity*

72. While this analysis has assumed that both NHSBT and the health service would have enough capacity to handle any increase in consent rate it is not clear if this is the case. Key issues raised by NHSBT include difficulty in accessing theatres outside of normal hours, the increased cost and use of pathology, and the perverse incentives such as fining Hospitals if elective surgery is cancelled for a transplant operation. We will seek further evidence of this during the public consultation. This also includes pathology.

### *Reputational risk*

73. There is a concern that errors might be made and organs taken from an individual who has opted-out. This would cause significant reputational damage. NHSBT:

*"With 23.6 million records on the NHS Organ Donor Register, a very rare error is hard/impossible to definitely prevent. For instance searching records to check that an individual has NOT opted out, this could lead to organs being taken without consent. Even a single instance of this might damage the reputation of organ donation and transplantation built up over many years. It should be noted that this risk already exists as people can already record a refusal but current very few people do. Changing legislation in England will increase this risk."*

## Appendices

### **Appendix 1: Derivation of size of waiting list and number of individuals transplanted**

1. If we assume that each year there are  $\beta_N$  new registrations and  $\beta_T$  transplanted individuals, then we can model the change in the size of the waiting list  $N_{WL}$  at time  $t$  using the following equation:

$$\frac{dN_{WL}(t)}{dt} = \beta_N - \beta_T - \lambda_{WL}N_{WL}(t)$$

where  $\lambda_{WL}$  is the annual rate at which individuals are removed from the waiting list either due to poor health or death and we assume  $N_{WL}(t) \geq 0$ . Solving the equation using  $N_{WL}(0) = N_0$  gives the following equation for the size of the waiting list at time  $t$ :

$$N_{WL}(t) = N_0 \exp(-\lambda_{WL}t) + (\beta_N - \beta_T) \left( \frac{1 - \exp(-\lambda_{WL}t)}{\lambda_{WL}} \right)$$

This can be re-written in the iterative form:

$$N_{WL}^t = N_{WL}^{t-1} \exp(-\lambda_{WL}) + (\beta_N - \beta_T) \left( \frac{1 - \exp(-\lambda_{WL})}{\lambda_{WL}} \right)$$

where  $N_{WL}^t = N_{WL}(t)$  and  $N_{WL}^{t-1} = N_{WL}(t-1)$ .

2. In the limit of  $t \rightarrow \infty$  the number of individuals on the waiting list simplifies to:

$$\lim_{t \rightarrow \infty} N_{WL}(t) = \frac{(\beta_N - \beta_T)}{\lambda_{WL}}$$

assuming  $\beta_N \geq \beta_T$  which follows from  $N_{WL}(t) \geq 0$ . If the annual number of transplants under an opt-out system of donation is given by  $\bar{\beta}_T$  and the size of the waiting list by  $\bar{N}_{WL}(t)$  then, assuming equivalent governing equations as given above, in the limit  $t \rightarrow \infty$  the difference between the size of the waiting list under an opt-in and an opt-out system converges to:

$$\lim_{t \rightarrow \infty} (\bar{N}_{WL}(t) - N_{WL}(t)) = \frac{(\beta_N - \bar{\beta}_T)}{\lambda_{WL}} - \frac{(\beta_N - \beta_T)}{\lambda_{WL}} = \frac{\Delta\beta_T}{\lambda_{WL}}$$

where  $\Delta\beta_T = \bar{\beta}_T - \beta_T$  is the number of additional transplants under an opt-out system of donation.

3. The number of person years on the waiting list in any given year  $S_{WL}(t)$  is given by:

$$\begin{aligned} S_{WL}(t) &= \int_t^{t+1} N_{WL}(t) dt \\ &= \left| \left( \frac{(\beta_N - \beta_T)}{\lambda_{WL}} - N_0 \right) \frac{\exp(-\lambda_{WL}t)}{\lambda_{WL}} + \frac{(\beta_N - \beta_T)t}{\lambda_{WL}} + C \right|_t^{t+1} \\ &= (\exp(-\lambda_{WL}) - 1) \left( \frac{(\beta_N - \beta_T)}{\lambda_{WL}} - N_0 \right) \frac{\exp(-\lambda_{WL}t)}{\lambda_{WL}} + \frac{(\beta_N - \beta_T)}{\lambda_{WL}} \\ &= \left( N_0 \exp(-\lambda_{WL}t) - \frac{(\beta_N - \beta_T)}{\lambda_{WL}} \exp(-\lambda_{WL}t) \right) \left( \frac{1 - \exp(-\lambda_{WL})}{\lambda_{WL}} \right) + \frac{(\beta_N - \beta_T)}{\lambda_{WL}} \end{aligned}$$

$$= \left( N_{WL}(t) - \frac{(\beta_N - \beta_T)}{\lambda_{WL}} \right) \left( \frac{1 - \exp(-\lambda_{WL})}{\lambda_{WL}} \right) + \frac{(\beta_N - \beta_T)}{\lambda_{WL}}$$

4. As the annual “survival” rate<sup>17</sup> of transplanted individuals (see above) changes from year to year following transplantation, the number of individuals transplanted is calculated with reference to their year of transplant. If we assume that in the reference year there are  $\beta_T$  transplanted individuals and the “survival” rate is constant at  $\lambda_T^0$ , then we can model the change in the number of individuals transplanted  $N_T^0$  using the following equation:

$$\frac{dN_T^0(t)}{dt} = \beta_T - \lambda_T^0 N_T^0(t)$$

where  $0 \leq t \leq 1$ . Solving the equation with  $N_T^0(0) = 0$ , in the same way as above, gives the following equation for the number of individuals transplanted in the reference year:

$$N_T^0(t) = \beta_T \left( \frac{1 - \exp(-\lambda_T^0 t)}{\lambda_T^0} \right)$$

The number of person years for individuals transplanted in the reference year  $S_T(0)$  is then given by:

$$\begin{aligned} S_T(0) &= \int_0^1 N_T^0(t) dt \\ &= \left| \frac{\beta_T \exp(-\lambda_T^0 t)}{(\lambda_T^0)^2} + \frac{\beta_T t}{\lambda_T^0} + C \right|_0^1 \\ &= \beta_T \left( \frac{\exp(-\lambda_T^0)}{(\lambda_T^0)^2} + \frac{1}{\lambda_T^0} - \frac{1}{(\lambda_T^0)^2} \right) \end{aligned}$$

5. For the 49 years following the reference year ( $1 \leq t \leq 50$ ), we model the change in the number of individuals transplanted  $N_T$  as:

$$\frac{dN_T(t)}{dt} = -\lambda_T(t) N_T(t)$$

where  $\lambda_T(t)$  is the annual “survival” rate. We have assumed that within each year  $y$  the “survival” rate is a constant so we can break the equation into individual years with the change in the number of individuals transplanted in each year  $N_T^y(t)$  given by:

$$\frac{dN_T^y(t)}{dt} = -\lambda_T^y N_T^y(t)$$

<sup>17</sup> This includes both death and transplant failure.

where  $0 \leq t \leq 1$  and  $\lambda_T^y$  is the constant “survival” rate for that year. This gives the solution:

$$N_T^y(t) = N_T^y(0) \exp(-\lambda_T^y t)$$

by noting that due to boundary constraints  $N_T^y(0) = N_T^{y-1}(1)$  this can then be rewritten in the iterative form:

$$N_T^y = N_T^{y-1} \exp(-\lambda_T^{y-1})$$

where  $N_T^y = N_T^y(0)$  and  $N_T^{y-1} = N_T^{y-1}(0)$ .

6. The number of person years for individuals who have been transplanted in the year  $S_T(y)$  is then given by:

$$\begin{aligned} S_T(y) &= \int_0^1 N_T^y(t) dt \\ &= \left| -\frac{N_T^y(0) \exp(-\lambda_T^y t)}{\lambda_T^y} + C \right|_0^1 \\ &= N_T^y(0) \left( \frac{1 - \exp(-\lambda_T^y)}{\lambda_T^y} \right) \end{aligned}$$

## Appendix 2: Modelling parameters

### Kidney

Item	Value	Description
<b>Transplant</b>		
No. per year (deceased)	1,877	Sourced from Quarterly ODT activity report England 2016/17
No. per year (live)	797	
Mean age of recipient	50	Sourced from ODT annual activity report 2016/17
Median survival	18.9	Data provided by NHSBT (2015)
QALYs gained per year of life	0.76	Sourced from Mendeloff et al (2004)
<b>Costs</b>		
Transplant	£15,893	Based on activity weighted NHS reference costs (2015/16) HRG LA01A/LA01B/LA02A/LA02B uprated using HM Treasury GDP deflator.
Follow up* (year 1)	£15,375	Based on activity weighted NHS reference costs (2015/16) HRG LA13A/LA13B uprated using HM Treasury GDP deflator. Assumes 25.5 episodes per transplant based on HES data (2015/16-2016/17) and includes £6.4k for immunosuppression and £2.9k for Valganciclovir (based on uprated from [NHS Kidney Care]).
Follow up* (year 2 onwards)	£10,650	Based on activity weighted NHS reference costs (2015/16) HRG LA13A/LA13B uprated using HM Treasury GDP deflator. Assumes 9.9 episodes per transplant based on HES data (2015/16-2016/17) and includes £8.3k for immunosuppression (based on uprated values from [NHS Kidney Care]).
<b>Medical management on waiting list</b>		
QALYs gained per year of life	0.56	Sourced from Mendeloff et al (2004)
Cost per year**	£31,029	Based on the combined activity weighted NHS reference costs (2015/16) for Haemodialysis and Peritoneal Dialysis** uprated using HM Treasury GDP deflator. It is assumed that 78% of patients undergo Haemodialysis (based on data from the UK renal registry) and that on average they have 3 sessions per week with annual patient transport service costs of approximately £3,100 (based on 61% usage [Kerr et al] and uprated 2009/10 activity weighted prices [PCTPTS_APC/PCTPTS_OP/PCTPTS_Oth]). A further cost of approximately £3,400 is added to account for 80% of patients undergoing dialysis being given high cost drugs not included in the best practice tariff (values based on NICE 2011 costing report uprated to 2016/17).
<b>Waiting list</b>		
No. 31st March 2017	6,910	Data provided by NHSBT (2017)
No. 31st March 2016	7,105	
New registrants 2016/17	3,084	
Transplants 2016/17	2,572	

\*As reference costs are based on full absorption costing no additional cost for immunosuppression in the first three months have been included (covered in HRG)

\*\*Due to the small numbers, home haemodialysis has been ignored

### Liver

Item	Value	Description
<b>Transplant</b>		
No. per year (deceased)	764	Sourced from Quarterly ODT activity report England 2016/17

No. per year (live)	26	
Mean age of recipient	47	Sourced from ODT annual activity report 2016/17
Median survival	15.5	Data provided by NHSBT (2015)
QALYs gained per year of life	0.78	Sourced from Mendeloff et al (2004)
<b>Costs</b>		
Transplant	£22,545	Based on activity weighted NHS reference costs (2015/16) HRG GA01A/GA01B/GA01C uprated using HM Treasury GDP deflator.
Follow up (year 1)	£15,375	Value for kidney used
Follow up (year 2 onwards)	£10,650	Value for kidney used
<b>Medical management on waiting list</b>		
QALYs gained per year of life	0.42	Sourced from Mendeloff et al (2004)
Cost per year	£26,239	Based on the average shadow costs in 1998/99 from Longworth et al scaled to 12 months and uprated using HM Treasury GDP deflator.
<b>Waiting list</b>		
No. 31st March 2017	441	Data provided by NHSBT (2017)
No. 31st March 2016	479	
New registrants 2016/17	934	
Transplants 2016/17	770	

## Heart

Item	Value	Description
<b>Transplant</b>		
No. per year (deceased)	163	Sourced from Quarterly ODT activity report England
Mean age of recipient	43	Sourced from ODT annual activity report 2016/17
Median survival	12.3	Data provided by NHSBT (2015)
QALYs gained per year of life	0.75	Sourced from Mendeloff et al (2004)
<b>Costs</b>		
Transplant	£45,118	Based on activity weighted NHS reference costs (2015/16) HRG ED02A/ED02B uprated using HM Treasury GDP deflator.
Follow up (year 1)	£15,375	Value for kidney used
Follow up (year 2 onwards)	£10,650	Value for kidney used
<b>Medical management on waiting list</b>		
QALYs gained per year of life	0.25	Sourced from Mendeloff et al (2004)
Cost per year	£26,239	Value for liver used
<b>Waiting list</b>		
No. 31st March 2017	221	Data provided by NHSBT (2017)
No. 31st March 2016	221	
New registrants 2016/17	252	
Transplants 2016/17	158	

## Lung

Item	Value	Description
<b>Transplant</b>		
No. per year (deceased)	150	Sourced from Quarterly ODT activity report England
Mean age of recipient	43	Sourced from ODT annual activity report 2016/17
Median survival	5.9	Data provided by NHSBT (2015)
QALYs gained per year of life	0.8	Sourced from Tengs et al (2000)
<b>Costs</b>		
Transplant	£33,072	Based on activity weighted NHS reference costs (2015/16) HRG DZ01Z/ED01Z uprated using HM Treasury GDP deflator.
Follow up (year 1)	£15,375	Value for kidney used
Follow up (year 2 onwards)	£10,650	Value for kidney used
<b>Medical management on waiting list</b>		
QALYs gained per year of life	0.65	Sourced from Tengs et al (2000)
Cost per year	£20,962	Based on the average cost of conventional care in 1999 of £15,000 from Anyanwu et al uprated using HM Treasury GDP deflator.
<b>Waiting list</b>		
No. 31st March 2017	286	Data provided by NHSBT (2017)
No. 31st March 2016	250	
New registrants 2016/17	263	
Transplants 2016/17	144	

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### Appendix 3: Sensitivity analysis

Variable	Baseline value	Minimum value	Maximum value	Minimum NPV (£m)	Maximum NPV (£m)	Change (£m)	Relative change
Modelled consent rate	70%	67%	74%	3,036	10,102	7,066	108%
Kidney WL: Cost per year	£31,029	£29,478	£32,581	5,973	7,165	1,192	18%
Kidney Tx: QoI	0.76	0.722	0.798	6,152	6,987	835	13%
Annual deceased donors	4,900	4,655	5,145	6,186	6,952	767	12%
Kidney Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	6,935	6,203	-732	11%
Kidney WL: Death/removal	10.09%	9.59%	10.60%	6,944	6,224	-720	11%
Kidney WL: QoI	0.56	0.532	0.588	6,730	6,408	-323	5%
Liver Tx: QoI	0.78	0.741	0.819	6,409	6,729	320	5%
Liver Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	6,705	6,433	-272	4%
NHSBT cost per donor	£44,210	£42,000	£46,421	6,633	6,505	-128	2%
Liver WL: Cost per year	£26,239	£24,927	£27,551	6,515	6,623	108	2%
Ongoing communications spend	£5,000,000	£4,750,000	£5,250,000	6,619	6,519	-100	2%
Liver WL: Death/removal	44.14%	41.94%	46.35%	6,610	6,532	-79	1%
Kidney Tx: Cost of transplant	£15,893	£15,099	£16,688	6,606	6,532	-74	1%
Kidney Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	6,604	6,535	-69	1%
Heart Tx: QoI	0.75	0.7125	0.7875	6,540	6,598	58	1%
Heart Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	6,594	6,544	-50	1%
Liver Tx: Cost of transplant	£22,545	£21,418	£23,672	6,590	6,548	-43	1%
Lung Tx: QoI	0.8	0.76	0.84	6,553	6,585	32	0%
Liver Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	6,583	6,555	-28	0%
Liver WL: QoI	0.42	0.399	0.441	6,582	6,556	-26	0%
Lung Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	6,582	6,557	-25	0%
Kidney Tx: Median survival	18.9	17.955	19.845	6,557	6,581	24	0%
Heart WL: Cost per year	£26,239	£24,927	£27,551	6,557	6,581	24	0%
Lung WL: Cost per year	£20,962	£19,913	£22,010	6,557	6,581	24	0%
Heart WL: Death/removal	42.42%	40.30%	44.54%	6,579	6,560	-20	0%
Heart Tx: Cost of transplant	£45,118	£42,862	£47,374	6,578	6,560	-18	0%
Liver Tx: Median survival	15.5	14.725	16.275	6,561	6,577	15	0%

Lung Tx: Cost of transplant	£33,072	£31,418	£34,725	6,575	6,563	-12	0%
Lung WL: Death/removal	30.86%	29.32%	32.41%	6,575	6,563	-12	0%
Lung WL: QoI	0.65	0.6175	0.6825	6,575	6,564	-11	0%
Heart Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	6,572	6,566	-6	0%
Lung Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	6,572	6,567	-5	0%
Initial communications spend	£13,000,000	£12,350,000	£13,650,000	6,572	6,567	-5	0%
Ongoing ODR spend	£200,000	£190,000	£210,000	6,571	6,567	-4	0%
Heart WWL: QoI	0.25	0.2375	0.2625	6,571	6,567	-3	0%
Lung Tx: Median survival	5.9	5.605	6.195	6,568	6,571	3	0%
Heart Tx: Median survival	12.3	11.685	12.915	6,568	6,570	2	0%
NHSBT initial ODR spend	£2,000,000	£1,900,000	£2,100,000	6,570	6,569	-1	0%
Kidney Tx: Live donors	797	757	837	6,569	6,569	0	0%
Kidney WL: New registrants	3,084	2,930	3,238	6,569	6,569	0	0%
Liver Tx: Live donors	26	25	27	6,569	6,569	0	0%
Liver WL: New registrants	934	887	981	6,569	6,569	0	0%
Heart WL: New registrants	252	239	265	6,569	6,569	0	0%
Lung WL: New registrants	263	250	276	6,569	6,569	0	0%