Title: An opt-out system of organ and tissue donation	Impact Assessment (IA)
IA No:	**Date: 13/6/2018**
Lead department or agency: Department of Health	**Stage: Final**
Other departments or agencies:	**Source of intervention:** Domestic
	Type of measure: Other
	Contact for enquiries: organdonation@dh.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

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**
£5,260m	£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 would be required to make the corresponding change to the legislation covering organ and tissue donation.

What are the policy objectives and the intended effects?

The reforms are intended to: 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.

The Government's preferred option is Option 1, which is thought likely to meet the policy objectives.

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.	**Micro** No	**< 20** No	**Small**No	**Mediu m**No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** 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	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)		
N/A	N/A	N/A	**Low:** Optional	**High:** Optional	**Central Estimate: 0**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Central Estimate	0		0	**0**

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.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Central Estimate	0		**0**	**0**

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)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	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	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)		
2016/17	2016/17	100 years	**Low: -95**	**High: 14,122**	**Central Estimate: 5,260**

COSTS (£m)	Total Transition (Years)		Average Annual (excl. Transition)	Total Cost (Present Value)
Low	97		0	**95**
High	97	3	23	**526**
Central Estimate	97		4	**120**

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

The transition costs: a) an £18m NHSBT spend on communications over the first 4 years; and b) £5.8m for managing opt-out registrations on the organ donor register (ODR). Both of these transition costs estimates have yet to be finalised and are hence subject to change. However, within any reasonable bounds of change, revisions to these estimates would not change the overall conclusions on value for money. The average annual cost: a) an annual one-off cost for any additional transplants and the ongoing medical costs of transplant recipients; b) NHS savings from individuals on the waiting list being transplanted.

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).

BENEFITS (£m)	Total Transition (Years)		Average Annual (excl. Transition)	Total Benefit (Present Value)
Low	0		0	**0**
High	8	3	319	**14,647**
Central Estimate	2		121	**5,380**

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 **Discount rate (%)** 1.5

Under Option 1 the consent rate is assumed to increase by 0, 7, and 13 percentage points under the low, central, and high estimates respectively. While the central assumption is based on recommendations from NHSBT, the high and low scenarios were chosen to reflect the substantial uncertainty we have over the most plausible change in consent rates. There is currently little evidence to support specific assumptions about the increase in the consent rate in England. The estimated NPV is extremely sensitive to this increase. Nevertheless, our analysis suggests that the policy's benefits would equal its costs if consent rates were to rise by just 0.6 percentage points. We suggest that this modest break-even level of increase is plausibly achievable.

Key assumption in these estimates is that following the reform there will be no change to the annual number of kidney and liver transplants from living donors

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	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. This change is expected to lead to higher levels of consent and in turn lead to more transplants. While any additional transplants would represent an increased cost to the NHS, these transplants are expected to generate more net social benefits than if the money were to be spent elsewhere in the health system.

This IA examines the evidence behind these expectations.

The Government held a public consultation on its opt-out proposals between December 2017 and March 2018. This Final IA updates the analysis that was presented in the Consultation IA.

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, such as communications campaigns, 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 statistically significant 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 have been questions over whether the health system has the capacity to transplant additional organs. During the consultation we discussed this issue with NHS England and NHS Blood and Transplant. We concluded that the transplantation system is under considerable pressure. However, NHSE concluded that the way we had estimated transplant costs already allowed for the possibility of additional capacity investment, and hence our analysis did not need to change.

Would implementing an opt-out policy be a good use of health system resources? There is currently very little evidence to support assumptions about the potential size of any increase in consent rates in England. A wide range of possibilities is presented in this IA. Nevertheless our analysis suggests that the policy's benefits would equal its costs if consent rates were to rise by 0.6 percentage points (and that this led to a proportionate increase in organ transplants). This is a change from the estimated break-even point reported in the Consultation IA (1.5 percentage point increase). The difference is almost entirely accounted for by NHSBT's recent decision that it would not need additional funding for on-going opt-out communications campaigns. We suggest that the 0.6 percentage point increase is plausibly achievable.

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[1]. 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[2]. 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 final impact assessment. It updates the consultation IA that was produced for the 12 week public consultation that was held between December 2017 and March 2018.

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[3]. 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.

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

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

[3] 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[4]. 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[5]. 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.

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4 http://webarchive.nationalarchives.gov.uk/20130124044543/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090295.pdf

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

12) The Government has consulted on moving from an opt-in system of organ and tissue donation to an opt-out system in England. The consultation asked people to express their views on how such a system should be implemented. In particular, it considered how the issue of 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 the role of the family.

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 to which families are consulted in decision making. The consultation sought views on different potential options.

14) In light of responses to the consultation, the Government has proposed that the legislation in England contains the same provisions as in the Welsh law, whereby:
    a) people can still register consent to donation by adding their name to the ODR
    b) those who do not will be presumed to have consented unless they have expressly opted-out (e.g. on the ODR)
    c) there will be some exemptions to this presumption:
        i) if the family can provide information to show that the deceased was opposed to giving consent
        ii) for those who have not been ordinarily resident in England for 12 months
        iii) for those under age 18
        iv) for adults without the capacity to understand the effect of the changes

Lessons from the public consultation

15) Although the consultation attracted approximately 17,000 responses, very few of them addressed the analysis in the consultation IA. Alongside the consultation, we held discussions with both NHSE and NHSBT. Several new insights led to changes in our analysis:

a) We gathered new information on the length of post-transplant survival. From this we generated new survival curves for use in our cost effectiveness analysis. The main effect was to reduce the median survival time post kidney transplant. Because kidney transplants are the most numerous type of transplant and are estimated to be cost saving to the NHS, they are the key driver of our cost benefit conclusions. The overall effect of changing all the median survival times was to reduce the NPV by about 1%.
b) In discussions with NHSE, we concluded that there are significant pressure points in the NHS's current transplant capacity, particularly around theatre access, surgical rotas and donor characterisation lab services. Whether new investment would be required as a direct result of adopting the opt-out policy is a moot point (through existing policies, there are already plans to increase capacity). Nevertheless, NHSE concluded that the way we had estimated transplant costs already allowed for the possibility of additional capacity investment, and hence our analysis did not need to change.
c) NHSBT reassessed its costs. In particular it reduced its estimates of the additional funds it would require to run its communications campaigns. Of special significance to our analysis was NHSBT's decision that it could fund its on-going opt-out communications as part of its "business as usual" communications, and would not have to curtail any of its other activities. This removed a significant annual expenditure from our analysis and hence significantly improved the policy's Net Present Value. It also substantially reduced the estimated improvement in consent rate that would be required for the policy's benefits to equal its costs – the consultation IA estimated that

the break-even point would be reached with a 1.5 percentage point increase in consent rate, whereas we now estimate that the required increase is 0.6 percentage points.

Costs and Benefits of Policy

16) 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.

17) 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.

18) 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: 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.

Transition costs

19) 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). The cost estimates provided here are subject to change. However, they represent a very small fraction of the overall costs assessed in this IA. We have therefore concluded that any feasible revisions of the communications and ODR costs would have no impact on our overall conclusions about value for money.

20) Following the change in Wales, the capability already exists for the ODR to record opt-out registrations. However, according to 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. NHSBT has estimated a cost of £5.8m (subject to revision) to absorb the increase in opt-out confirmation and validation tasks, enquiries to the National Call Centre, and potential ODR system changes.

21) 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 £18m (subject to revision) over a four year period.

22) Note that in the Consultation IA, we reported that NHSBT assessed that it would need an additional £5 million to cover the costs of on-going communications campaigns. NHSBT has recently reassessed this requirement and no longer believes that this additional funding would be required.

Instead it would fund its on-going opt-out communications as part of its "business as usual" communications, and would not have to curtail any of its other activities.

23) There may be further additional costs as the health system moves to new technologies in the future to improve the overall system of organ donation. Such costs would be for example perfusion costs currently estimated at £7m per annum. However, these costs are not addressed in this impact assessment which considers the impact of deemed consent in isolation. Perfusion costs and other new technologies in the future will the subject of further investigation and analysis to demonstrate their own inherent value for money within the overall strategy for organ donation.

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 have only considered single-organ kidney, heart, liver, and lung transplants as these make up 94% of all organs transplanted[6] 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 1,214 DBD and 3,611 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.

[6] Organ Donation and Transplantation Activity Data: ENGLAND available from https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/

30) As discussed in paragraph 10, the view of DHSC's Chief Scientific Adviser's (see paragraph 10) is that we can be moderately certain that, when introduced as part of a wider package, opt-out systems can lead to higher organ donation. However, there is currently little evidence to assess what might be a plausible extent of any increase in England. In our analysis we have therefore presented a range of possibilities. 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 parameters suggested by NHSBT[7]:
    - Central estimate, in which the overall consent rate increases from the 2016/17 value of 63% to 70%;
    - Lower estimate, in which the overall consent rate remains unchanged; and
    - Upper estimate, in which the overall consent rate increases to 76% in line with the percentage increase seen so far in Wales[8].

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:

Scenario	Consent rate	Additional donors per year	% Change
Lower estimate	63%	0	0%
Central estimate	70%	100	9%
Upper estimate	76%	208	18%

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[9] there were 1,877 kidney, 764 liver, 163 heart, and 150 lung transplants[10]. While organs can be imported from overseas the annual numbers are relatively small and so have been ignored in this analysis[11]. The number of additional transplants is then calculated

[7] In the consultation IA we reported different figures to those that now appear in the table. We based our original figures on calculations we performed using NHSBT figures. Our estimates differed from those produced by NHSBT. We subsequently discovered from NHSBT that inconsistencies in the data sources used by NHSBT mean that the 2016/17 donor numbers can't be calculated from the reported consent rates. For the sake of consistency, we have adopted NHSBT's estimates, although this required us to use an implied 2016/17 consent rate of 64% in our analysis.

[8] The change in Wales has not yet been proven to be statistically significant. The small numbers involved in the Welsh experience means that there is significant year to year random variation in consent rates. The lack of statistical significance does not mean that an increase due to the opt-out policy has not taken place.

[9] See 6

[10] These numbers are for recipients on the English transplant waiting list and with postcodes resident in England, Channel Island and Isle of Man

[11] See Appendix of "Organ Donation and Transplantation: Annual activity report" available from https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/

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:

Scenario	No. of additional transplants per year				
	Kidney	Liver	Heart	Lung	Total
Lower estimate	0	0	0	0	0
Central estimate	161	66	14	13	254
Upper estimate	335	137	29	27	528

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.

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:
   a) the number of new registrants to the waiting list each year remains unchanged over time;
   b) the annual number of living donors remains unchanged over time (including for any change in deceased donor consent rate); and
   c) 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 Healthcare Resource Group (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[12].

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.

[12] Cost provided by NHSBT

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) For this Final IA we have examined wider impacts to society as a whole (for example transplanted individuals being able to return to work). These wider impacts can either add to societal welfare through increased production of goods and services (both paid and unpaid) or reduce societal welfare through increased consumption of such things as formal and informal care, private goods and government provided services. We examined the likely balance between additional production and consumption (both as a result of health gains associated with transplantation and as a result of the foregone health gains from redirecting expenditure to transplantation from alternative health interventions). We concluded that the overall effect was too ambiguous to estimate with any confidence and hence we have not included wider societal impact estimates in this final IA.

Steady state result

54) The steady state difference[13] in costs and QALY gains for each type of transplant under the central 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:

Transplant type	**Cost (£k) [a]**	**QALY gain [b]**	**Opportunity cost (£k) [c = a * £60k / £15k]**	**Net Value (£k) [b * £60k - c]**
Kidney	-£12,253	1,334	-£49,011	£129,031
Liver	£11,305	837	£45,222	£5,004
Heart	£2,601	170	£10,404	-£221
Lung	£1,017	62	£4,067	-£357
Total*	£2,670	2,402	£10,681	£133,456

*May not sum due to rounding

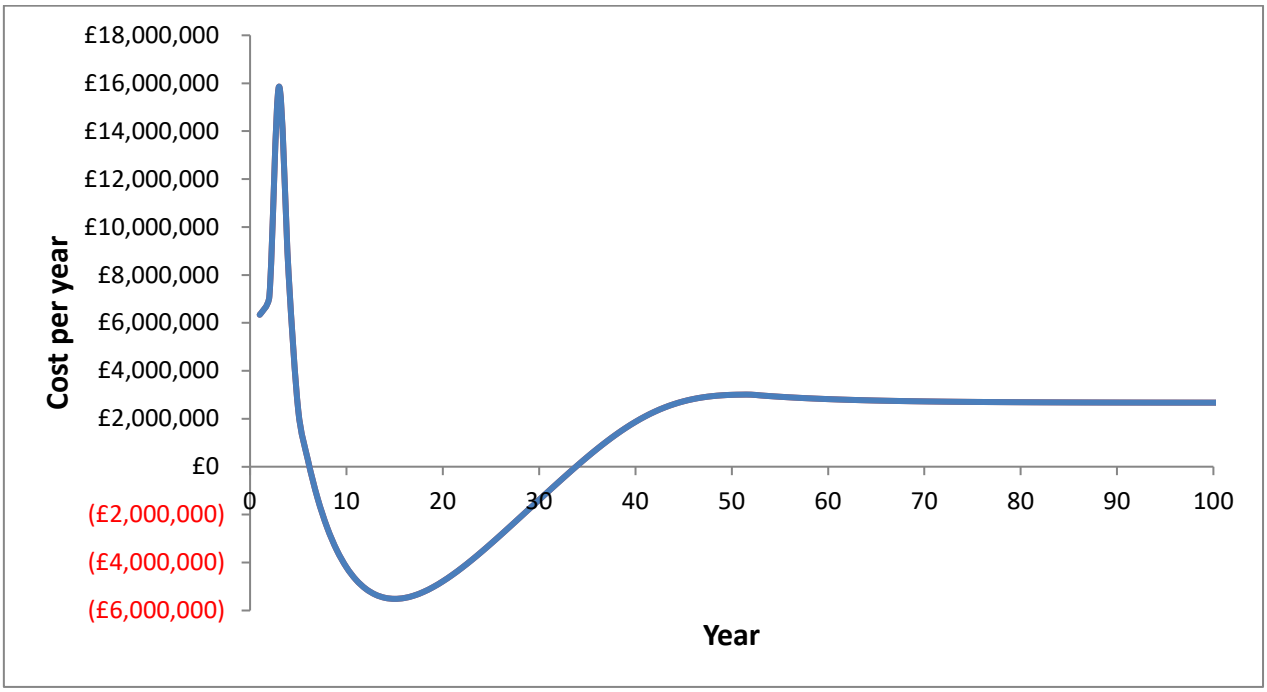
55) As can be seen, all additional organ transplants provide QALY gains to the health system under the steady state. For the additional heart, lung, and to a lesser extent liver transplants the proportion of the total net value they represent is small and given the inherent uncertainty in the model it 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 97% of the total value given by the additional deceased donors each year.

56) This gives a steady state cost of £2.7m that generates £144.1m worth of value and represents a £10.7m opportunity cost giving a net value of £133.5m.

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:

[13] 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.



58) The initial peak of £15.9m at 3 years occurs as the proposed policy comes into effect and there are 254 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 £5.5m per year in years 15 and 16. 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 £3.0m after 50 years before reverting to the steady state cost of £2.7m when the costs due to transplanted individuals reach equilibrium (the number of transplanted individuals lost each year equals the number of annual transplants).

Health system costs per additional donor

59) The table below provides estimates of the NHS and NHSBT direct costs associated with each additional donor. The estimates include the NHSBT costs of retrieving organs from the donor, and the NHS costs of a) transplantation, b) costs of organ recipient medical maintenance post-transplant, and c) cost savings from not having to medically maintain patients on the transplantation waiting lists. Future costs have been discounted at 1.5%.

60) Note that these costs do not include indirect costs that arise because of waiting list effects. Each additional donor reduces the time that all patients on the waiting lists have to wait to undergo transplantation. This brings forward transplantations and hence also their associated costs and cost savings. The size of this indirect effect is small compared with the direct costs.

	NHSBT organ retrieval (Year 1)	NHSE Transplant (Year 1)	NHSE Maintenance						
			Year 1	Year 2	Year 3	Year 4	Year 5	Years 6 - 50	Total
Costs	£44,000	£51,000	£19,000	£31,000	£24,000	£22,000	£21,000	£281,000	£493,000
Savings	£0	£0	£67,000	£55,000	£46,000	£39,000	£33,000	£248,000	£487,000
Total costs	£44,000	£51,000	-£48,000	-£24,000	-£22,000	-£17,000	-£13,000	£34,000	£6,000

61) The table indicates that in the year of transplantation, there is a net cost to the health system of £47,000 (£44,000 NHSBT organ retrieval costs + £51,000 NHSE transplant cost + £19,000 NHSE transplanted patient maintenance cost – £67,000 NHSE cost saving from no longer maintaining transplanted patients on the waiting list). In years two to five after transplantation, the NHS benefits from a net cost saving in each year. In aggregate, over fifty years (which is approximately the maximum potential lifespan of an organ recipient post-transplant), the health system bears a net discounted cost of £6,000. This estimate is sensitive to the choice of discount rate. Using a 3.5% discount rate, the analysis suggests that the health system benefits from a net cost saving of £13,000 over the fifty year period.

Net Present Value

62) 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	63%[14]	0	95	-95
Central estimate	70%	5,380	120	5,260
Upper estimate	76%	11,189	147	11,042

63) Our central 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.

Breakeven analysis

64) Due to the considerable uncertainty around the potential increase in consent rate following implementation of the proposed opt-system a breakeven analysis has been performed to calculate the consent rate required for the estimated societal benefits to equal the estimated societal costs. Implementing the opt-out system will represent value for money if it increases the consent rate by more than 0.6 percentage points. We suggest that this modest increase is plausibly achievable.

Sensitivity analysis

65) Sensitivity analysis has been performed on all input variables in the model. The baseline values used under the Central 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	1,888	8,633	6,745	64%
Kidney WL: Cost per year	4,840	5,681	842	8%
Annual deceased donors	4,993	5,528	536	5%
Kidney Tx: QoI	5,000	5,520	520	5%
Kidney WL: Death/removal	5,525	5,017	-508	5%

[14] See footnote 12

Kidney Tx: Cost of follow up (y2+)	5,486	5,034	-452	4%
Kidney WL: QoI	5,374	5,146	-228	2%
Liver Tx: QoI	5,155	5,365	210	2%
Liver Tx: Cost of follow up (y2+)	5,349	5,172	-177	2%
NHSBT cost per donor	5,305	5,215	-90	1%
Liver WL: Cost per year	5,222	5,298	76	1%
Liver WL: Death/removal	5,289	5,234	-55	1%
Kidney Tx: Cost of transplant	5,286	5,234	-52	0%
Kidney Tx: Cost of follow up (y1)	5,285	5,236	-48	0%
Heart Tx: QoI	5,240	5,281	42	0%

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

66) The input variable with the greatest impact was the modelled consent rate where a 10% change led to a 64% 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.

67) 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.

68) 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.

69) 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. We could find no method in the academic literature for correcting for this effect.

70) 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.

71) 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 costs.

72) The Government proposes to set an ambition to see consent rates increased to 80%. If this can be realised, it would mean about 280 more donors than current levels, which is equivalent to about 700 more organ transplants.

Risks, assumptions and affordability

Living donors

73) 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. No new evidence came to light during the consultation.

Potential of limited increase

74) 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. No new evidence came to light during the consultation.

Limitation of model

75) 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 high level and does not consider 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. Whilst the underlying data was updated during the consultation, no structural changes to the model were developed.

Reputational risk

76) 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 β_N new registrations and β_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 λ_{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 $t \to \infty$ the number of individuals on the waiting list simplifies to:

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

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 $t \to \infty$ the difference between the size of the waiting list under an opt-in and an opt-out system converges to:

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

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:

$$S_{WL}(t) = \int_t^{t+1} N_{WL}(t)\, dt$$

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

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

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

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

4. As the annual "survival" rate[15] 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 β_T transplanted individuals and the "survival" rate is constant at λ_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:

$$S_T(0) = \int_0^1 N_T^0(t)\, dt$$

$$= \left|\frac{\beta_T \exp(-\lambda_T^0 t)}{(\lambda_T^0)^2} + \frac{\beta_T t}{\lambda_T^0} + C\right|_0^1$$

$$= \beta_T\left(\frac{\exp(-\lambda_T^0)}{(\lambda_T^0)^2} + \frac{1}{\lambda_T^0} - \frac{1}{(\lambda_T^0)^2}\right)$$

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 eacht year $N_T^y(t)$ given by:

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

[15] This includes both death and transplant failure.

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

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

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:

$$N_T^Y = N_T^{Y-1}\,\exp\left(-\lambda_T^{y-1}\right)$$

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:

$$S_T(y) = \int_0^1 N_T^y(t)\,dt$$

$$= \left| -\frac{N_T^y(0)\exp(-\lambda_T^y t)}{\lambda_T^y} + C \right|_0^1$$

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

Appendix 2: Modelling parameters

Kidney

Item	Value	Description
Transplant		
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	14.7	Data provided by NHSBT (2015)
QALYs gained per year of life	0.76	Sourced from Mendeloff et al (2004)
Costs		
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]).
Medical management on waiting list		
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).
Waiting list		
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
Transplant		
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	13.6	Data provided by NHSBT (2015)
QALYs gained per year of life	0.78	Sourced from Mendeloff et al (2004)
Costs		
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
Medical management on waiting list		
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.
Waiting list		
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
Transplant		
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	12.7	Data provided by NHSBT (2015)
QALYs gained per year of life	0.75	Sourced from Mendeloff et al (2004)
Costs		
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
Medical management on waiting list		
QALYs gained per year of life	0.25	Sourced from Mendeloff et al (2004)
Cost per year	£26,239	Value for liver used
Waiting list		
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
Transplant		
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	6	Data provided by NHSBT (2015)
QALYs gained per year of life	0.8	Sourced from Tengs et al (2000)
Costs		
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
Medical management on waiting list		
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.
Waiting list		
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%	1,888	8,633	6,745	64%
Kidney WL: Cost per year	£31,029	£29,478	£32,581	4,840	5,681	842	8%
Annual deceased donors	4,825	4,584	5,066	4,993	5,528	536	5%
Kidney Tx: QoI	0.76	0.722	0.798	5,000	5,520	520	5%
Kidney WL: Death/removal	10.09%	9.59%	10.60%	5,525	5,017	-508	5%
Kidney Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	5,486	5,034	-452	4%
Kidney WL: QoI	0.56	0.532	0.588	5,374	5,146	-228	2%
Liver Tx: QoI	0.78	0.741	0.819	5,155	5,365	210	2%
Liver Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	5,349	5,172	-177	2%
NHSBT cost per donor	£44,210	£42,000	£46,421	5,305	5,215	-90	1%
Liver WL: Cost per year	£26,239	£24,927	£27,551	5,222	5,298	76	1%
Liver WL: Death/removal	44.14%	41.94%	46.35%	5,289	5,234	-55	1%
Kidney Tx: Cost of transplant	£15,893	£15,099	£16,688	5,286	5,234	-52	0%
Kidney Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	5,285	5,236	-48	0%
Heart Tx: QoI	0.75	0.7125	0.7875	5,240	5,281	42	0%
Heart Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	5,279	5,242	-36	0%
Liver Tx: Cost of transplant	£22,545	£21,418	£23,672	5,275	5,245	-30	0%
Lung Tx: QoI	0.8	0.76	0.84	5,249	5,272	23	0%
Liver Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	5,270	5,251	-20	0%
Kidney Tx: Median survival	14.7	13.965	15.435	5,251	5,269	18	0%
Liver WL: QoI	0.42	0.399	0.441	5,269	5,251	-18	0%
Lung Tx: Cost of follow up (y2+)	£10,650	£10,117	£11,182	5,269	5,251	-18	0%
Heart WL: Cost per year	£26,239	£24,927	£27,551	5,252	5,269	17	0%
Lung WL: Cost per year	£20,962	£19,913	£22,010	5,252	5,269	17	0%
Heart WL: Death/removal	42.42%	40.30%	44.54%	5,268	5,254	-14	0%
Heart Tx: Cost of transplant	£45,118	£42,862	£47,374	5,267	5,254	-13	0%
Liver Tx: Median survival	13.6	12.92	14.28	5,255	5,266	11	0%
Lung Tx: Cost of transplant	£33,072	£31,418	£34,725	5,265	5,256	-9	0%

Lung WL: Death/removal	30.86%	29.32%	32.41%	5,265	5,256	-8	0%
Lung WL: Qol	0.65	0.6175	0.6825	5,264	5,256	-8	0%
Heart Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	5,262	5,258	-4	0%
Lung Tx: Cost of follow up (y1)	£15,375	£14,606	£16,144	5,262	5,259	-4	0%
Heart WL: Qol	0.25	0.2375	0.2625	5,262	5,259	-2	0%
Lung Tx: Median survival	6	5.7	6.3	5,259	5,261	2	0%
Heart Tx: Median survival	12.7	12.065	13.335	5,260	5,261	1	0%
Kidney Tx: Live donors	797	757	837	5,260	5,260	0	0%
Kidney WL: New registrants	3,084	2,930	3,238	5,260	5,260	0	0%
Lung WL: New registrants	263	250	276	5,260	5,260	0	0%
Liver WL: New registrants	934	887	981	5,260	5,260	0	0%
Initial communications spend	£18,000,000	£17,100,000	£18,900,000	5,260	5,260	0	0%
Initial ODR spend	£2,000,000	£1,900,000	£2,100,000	5,260	5,260	0	0%
Liver Tx: Live donors	26	25	27	5,260	5,260	0	0%
Heart WL: New registrants	252	239	265	5,260	5,260	0	0%