Organ Donation and Transplantation: Meeting the Need

A ten-year vision for organ donation and transplantation in the United Kingdom

First draft for Board
N.B. All data, tables, targets etc. are to be confirmed

Acknowledgements

To be added

Contents

To be added

Foreword

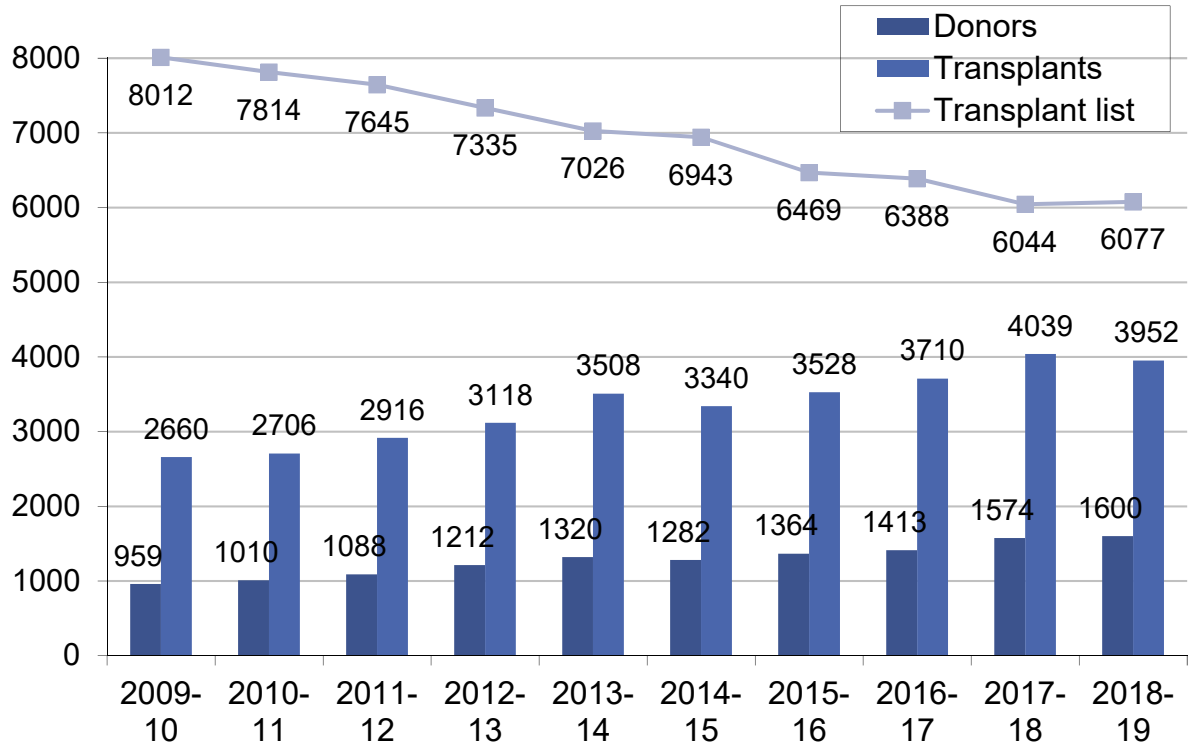
Aim for statement from Chairman, Director of ODT and 4 Health Ministers on behalf of the UK's home countries

Summary

For over fifty years, the United Kingdom has made great progress and developed world-leading expertise in organ donation and transplantation medicine and surgery – thereby giving hope to everyone needing a transplant to save and improve their life.

Following the publication of the Organ Donor Taskforce Report *Organs for Transplant* in 2008 and the subsequent strategies *Taking Organ Transplantation to 2020* and *the Living Donor Kidney Transplant 2020 Strategy,* the UK has made a step change in increasing the number of organs available and transplanted.

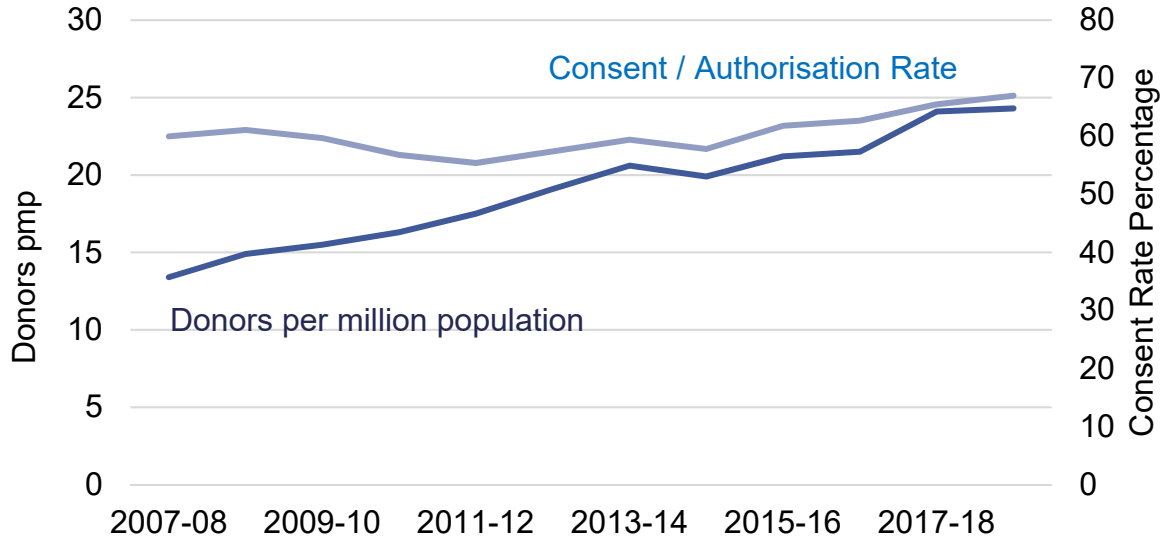
Since 2009, the number of deceased organ donors has risen from 959 (2009/10) to 1,600 (2018/19) and the number of transplants from these donors has increased from 2,660 to 3,951.



This dramatic achievement follows the focus in earlier strategies on ensuring that the NHS embraced organ donation as a usual part of end-of-life care. The foundation of this success was a model of local clinical and donation committee leadership and a focus on consent or authorisation for deceased organ donation.

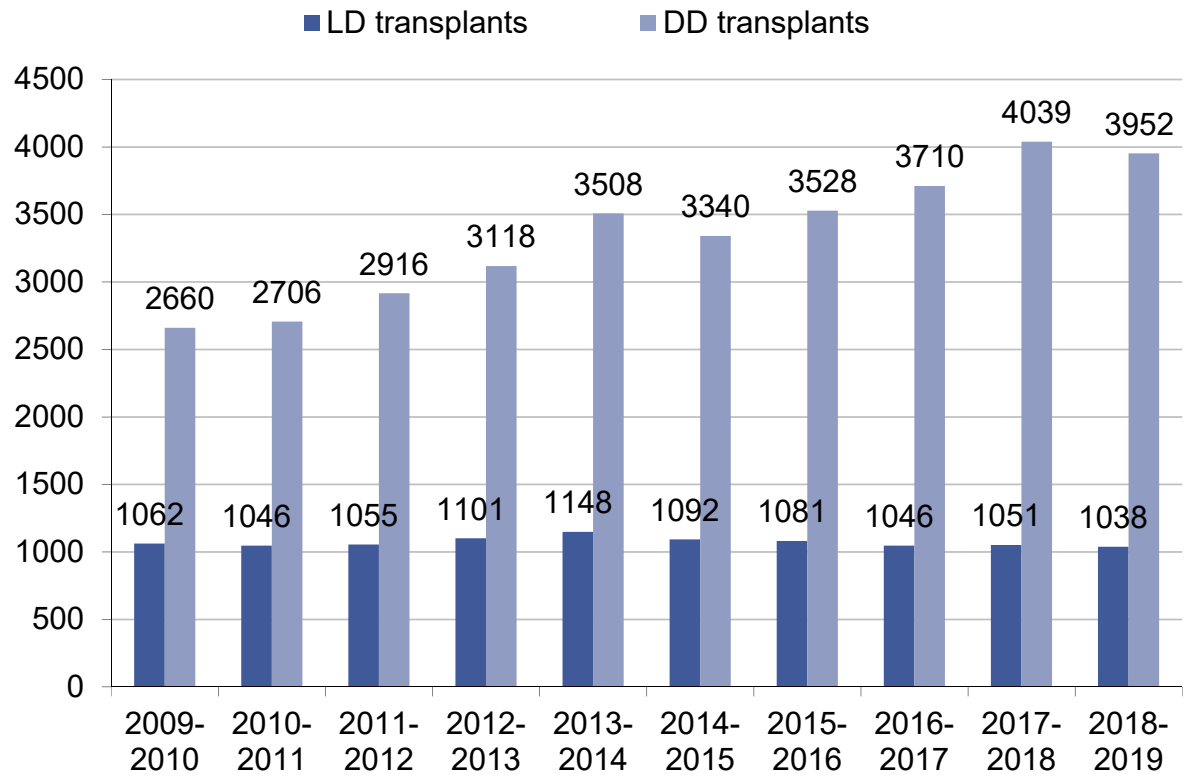
In 2015, another milestone was reached when Wales implemented deemed consent legislation (a “soft opt-out” system). Over time, the change in law in Wales has seen their consent rate rising significantly. Scotland and England have recently passed similar legislation for planned implementation in 2020, with Jersey and Guernsey having already done so.

Making the most of this opportunity remains vital to progress in the coming years.

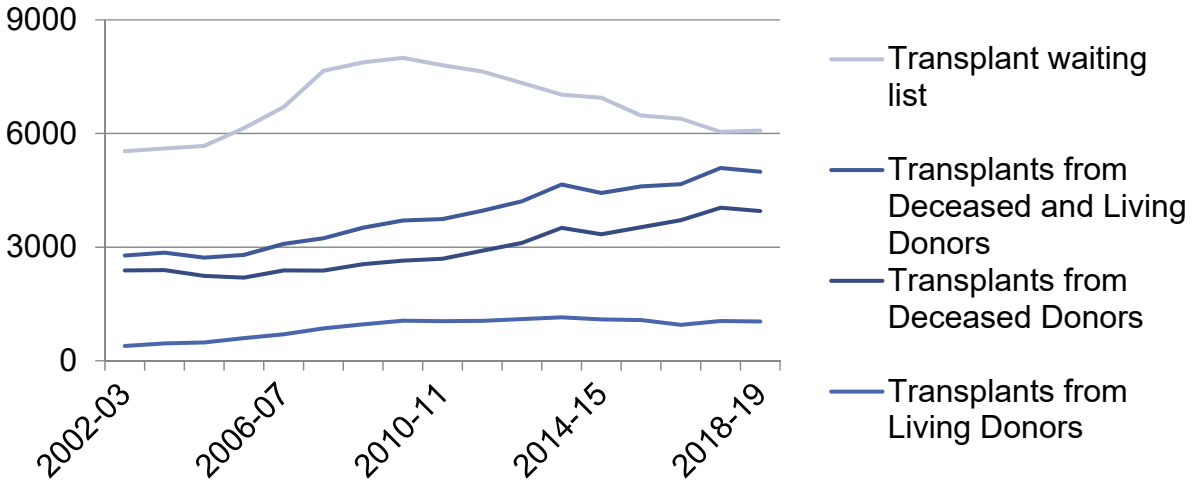


During the same period, the number of people coming forward as living donors has remained relatively stable at approximately 1,000 each year – partly due to the reduced wait for an organ from a deceased donor. The contribution of non-directed donors has also increased the quality and number of transplant opportunities available to people waiting for a kidney transplant, thereby reducing the demand for more complex transplant options for long-waiting patients.

1,038 living donor transplants were performed in 2018/19, including almost 90 non-directed living donors who donated to a stranger.



As a result of these increases, there are fewer people now waiting for a transplant.



Our existing Strategies

Our *Taking Organ Transplantation to 2020* strategy was published in 2013 with the aim of matching world-class performance in organ donation and transplantation. Four areas of focus were set out:

Who	Outcome	Achieved?
Society and Individuals	Attitudes to organ donation will change and people will be proud to donate, when and if they can.	Consent / authorisation rate 80% (was 57%) Currently 68%
NHS hospitals and staff (donation)	Excellent care in support of organ donation will be routinely available and every effort made to ensure that each donor can give as many organs as possible.	26 deceased donors per million population (was 19 pmp) Currently c.25 pmp
NHS hospitals and staff (transplantation)	More organs will be usable and surgeons will be better supported to transplant organs safely into the most appropriate recipient.	Transplant 5% more of organs offered from consented, actual donors Not achieved (varies by organ group)
NHSBT and commissioners	Better support systems and processes will be in place to enable more donations and transplant operations to happen.	Deceased donor transplant rate of 74 pmp (was 49 pmp) Currently 64 pmp

In response, strategies for Living Donation, Organ Utilisation and Paediatric Donation were later published. These will be incorporated into this single new strategy.

More people could benefit from a transplant

The UK has achieved clear progress in all areas since 2013, overcoming many challenges to give more people the life-changing benefit of a transplant.

However, our progress also indicates that continued action is needed in two specific areas: to raise consent / authorisation and to improve organ utilisation. There also remains unmet need – and potentially another 2,200 transplants per year would be required to meet current demand. In addition, the UK's substantial achievements to date have been uneven in their impact.

This is because the fall in the number of people waiting for a kidney, liver or pancreas masks an increase in the number of people waiting for a heart or lungs.

Despite progress, people who are black, Asian or of a minority ethnicity are also still disproportionately affected by shortfalls and longer waits for a suitable organ for transplantation. This is partly because of lower rates of organ donation amongst these communities.

The new Strategy

Noting the huge successes of donation and transplantation in the UK so far, there remain substantial challenges – and enormous opportunities – to securing a suitable organ for everyone who needs a transplant. This Strategy will represent both evolution and revolution: some of our existing initiatives will continue, while some will be new. Both are important.

Previous strategies have mainly delivered by focusing on organ donation initiatives. While there remains great potential for increases in donor numbers as a result of action in living and deceased organ donation, there are also opportunities for the UK to raise organ utilisation and seize the benefits of emerging new transplantation technologies and techniques.

This new era will see a new focus on addressing the organ utilisation challenges common to all organ groups, but also each group individually. We will also develop models of organ recovery – where organs can be assessed and treated with precision medicine, including outside of the body of the donor, prior to transplantation. The ambition is that the UK will deliver a shift in transplantation, which will transform outcomes for those waiting for a transplant and those who receive this life-enhancing gift.

Underpinning these developments will be a focus on diversity and inclusion, ensuring that we reach the best possible outcomes for all. The importance of a strategic approach to addressing issues related to BAME communities was highlighted throughout out stakeholder events. We will also continue to transform the UK's donation and transplantation services, such that we are sustainable and well-prepared for the future. We will also develop the UK's world-leading, pioneering culture of research and innovation.

Our stakeholders' voices

In developing this strategy, we have engaged with the UK's diverse and experienced organ donation and transplantation communities. These included donors and their families, transplanting teams, government health departments, commissioners, NHS

delivery teams and interest groups. Over 700 stakeholders were approached to join us in developing the various aspects of this strategy, including at 10 participative events around the UK. One of these, arranged jointly with the National BAME Transplant Alliance, focused on BAME issues.

The events were a success, with participants contributing over 4,000 ideas, questions and suggestions. We have used these to develop our evidence base and plans.

Our approach

We aim to be the best organ donation and transplantation system in the world, achieved by working together across the UK and the NHS. Our focus is to increase the availability of transplants and to tackle inequalities.

Working towards this, we will focus on six key areas of action required to achieve ambitious outcomes for patients:

Our Objectives	
1	*Living and deceased donation will become an expected part of care for all those in need across the UK*
2	*We will achieve world class organ utilisation in every organ group, harnessing new technologies and techniques to help achieve this*
3	*For the most effective use of a precious donor organ, recipient outcomes will be among the best in the world*
4	*People of all races and genders have access to the organ they need, at the time they need it*
5	*As donation numbers increase due to new legislation, we will secure a sustainable service across the UK, making the most of every opportunity for a donation or a transplant*
6	*We will build further support for the world-leading, pioneering culture of research and innovation for the UK*

We will aim for ambitious outcomes for patients, progressively improving rates of all organ donation, organ utilisation and transplantation.

Action by	Measure	2018/19	2025	2030
Individuals and donor hospitals	Total, deceased & living donors PMP	40	48	51
Transplant centres, commissioners and NHSBT	Utilisation rate (organs per donor)	2.6	2.8	3.1
Transplant centres, commissioners and NHSBT	Total, deceased & living transplants PMP	79	93	102

Taken together, this detailed strategy describes the main areas that need to be addressed as the UK continues to save and improve more lives through organ donation and transplantation after 2020.

Summary Action

Objective 1: ***Living and deceased donation will become an expected part of care for all those in need across the UK***

Action	*Impact*
Support implementation of changes to the law around organ donation	***Public are informed of changes and make a decision about organ donation, recorded via the NHS Organ Donor Register. NHS staff are trained to support donation.***
Public visibility and promoting the benefits of living and deceased organ donation	***Donation is consolidated as an expected part of end-of-life and transplant care. There will be high rates of visibility of living and deceased donation.***
Expand the deceased donor pool by identifying the potential for donation outside ICU and hospitals	***Potential donor pool is enlarged, as possibilities for donation in new settings is defined and supported***
Maximising transplant opportunities through the living kidney sharing scheme	***Innovative sharing scheme, to maximise transplant opportunities (new IT platform to support best clinical practice)***
Ensuring that "transplant first" is encouraged and that living donation is part of the transplant conversation	***Pre-emptive transplant will avoid unnecessary or extended time on kidney dialysis, saving NHS resources. Higher uptake of living donation results in reduced demand for deceased donation and high quality transplants.***

Objective 2: ***We will aim for world class organ utilisation in every organ group, harnessing new technologies and techniques to help us achieve this***

Action	*Impact*
Work with NHS delivery bodies to set out organ utilisation improvement plans	***Specifically tackles barriers to improved organ utilisation and addresses challenges by organ group and country / region***
Agree regulation, policy and custodianship for extended-criteria organs, which could be subject to ex-situ perfusion	***Defines the role of perfusion in overcoming clinical and logistical issues that would otherwise prevent transplant***

Pilot models of Assessment & Recovery by providing services	***Achieves early clarity on which models provide greater utilisation and ensures that previously discarded organs are transplanted. More, safe organs; with predictable timings***
Alongside this, we will run service evaluation of models of Assessment & Recovery	***High quality outcome-based data, to assess service and progress further developments for each organ group***
Maintain close scrutiny of emerging technologies and techniques	***Early identification of potential for new methods, through research monitoring groups and other methods***

Objective 3: ***For the most effective use of a precious donor organ, recipient outcomes will be among the best in the world***

Action	***Impact***
Deliver new outcomes measures, focused on quality of life	***New data used to develop best practice in living donation and deceased donor transplantation***
Focus research on access to transplantation and re-transplantation	***Improved access to transplantation, as measured by ethnicity and social class and an action plan to improve rates of re-transplantation***
Continued focus in organ offering schemes on disadvantaged populations	***Further improved access to transplantation, especially for BAME and hard-to-match people – including named-patient offering where appropriate***
Transform data collection to a digital model	***Safeguard data collection and reduce burden to NHS colleagues***
Enable easy access and effective use of data	***Benefits of easier access to data, sharing and linkage to partners***

Objective 4: ***People of all races and genders have access to the organ they need, at the time they need it***

Action	***Impact***
Improve insight on ethnicity and religion	***Targeted promotion and action planning, based on higher quality data and insights***

Empowering BAME communities to lead on promoting organ donation	***Increased consent/authorisation rates for BAME and other groups***
Tackle disadvantage in listing and outcomes	***Improved outcomes for BAME recipients***
Increase the diversity of ODT's workforce	***Representative (c.14% BAME) patient-facing workforce within 3-5 years***
Develop and sustain long term Diversity action plans	***Confidence that action plans for delivering priorities are effective, through a multi-year approach***
Improve partnerships between NHSBT and external supporters	***Productive partnerships, leading to measurable benefits to patients***

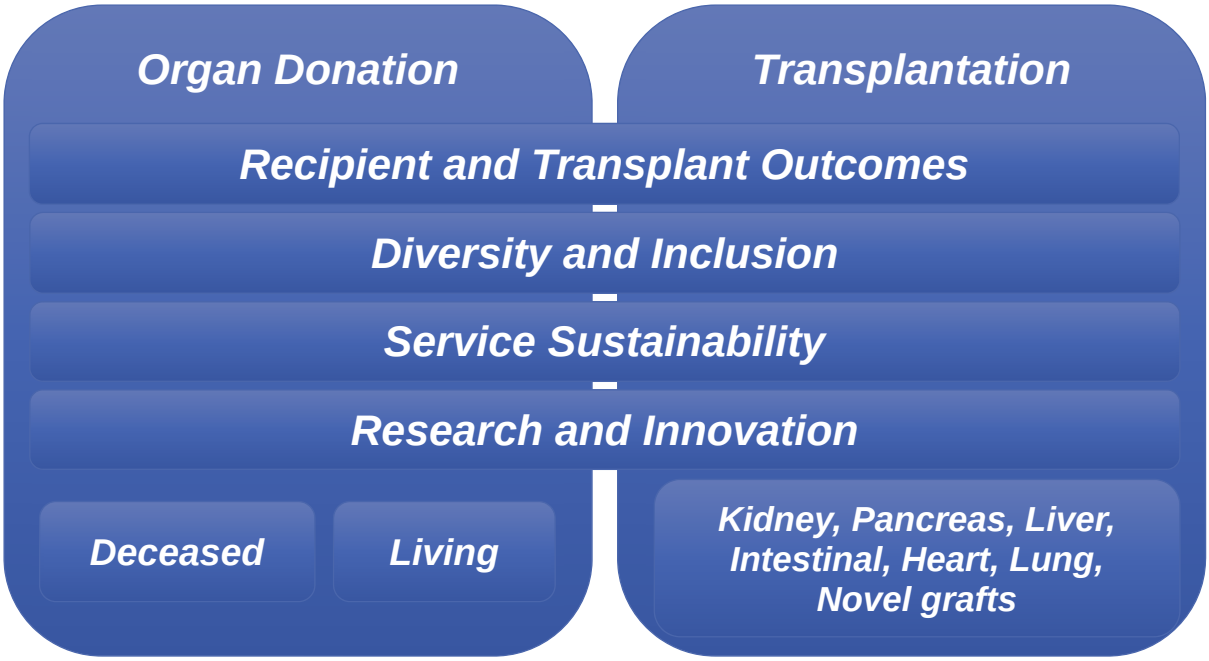
Objective 5: ***As donation numbers increase due to new legislation, we will secure a sustainable service across the UK, making the most of every opportunity for a donation or a transplant***

Action	***Impact***
Strengthen the role of NHSBT in the transplant commissioning and delivery monitoring process	***More detailed transplant system planning, leading to improved sustainability and tackling of unwarranted variation***
Ensure that we are easy to work with by transforming our digital and IT-enabled support to NHS	***Safe, simple and supportive experience for NHS colleagues. Maximised use of NHS resources and cost avoidance***
Increase organ retrieval capacity as donation activity grows: through selective service re-design	***Best use of NHS resources via collaboration and, where needed, additional capacity – to ensure no missed opportunities***
Focus on length and timing of the ODT process	***Reduced length and / or more predictable timing of process, including reduced night-time transplantation***
Further development of ODT operating model	***New target operating model ensuring that more clinicians' time is spent on clinical activities and safer, responsive co-ordination of NHS resources***

Objective 6: ***We will build further support for the world-leading, pioneering culture of research and innovation for the UK***

Action	*Impact*
Initiate and support behavioural research	***Provides evidence on high-impact interventions that increase consent / authorisation levels for BAME donors in both deceased and living donation***
Continued support for essential infrastructure	***Underpins high-quality research and innovation to advance clinical practice and improve outcomes***
Stimulate increased investment in the highest priority research and innovations	***Improve patient care and more lives saved by transplanting more organs that last for longer***
Enable enhanced data sharing and automated data capture	***Fosters an environment of transparent and convenient data sharing, to maximise the opportunities of advances in healthcare data science and big data***
Support for emerging service developments	***Increased translation of research and service developments to quantify organ quality prior to transplantation (e.g. Assessment & Recovery)***

Our detailed approach



1. Organ Donation

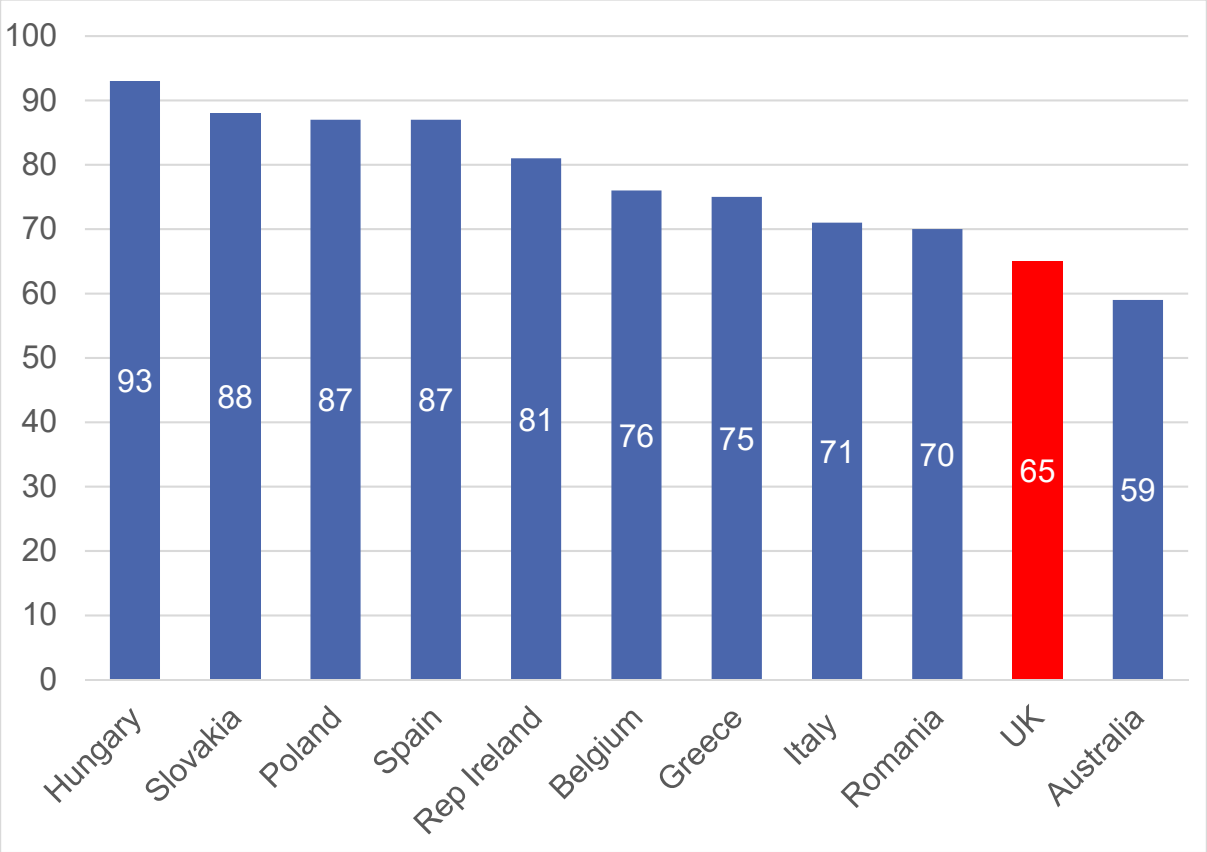
Objective 1: *Living and deceased donation will be an expected part of care for all those in need across the UK*

Much of the progress in transplanting ever-greater numbers of patients has been achieved through the generosity of donors and their families and pioneering initiatives in living and deceased donation. Despite us identifying new promise in transplantation, we will not reach our goals without further innovation in the care practices of organ donation and grasping the opportunities of changes to the law in most parts of the UK.

The overall number of people who die in circumstances where organ donation is currently considered possible[1] is relatively static at about 6,000 people each year (about 1% of deaths in the UK). While the number of potential donors has remained relatively static, the demographics of potential donors is changing over time. Potential donors are now older, have greater co-morbidities and a higher Body Mass Index than in the past, and are dying from conditions different from the past (less trauma and brain haemorrhage, more hypoxic causes), making a successful transplant harder to achieve.

[1] A patient who is intubated and ventilated, generally on an Intensive Care Unit or Emergency Department, without an absolute medical contraindication to organ donation.

Set against this, the UK has achieved huge advances by identifying more potential donors, referring for assessment and obtaining consent from donor families. While other countries have experienced declines in living donation, we have continued to make advances thanks to the extraordinary kindness of altruistic and paired donors. Yet, although there are over 25 million people registered to donate on the NHS Organ Donor Register and the consent rate for deceased donation in the UK has risen, it still does not match the best in the world (as at 2017, below):



There are also particular challenges in securing consent for deceased donation from our black and Asian citizens – where the need is greater but there are barriers, to both deceased and living donation.

1.1 Deceased Donation

Changes in the Law – a Revolution in Consent / Authorisation

From a public perspective, the biggest change since the publication of the strategies to take us to 2020, is the change in legislation in Wales and the progress towards adoption of legislation in England and Scotland.

In December 2015, Wales changed their consent legislation so that if you haven't made a decision about organ donation before your death, you are deemed to have made a decision to donate. Families continue to be closely involved in the process and are always asked about the last known decision of their relative and whether there are any faith requirements that need to be considered. Families are also asked for

medical and social history to ensure that any donated organs would be safe to transplant. Since Wales implemented their legislation they have seen steady increases in consent.

Following Wales' lead, other home nations and Crown Dependencies (England, Scotland, Jersey, Guernsey, Isle of Man[2]) are now developing – or have implemented – legislation that expects citizens to record a decision to 'opt out', preferably on the NHS Organ Donor Register, if they have decided not to donate their organs after death. People who do not 'opt out' will be deemed to have consented to or authorised donation. It will still be possible for citizens to record their decision to donate on the NHS ODR: over 26 million people have already done this, including those who 'opt out'. In all of the proposed legislations the family will still be involved in the donation decision – making these 'soft opt-out' legislations.

The challenge with these new legislations is to ensure that the gains observed in Wales are realised. Colleagues across the NHS are seeking to deliver:

- Effective public information campaigns explaining how the law has changed and encouraging citizens to make an organ donation decision and share it with their family.
- Training for all NHS staff involved in supporting families through the donation process. It is particularly important to retain clinical confidence in the consent/authorisation process.
- New tools to make it easier to record a donation decision such the new faith declaration: in England this has included linking the new NHS App to the Organ Donor Register.

Making the most of the opportunities presented by new legislation is our best chance to increase the number of individuals, supported by their families, becoming donors. It is anticipated that it may take up to 5 years to realise all the benefits of legislation changes.

Along with the legislation change we will continue to empower individuals to promote organ donation through accelerating our donor ambassador programme, to educate and raise the visibility of organ donation across a diverse range of communities.

Transformation in Practice

Increasingly, potential donors are older with complex health and disease problems making their organs potentially harder to transplant. As a result, the number of deceased donor transplants is currently not keeping pace with the increases in donors. Whilst we will continue to support donor hospitals in their work to make the most of every opportunity, over the next 5 years the focus will progressively move to the potential evident in transplantation.

[2] Northern Ireland have chosen to remain with their present opt-in system, where the government is responsible for and leading on, promoting organ donation.

However, there can be no transplantation without donation, so we must continue to explore new approaches to organ donation initiated through the UK's model of local medical Clinical Leads, Specialist Nurses and Donation Committee Chairs. With so few people dying in circumstances where organ donation is an option it is essential that we strive to get it right 100% of the time – and look for new potential donors outside the existing pool.

We will continue to audit all deaths under the age of 80 in Intensive Care and Emergency Departments to assess whether every potential donor has been identified, neurological death tested (where appropriate), referred and the donor family approached in a collaborative manner in line with best practice and the new legislations. The UK Potential Donor Audit, a world leading audit tool, will be developed to provide the best data to hospitals in the future as the basis for learning and improvement.

We will also look again at the size and characteristics of the UK's potential deceased donor pool. We will specifically explore the potential for donation outside the traditional hospital settings of intensive care and emergency medicine, supporting those initiatives that show the best potential. Enabling these changes, we will re-establish a forum for ethical discussions as new practices emerge and develop.

Although great progress has been made to increase the number of adults who donate their organs after death, the number of paediatric donors has remained largely unchanged. A Paediatric Strategy was launched in 2019 to tackle this issue: this will now be incorporated into the new over-arching strategy.

In hospitals, while great progress has been made to ensure that suitable recipients are sought for every organ that has been generously offered by deceased donors and their families, this has had the unintended consequence of increasing the length of the donation process. The length of the donation process is now a frequent reason for families to withhold or withdraw their consent/authorisation for organ donation. The length of the process for donor characterisation, organ offering and retrieval have increased so much that transplantation is becoming a night time procedure, increasing the challenges for the surgical team and stretching resources further. We will act together with colleagues across the donation and transplantation pathway to address the issues of the length and timing. Locally, this will include the expansion of collaborative working to expand the current hospital Organ Donation Committees into Organ Donation and Transplantation Committees, in those hospitals who have transplant centres.

Working with transplant colleagues, we will further develop donor selection and donor management policies, which may offer the potential to expand the number of donor organs considered suitable to transplant. There are a range of interventions that are undertaken in many other countries to increase the number and quality of organs from donors. For example, heparin (a drug to reduce the chance of blood clots forming in the organs) is routinely given to donors prior to death. We will encourage research and service evaluations in the UK, as well as the proposed forum for ethical discussion, to evaluate the impact and efficacy of donor management and drug therapies.

Donors and their families make the generous decision every day to save and improve the lives of transplant recipients every single day and inspire their communities to donate life. NHSBT's partnership with the Order of St John in presenting the posthumous Order of St John Award for Organ Donation will be continued. To support the generosity of donor families we will provide the highest level of support. This will include developing NHSBT's family after-care programme offering requested information on the donation outcome, facilitating correspondence and providing referrals for grief support.

Objective 1: Living and deceased donation will become an expected part of care for all those in need across the UK

Deceased Donation

	Action	Impact	Who
1.1	Support implementation of changes to the law around organ donation	Public is informed of changes and make a decision about organ donation, recorded via the NHS Organ Donor Register. NHS staff are trained to explore and support donation.	NHSBT Devolved Govts. Public
1.2	A revolution in consent/authorisation – driven by public visibility and promoting the benefits of organ donation	Donation becomes an expected part of end-of-life care. High rates of visibility of deceased donation and personal responses to new laws. 80% consent/authorisation rate by 2023.	NHSBT Devolved Govts. Public
1.3	Continue to promote organ donation through a Donor Ambassador programme	Diverse community advocates for the benefits of organ donation	NHSBT
1.4	Develop the Potential Donor Audit (digital tool)	Greater evidence to inform new practices and identify the greatest potential for more donors	NHSBT
1.5	Expand the deceased donor pool by identifying the potential for donation outside ICU and hospitals	Potential donor pool is enlarged, as possibilities for donation in new settings is defined and supported	NHSBT
1.6	Establishing a forum for ethical discussions as donation practice continues to innovate	Ethical issues associated with innovative new practices are addressed and endorsed	NHSBT
1.7	Further develop donor selection and donor management procedures	Potential additional 100 transplants across all organ groups	NHSBT
1.8	Establish Organ Donation and Transplantation Committees in hospitals with transplant centres	Integrated, local action planning to address cross-pathway issues	NHSBT NHS

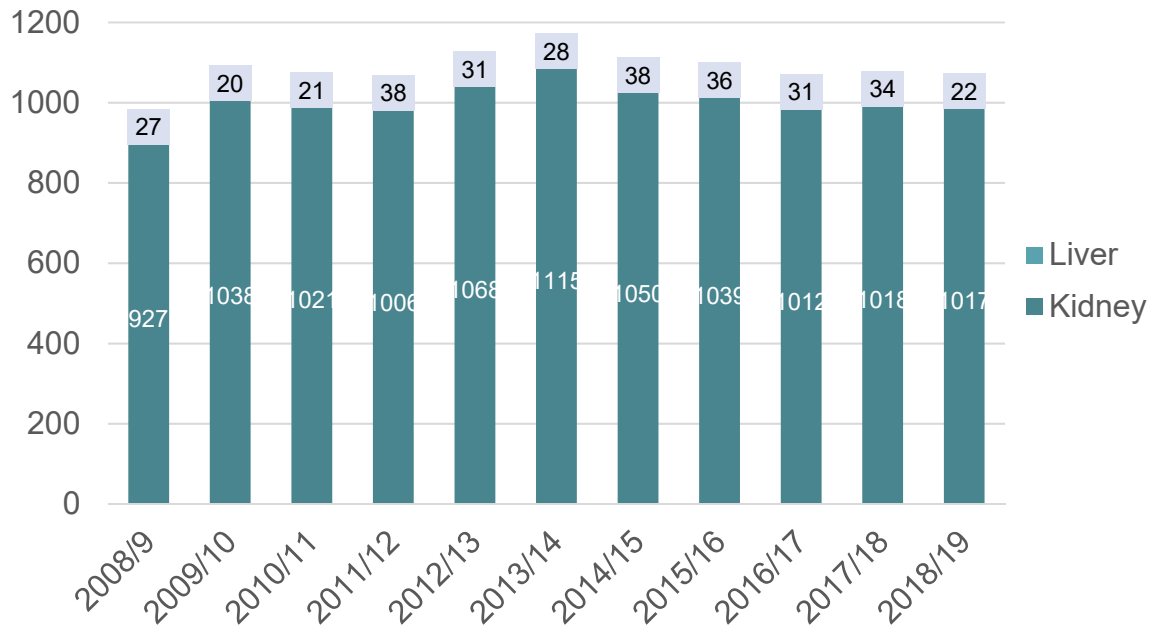
1.9	Develop and sustain donor family after-care	Higher quality care for donor families and associated promotional benefits	NHSBT

1.2 Living Donation

Continued benefits

Living donation offers a double benefit for patients waiting for a kidney or liver transplant: it gives more patients the possibility of a successful transplant and adds to the overall supply of organs for all those who are waiting. Living donors may be friends or family members who donate directly to their recipient; part of the paired and pooled scheme (where a willing donor cannot give to the recipient of their choice and instead gives to another recipient in return for a reciprocal donation); or non-directed altruistic (anonymous donation to a stranger).

Living donor transplantation contributed 21% of overall transplant activity in the UK in 2018/19, with 98% being kidney donations.



Overall rates of living kidney donation trebled between 2000 and 2010 and peaked in 2014 due to an increase in non-directed donation in that year. However, activity has subsequently stabilised slightly below the levels of 2014.

This is despite the benefits of living donation for kidney recipients, which include better and more immediate transplant function and the opportunity for transplantation before dialysis. Living donor liver transplantation makes up a very small proportion of living donation activity in the UK and has focused more on children than adult recipients. This strategy offers an opportunity to consider living donation as one of a range of options for transplantation for suitable recipients.

Approaching family and friends to ask them to consider living donation is a considerable prospect for most people seeking a kidney or liver transplant. As the number of deceased donors has increased over recent years, it seems that more people in need of a kidney transplant have chosen to wait for a deceased donor – especially when the typical waiting time has been improving. This trend is evident across all countries where deceased donation has been rising; yet declines in living donation rates, particularly in kidney, have often been greater than that of the UK.

The generosity of strangers

The UK has directed its efforts through the *Living Donor Kidney Transplantation to 2020* strategy. In recent years, a greater number of people have volunteered to donate a kidney without any personal connection to a recipient (non-directed altruistic donation), often donating into a 'chain' of transplants with people in the paired / pooled scheme. This trend has partly offset the decline in overall living donation activity, creating transplant opportunities within the UK living kidney sharing scheme and for recipients on the UK transplant list that would not have otherwise existed.

These acts of generosity have enabled many transplants to be achieved through the UK living kidney sharing scheme, particularly benefiting long-waiting patients who are immunologically complex and/or from non-Caucasian backgrounds. As a result, the UK is an international leader in kidney exchange, has reduced the need for antibody removal treatments to facilitate transplants between incompatible donors and their recipients. The UK has achieved improved rankings of living donation by international comparison despite the challenges outlined above.

There have also been notable achievements through the targeting of modest resources and awareness raising amongst black and Asian communities that offer templates for future progress.[3] Taken together, the quality of matches in living donation have continued to improve.

If the UK is to increase the total number of transplants and reduce the waiting time (for kidney in particular), then living donor kidney transplants will be a key component, especially for people for whom it is hard to find a match.

Living liver donation is also important, but the risks to the donor, particularly in adult to adult living donor liver transplantation, must be carefully balanced with the chance of a successful transplant for the recipient. Transplant centres currently discuss this option for children and for carefully selected adult patients, where modest increases are possible in this area of practice if living donor liver transplantation is offered as one of a range of options for people who need a transplant.

We will continue to work with all governments to promote living donation and to provide information to patients on the waiting list, which will help them weigh up the options for achieving the best transplant option for them with the least delay. Transplant centres should explore all donor options at an early stage and in the context of other available treatment options. Transplant teams must be open about which option is

[3] Final Report of the Living Transplant Initiative, 2019

likely to lead to the most successful transplant at the right time for the person who needs it and with the best long-term outcome.

We will continue to support pooled, paired and chains of donors to increase the number of transplants, developing the existing UK living kidney sharing scheme. As a precursor to further development and expansion of the sharing scheme, NHSBT will renew the underpinning support for this (IT platform).

Living Donation

	Action	Impact	Who
1.10	Maximising transplant opportunities in the UK through the living kidney sharing scheme	Innovative sharing scheme, to maximise transplant opportunities (new IT platform to support best clinical practice)	NHSBT
1.11	Encouraging the option of “transplant first” for suitable kidney recipients including pre-emptive transplantation	Avoiding unnecessary or extended time on kidney dialysis, saving NHS resources	NHSBT, Transplant Centres
1.12	Making it easy for people to give or receive a living kidney or lobe of liver	Addressing barriers (including financial), resulting in more access to donation and maximising transplant opportunities	NHSBT, Transplant Centres
1.13	Promotion: raising public and patient awareness and engagement in living donation across all areas of society	To increase transplant opportunities for patients who may currently be disadvantaged (including liver recipients; people with whom we could engage more effectively; increasing proportion of non-directed living donors	NHSBT
1.14	Addressing unwarranted variation in clinical practice	Living donation is part of a “menu of choices” for potential transplant recipients and their families, resulting in more kidney and liver donor transplantation for suitable recipients	NHSBT Transplant Centres
1.15	Ensuring that experience, safety and welfare of living donation is the best it can be	Improved donor and recipient clinical pathways and data quality via existing UK Registry and donor self-reported outcome and experience tools (digital infrastructure), to inform clinical practice and enhance quality and patient outcomes	NHSBT

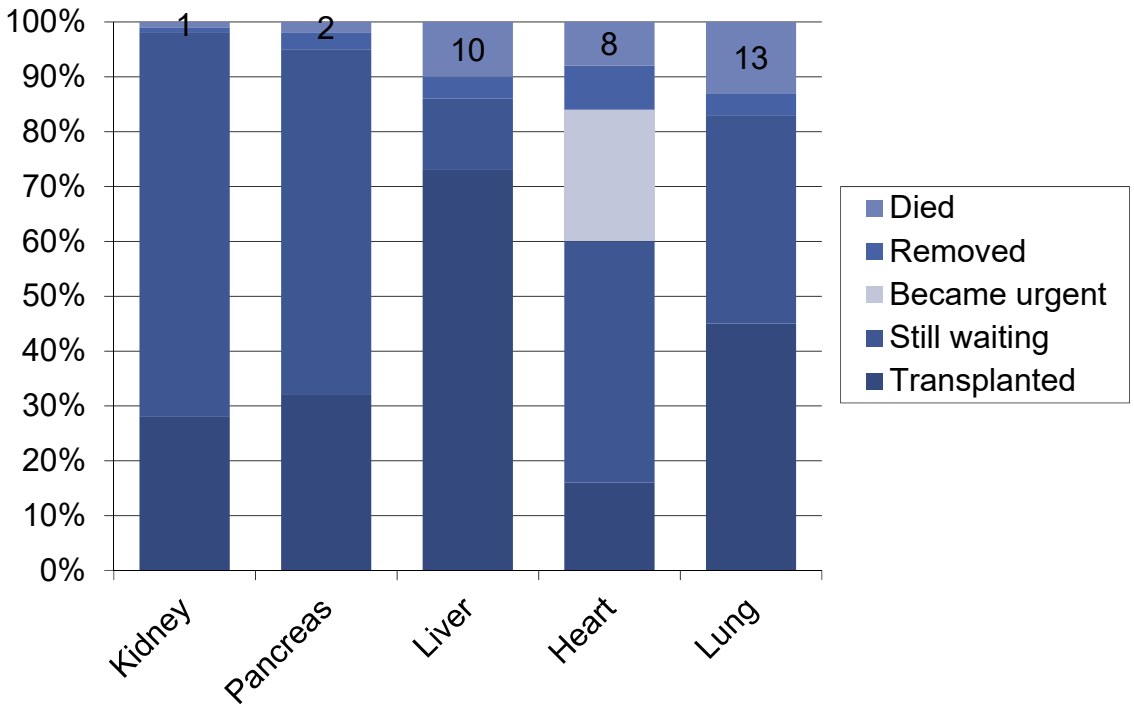
2. Transplantation

Objective 2: *We will achieve world class organ utilisation in every organ group, harnessing new technologies and techniques to help achieve this*

It took advances in medical and surgical technologies and techniques to first establish organ transplantation as a possible treatment for end stage organ failure, before transplantation could become a regular therapeutic approach for patients.

In previous strategies, the UK has focused on increasing the number of donors as the means of reducing not only the wait for a transplant but also reducing the numbers of people who die or who become too sick to transplant before an organ is available for them.

Sadly, although the absolute number listed for a transplant has fallen and the waiting time for a transplant has reduced, still too many people wait too long or die before transplantation. There may also be further unmet need, in that not all patients who could benefit from a transplant are currently added to the transplant waiting list.



These factors underline the need for a further transformation, which will now see precision medicine used to help assess, retrieve and treat organs prior to transplantation. This will be in addition to actions to improve organ utilisation by each organ group and collective action to transform recipient and transplant outcomes.

Organ Utilisation and Organ Quality

Transplantation has inherent risks. Even with the most effective donor characterisation and careful offering schemes, ultimately it is the transplant team, together with their patient, who have to decide whether an available organ is suitable at that particular time.

The delivery of *Taking Organ Transplantation to 2020* has led to challenges in some areas. While the number of deceased donor organs offered to transplant centres has risen substantially in recent years, many more of these organs come at higher risk owing to changes in donor demographics and our expansion of the donor selection criteria.

Donors are increasingly older, heavier and often have other health issues – compared with the smaller number of donors in years gone by. It is a credit to the UK's transplant services that so many of these organs have resulted in a successful transplant.

The *Taking Organ Utilisation to 2020* strategy recognised these challenges and set an aim to match world class performance with action in donation, organ offering, acceptance, retrieval and infrastructure. Future improvements in donor referral, together with changing donor demographics, mean that these trends are likely to continue, and further action will be required. This strategy sets out a vision for further action, taking advantage of the promising developments in clinical technologies.

International data show that UK kidney and pancreas transplant rates are world-leading. However, there is more to do to meet the ambition to meet unmet demand for transplantation.

Liver transplantation rates are competitive by international standards, although in the UK c.30% of livers donated from deceased donors are not utilised.

The UK has comparatively poor rates of both lung and heart transplantation compared with international colleagues, with 19% of people waiting for a lung transplant and 16% of people waiting for a heart transplant[1] dying or being removed from the list within a year of being listed for a transplant.

The challenges of organ utilisation vary by organ group, meaning that the solutions for each will be different. Building on work such as the October 2019 Lung Utilisation Summit, NHSBT will seek to influence UK organ transplant bodies to work in partnership and progressively set out plans to improve organ utilisation by each distinct organ group.

Common areas of action across all organ groups will be captured and utilised. One of these is to find affordable technological solutions to increase the use of all donated organs will be important to give hope to patients waiting for transplants.

NHSBT will also continue to encourage the national adoption of donor utilisation initiatives (such as that focused on Hepatitis C donors) and maintain close scrutiny of emerging developments through our research group (RINTAG) and other methods.

A Revolution in Organ Utilisation

In October 2018, a UK Summit on Innovation in Perfusion and Preservation strategies in solid organ transplantation concluded that novel methods of Preservation and Machine Perfusion are highly likely to transform organ donation and transplantation in clinical management, logistics and outcome. The UK has a decade of practical experience in this field.

There is growing evidence that new perfusion technology would give surgeons greater confidence to implant more organs successfully. Enabling routine adoption of these technologies is a financial and operational challenge but is key to making transplantation a modern sustainable service. As transplant teams seek to use organs that were previously rejected, it is vital that potential recipients understand the benefits and risks of these opportunities.

Existing initiatives supported by NHSBT – normothermic regional perfusion of liver and the transplantation of hearts from non-heart-beating donors – are working. Building on these initiatives, there is the challenge of taking advantage of further developments. The key question is: how does this new technology increase the number of organs?

A vision for a model of Assessment and Recovery

Developed in collaboration with nominated experts from the British Transplantation Society, a proposed approach is the creation of a national model of organ Assessment and Recovery. It is anticipated that donated organs, especially those with higher risk profile, could be investigated and, if possible, interventions would be made to improve function prior to onward transplantation. There are several potential approaches that we would wish to investigate.

Assessment will allow triaging of organs, identifying those that need little intervention, those higher risk organs that require a lot, and those that should never be transplanted. In the future, such interventions are likely to include novel drugs and cell delivery to the donated organ in order to improve or transform function. The UK will need to continue to invest in research to maximise organ utilisation and our approach is detailed later in this strategy.

Specifically, NHSBT will seek to act, with other organisations in the NHS or beyond, to pilot Assessment and Recovery approaches. This will be with the aim of understanding which approach delivers an increase in the number and / or quality of organs utilised as a result of these technologies.

NHSBT will view these investigations as service developments and would look to work with others, while considering the support to set-up the service and potentially to provide enabling resources such as organ recovery specialists. In looking to achieve this, novel partnerships will be considered (such as other NHS organisations, third sector) and NHSBT will, in parallel, encourage bids for complementary research.

Which organ perfusion and preservation approaches could we investigate?

1) Recipient centre model

This model might be suitable for most organs to increase utilisation, requiring an initial period of cold storage and then rapid transportation to the recipient centre. It may be attractive to transplanting centres, as they could control the process and any reconstructions might be done by trusted surgeons. However, centres' expertise in new methods may vary without central development and support.

2) Dedicated off-site model

Dedicated expertise could be established in one or more centres of excellence for organ perfusion and preservation. This model would also require a period of cold storage first. It may not be ideal for some organs, partly due to the logistical challenges of how to transport organs to such a centre in the right conditions.

3) Donor hospital model

This model would involve taking machines to the donor hospital, which would remove the urgency of transporting donor organs within a certain timeframe. The model could, however, preclude more advanced interventions to some organs.

NHSBT will seek to co-ordinate, establish infrastructure where it does not yet exist and to enable experts to decide what technologies should be deployed for service development. Part of this process will involve the provision of enabling resources to facilitate services for a set time, with a rigorous review based on deliverables (e.g. increased utilisation of marginal organs).

Objective 2: We will achieve world class organ utilisation in every organ group, harnessing new technologies and techniques to help achieve this

	Action	Impact	Who
2.1	Deliver organ utilisation improvement plans for each organ group, working with colleagues across the UK	Clear plans for improving utilisation for each organ group, contributing to overall increases in utilisation	NHSBT Transplant Centres Commissioners
2.2	Support the development of Normothermic Regional Perfusion for Livers	Increase in Liver transplants	NHSBT Transplant Centres Commissioners
2.3	Continued support for transplantation of Donation after	Increase in use of DCD Hearts	NHSBT Transplant Centres Commissioners

	Circulatory Death (DCD) hearts		
2.4	Investigate the utility of new technology for Lung utilisation	Increase in use of Lungs	NHSBT Transplant Centres Commissioners
2.5	Investigate the use of technology that is presently used, in order to allow utilisation of organs from donors who are unstable	Increase in use of organs from donors who are unstable	NHSBT Transplant Centres Commissioners
2.6	Clarify custodianship of donor organs undergoing ex-situ assessment and optimisation prior to transplant	To clarify who is responsible for organs removed from the donor but prior to transplantation and provide clear governance	Devolved Govts. NHSBT Transplant Centres Commissioners
2.7	Agree national guidelines and policy on approved scenarios in which extended criteria organs could be subject to ex-situ perfusion	Clarifies the role of perfusion in overcoming logistical issues that would otherwise prevent transplant. Standards for acceptance and utilisation of organs as technology becomes more widespread.	NHSBT Commissioners
2.8	Work with regulators, to define how the introduction of new technologies to assess and improve organs should be regulated	Defined quality assurance processes and minimum standards for where perfusion can be performed, by whom and what systems are approved.	NHSBT Regulators (MHRA, HTA)
2.9	Evaluate models of Assessment & Recovery through a service provision pilot	Clarity on which models provide greater utilisation and ensure that previously discarded organs are transplanted. Safe, “non-inferior” organs; predictable timings	NHSBT
2.10	Evaluate models of Assessment & Recovery through a parallel service evaluation	High quality outcome-based data, to assess service and progress further developments	NHSBT
2.11	Co-ordinate an associated research programme for Assessment & Recovery	Links to Research & Innovation theme	NHSBT
2.12	National implementation of the Hepatitis C Donor utilisation programme	Increase in organs currently discarded for Hep C	NHSBT

2.13	Maintain close scrutiny of emerging technologies and techniques	Early identification of potential for new methods, through RINTAG and other methods	NHSBT

3. Recipient and Transplant Outcomes

Outcome 3: *For the most effective use of a precious donor organ, recipient outcomes will be among the best in the world*

Drafting note: *Will refer to NHS-wide initiatives in 4 home countries, such as Getting It Right First Time (England, renal), once these are available.*

NHSBT has continued to develop the UK's organ offering schemes since the publication of *Taking Organ Transplantation to 2020*, delivering new offering schemes and important developments for each solid organ group since 2016. These have enabled a range of benefits to patients, including a better chance of an organ offer for those people who have historically been harder to match with a suitable organ donor.

However, there remain key areas for development that will help us to reach our aspiration of becoming the world's best organ donation and transplantation service. This will be achieved through ensuring that patients have access to the right specialist, with the right information, at the right time.

Working with clinical and patient advisors from across the UK, NHSBT will continue to develop access to transplantation through organ offering schemes, ensuring there are continued improvements in access and outcomes. We will also seek to enhance the post-transplant data beyond measuring the life of a patient or graft, to increasingly taek into account quality of life factors that are not currently reported.

There is some evidence for access issues, by ethnicity and class, although data is currently limited. There are also variations in patient follow-up, management of organ rejection and post-transplant care. Many of these decisions, including whether to list a patient for a transplant, remain a personal one for the patient and their transplanting team. NHSBT will develop its data and information capabilities and, working with commissioning partners across the UK, seek to challenge unwarranted variations in practice where these might emerge.

In the UK, short term (5-year) graft survival rates are positive, but it has become clear that around long-term outcomes have not changed in some time. Although the background to each case is again personal and can be complex, one notable aspect is that around 8-900 patients per annum return to the transplant waiting list. This area will therefore be a focus, with the aim of ensuring that actions and further research address the burden on patients and the NHS.

Improvements in clinical technology point to the potential for improved outcomes and research is emerging in this area, especially around pharmaceutical interventions. NHSBT will focus on outcomes from patient perspectives, rather than only on the life of graft / patient, with the aim of introducing self-reported quality measures for patients' life experiences after transplant.

Transplant data in UK is considered world class, but the sharing of follow-up data must be developed to a digital-first model as we anticipate tracking the transplants of up to 65,000 transplant recipients in the next 5 years. NHSBT will therefore focus on digitising data collection, driven by the benefits to the wider NHS.

Objective 3: For the most effective use of a precious donor organ, recipient outcomes will be among the best in the world

	Action	Impact	Who
3.1	New outcomes measures, focused on quality of life	New data used to develop best practice in living donation and deceased donor transplantation	NHSBT
3.2	Focus research on access to transplantation and re-transplantation	Improved access to transplantation, as measured by ethnicity and social class and an action plan to improve rates of re-transplantation	NHSBT Devolved Govts. Public
3.3	Continued focus in organ offering schemes on disadvantaged populations	Further improved access to transplantation, especially for BAME and hard-to-match people – including named-patient offering for hearts and lungs	NHSBT
3.4	Transform data collection to a digital model	Safeguard data collection and reduce burden to NHS colleagues	NHSBT
3.5	Enable easy access and effective use of data	Benefits of easier access to data, sharing and linkage to partners	NHSBT

4. Diversity and Inclusion

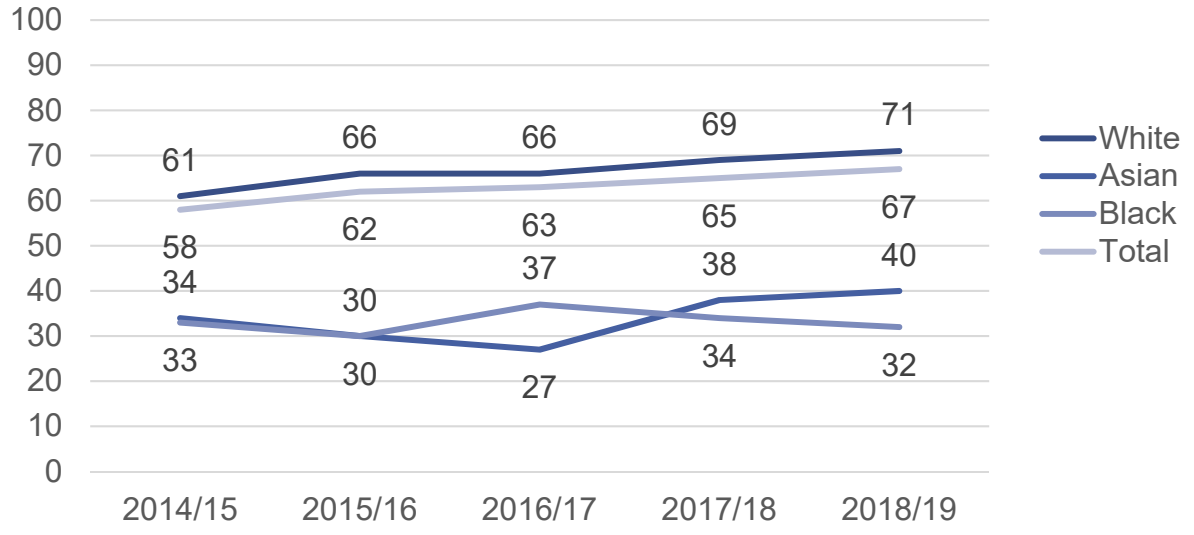
Outcome 4: *We aim to ensure that people of all races and genders have access to the organ they need, at the time they need it*

Important research and reports have noted for twenty years that Black and Asian citizens needing a transplant are doubly disadvantaged[4]. More black and Asian people need transplants than the rest of the UK population, partly explained because of higher rates of diabetes and hypertension (high blood pressure). Today, a third of the people – approximately 1,800 – in the UK waiting for a transplant are black, Asian or minority ethnicity[5] while they together comprise c.14% of the UK population.

Donated organs, particularly kidneys, need to be from a donor who matches the recipient. This means they generally need to have the same blood group and be a human leukocyte antigen (HLA) match too.[6] This is more likely if donor and recipient are from the same ethnic group.

However, the number of people from our BAME communities who die in circumstances where deceased donation is possible is around 550 a year, i.e. not enough to meet demand, even if every organ were able to be used to meet the need.

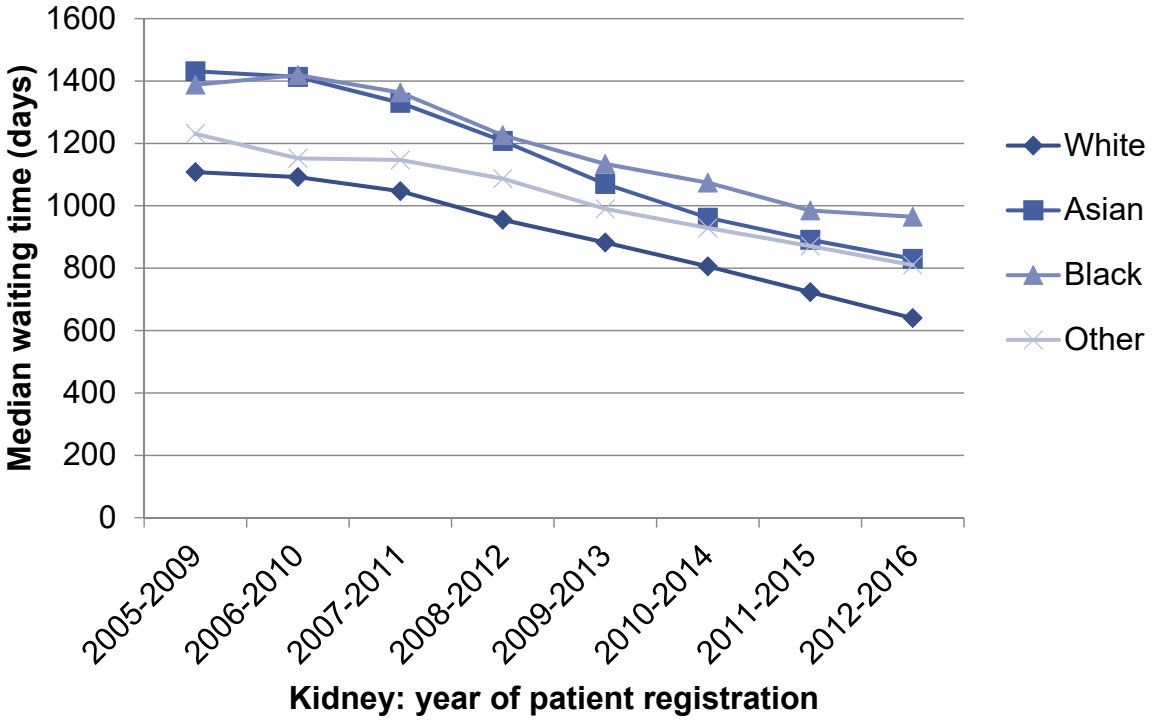
Furthermore, despite progress in recent years, our black and Asian citizens are less likely to give consent/authorisation for organ donation. This challenge is not unique to the UK and has been experienced and tackled through a variety of interventions across the world[7].



[4] For example: Preventing kidney disease: the ethnic challenge, Prof L. Lightstone, 2001
[5] Organ Donation and Transplantation data for Black, Asian and Minority Ethnic (BAME) communities (2018-2019)
[6] HLA is an immunological marker dictated by genetics
[7] Organ Donation: Breaking Taboos Amongst British BAME Communities, Nishtha Chugh, 2016

In the UK, there has been progress. Positive outcomes are visible in living donation, where Black and Asian people are now more likely to donate than the general population. Much work has also been done to engage with black and Asian citizens about the importance of donation, both deceased and living.

However, while waiting times have been reducing for black and Asian patients, this is often due to the donation of an organ from a deceased white person. There remains significant unmet need.



Surveys show that black and Asian families are less likely to discuss organ donation and are much more likely to decline to donate organs due to lack of knowledge or incorrect information. Not knowing what their relative wanted is one of the biggest reasons given by BAME families for saying no to donation when approached by specialist nurses, meaning opportunities for lifesaving transplants are being missed because families are reluctant to discuss the topic of organ donation.

The opportunities presented by consent / authorisation legislation to change behaviour in these communities are therefore important. Just as important, given the shortage of potential donors, is to maximise the opportunity presented by living donors, finding family or friends who can help.

Insights

While insights into some aspects of diversity and inequalities exist, there remain limitations in terms of the source of these insights and research gaps. NHSBT will seek to support action to improve insights and to initiate and support research where there are evidence gaps (e.g. consent / authorisation behaviour).

Promoting organ donation

Building upon the existing models of the community-based and Living Transplant Initiatives, which support community and faith-based organisations to promote organ donation, work will continue to ensure that all major BAME groups, religious groups and geographic areas are able to secure support to promote organ donation, subject to a rigorous process for the assessment of proposed initiatives.

Peer educator model

Data and experience shows, across the UK, that the decisions of an individual have been overturned at the time of potential deceased organ donation. The concept of an intervention with a peer-educated person and specialist indicates the potential for improvements in consent. The potential for this approach to be adapted to different settings, this work would consider the potential for peer educators to be available at all times of day and night, a necessity if significant numbers of donor families are to benefit from the initiative.

Listing and outcomes

There is evidence that rates of listing and successful transplantation are lower for people who are black and Asian and, in the case of living donation, for those from lower socio-economic groups. This strategy will focus activities on improving outcomes for people of all backgrounds and, where relevant, this will include continuing to give advantage to people who are harder to match in organ offering schemes (generally, BAME). Any evidence of disparities in listing for a transplant will be investigated and challenged to ensure parity of access.

Diversity and inclusion of our people

NHSBT will continue to develop diversity and inclusion plans to ensure that, within 3-5 years, patient-facing services are representative of the communities served. We also call upon organisations across the NHS to maximise the opportunities to attract and retain a diverse, representative workforce to the donation and transplantation community.

Action Plans and Partnerships

The main challenge in delivering partnership-based action plans is that support is typically on an annual basis. This makes it difficult for partners to sustain the resources needed to deliver progress over the longer term. Work will take place between NHSBT and partners to set out the benefits of multi-year action plans to funders, with the aim of achieving high-impact benefits from this approach.

Action to create and develop positive relationships with partners will continue, ensuring that these continue to be productive and deliver measurable benefits to patients. Over the length of the strategy it will be essential to take advantage of national and international opportunities which might allow the promotion of the benefits of donation

and transplantation on a societal scale. The Commonwealth Games in Birmingham 2022 presents a unique opportunity to do this.

Objective 4: We aim to ensure that people of all races and genders have access to the organ they need, at the time they need it			
	Action	**Impact**	**Who**
4.1	Improve insight on ethnicity and religion	Targeted promotion and action planning, based on higher quality data and insights	NHSBT
4.2	Empowering BAME communities to lead on promoting organ donation	Increased consent/authorisation rates for BAME and other groups	NHSBT Devolved Govts. Public
4.3	Further explore a community-led peer educator model as part of consent conversations, to achieve behaviour change	Gather more evidence and, as appropriate, implement a peer-educator model for interventions in consent conversations	NHSBT
4.4	Tackle disadvantage in listing and outcomes	Improved outcomes for BAME recipients	NHSBT
4.5	Increase the diversity of ODT's workforce	Representative (c.14% BAME) patient-facing workforce within 3-5 years	NHSBT
4.6	Develop and sustain long term Diversity action plans	Confidence that action plans for delivering priorities are effective, through a multi-year approach	NHSBT
4.7	Improve partnerships between NHSBT and external supporters	Productive partnerships, leading to measurable benefits to patients	NHSBT

5. A Sustainable, Responsive UK Service

Objective 5: *As donation numbers increase due to new legislation, we will secure a sustainable service across the UK, making the most of every opportunity for a donation or a transplant*

The UK's success in growing donation and transplantation since 2007/8 has resulted in a system which must expand and reform. With this Strategy in place, forecasts suggest that the UK could achieve 260 more deceased donors each year by 2025 and c.1,000 more transplants (950 kidneys, 450 livers, 100 pancreases, hearts and lungs). Already there are 50,000 people with transplants being cared for and this could increase to around 65,000 by 2025.

This must be achieved through the continued renewal of current infrastructure, developing our workforce and addressing the patterns of work in transplantation services across the NHS.

NHSBT will lead and co-ordinate these developments, working closely with our partners to tackle the length and timing of the donation process. This has grown in recent years and there is evidence that donor families are impacted and increasingly do not give consent / authorisation because of the length of the process.

To address these issues, we call upon the whole donation and transplant system to take action key areas:

Retrieval Capacity and Commissioning

If the target of c.1,000 additional transplants forecast by 2025 is to be achieved, and disparities in transplant outcomes are to be addressed, NHSBT must work in partnership with the wider NHS across the UK to deliver further transformation. NHSBT will strengthen the organisational leadership role within the donation and transplantation pathway, working collaboratively to co-ordinate the required changes with partners across the UK.

It is already apparent that both retrieval and transplant capacity (people and infrastructure) will need further support to meet demand at peaks of activity. A review of retrieval activity has already led to agreement to change in the organisation of the service and investment from April 2019. This will be kept under review and as new perfusion technologies are introduced and donor numbers increase, new models of retrieval will be considered for abdominal and cardiothoracic organs.

Work will take place with commissioners of transplant services across the UK to consider how they best secure the capacity to undertake increasing numbers of transplants. Some kidney transplant centres in London are collaborating to consider how best to network their resources to boost capacity at times of peak demand.

NHSBT will work closely with commissioners to keep demand and capacity for liver and other forms of transplantation under review and consider whether the predicted levels of demand for cardiothoracic transplantation merits further review.

Our People

Emerging people plans across the UK identify that the recruitment of nursing, scientific and medical colleagues to work in the NHS is increasingly challenging and, based on evidence so far, this applies to the organ donation and transplant system. The nature of transplantation, with much of the activity happening at night, can make achieving a good work / life balance challenging. Many of those in the system have come from outside the UK.

NHSBT will continue to address nursing workforce issues by further refining the working pattern and broadening the criteria for entry. There is also a commitment to increasing the diversity of the donor-facing workforce, ensuring that it is representative of the population it serves. Future roles and role requirements will be carefully examined, to attract and maximise the best talent capable of undertaking roles across the system.

The British Transplantation Society is leading work to consider how best to promote careers in transplantation and the peer reviews led by NHS England have identified recruitment challenges. This work will be reflected upon and transplant centres will be encouraged to work together regionally to ensure they develop the capacity to match the predicted service growth.

Covering rotas out of hours for scientific staff such as in diagnostic and testing services is a challenge and, over the next five years, technological and collaborative solutions will be explored to maintain the service. Specialist training for the workforce, particularly with the introduction of legislative change and novel organ technologies, will continue to be important.

For these reasons, NHSBT will develop a Donation and Transplantation Academy to build on its efforts to deliver education and training of donation, retrieval and transplantation health care professionals. This will include exploring the cost-effectiveness of building a world-class education facility and / or network. We will also explore ways of how we can work with our colleagues across the system in order to deliver joint training and consider opportunities to develop learning networks.

Digital

A range of new digital solutions have been implemented to support donor characterisation and controlled document access for specialist nurses, to assist with donor referral and triage, to digitise some regulatory forms and to transform the donor-to-recipient offering algorithms. These developments, under the umbrella of the ODT Hub programme, have sought to make the working life of colleagues in organ donation and transplantation simpler, safer and more supportive.

However, much remains to be done and this transformation needs to continue so that information access and data transfer throughout the donation and transplantation

pathway is increasingly automated. Key outcomes will be to enable digital acceptance of organ offers and digital transfer of testing results.

The new NHS Organ Donor Register (developed 2015) has been linked to the NHS App to simplify and promote public access in England. It is expected that the other UK nations will consider similar developments. During the life of this strategy there will be a review as to whether partnerships such as those with the DVLA and Boots, linking citizens to the Organ Donor Register, remain valuable.

In a deemed consent/authorisation environment, it is essential to engage frequently with citizens to ensure that they are aware of their rights and responsibilities with regard to organ and tissue donation. Increasingly this engagement will be digital, speeding up response times and making personally tailored communication simpler.

Processes

The journey from donor referral to organ transplantation has increased in length and certain activities happen at times which are sub-optimal. Too often, there are long waits overnight for donor families before the organ retrieval operation commences during daytime; impacting on hospital operating schedules; resulting in transplant operations at night when evidence suggests this is less safe.

Work will be undertaken to develop processes for donor referral and triage and to shorten and change the timing of the donation journey. Pilots will take place in major hospitals to match timing to resources. This will be developed so that the stress on the system and the people within it is reduced.

A particular opportunity is how best to follow up and support the growing number of people living with a transplant. We will call upon transplant centres and other hospitals who undertake this work to collaborate to find new ways of supporting their patients in future, so that everyone who has had a transplant has the best quality of life they can achieve. NHSBT will continue to support follow-up data collection, with a renewed focus on digital data collection.

NHSBT will maximise the opportunities for donation and transplantation from closer working between organ donation and transplantation and tissue and eye services. We will also explore the potential for receiving charitable donations and commissioning developments from such donations.

Support for learning and decision-making

Key to assessing organ risk is good clinical data to inform the transplant team. Following a Donor Characterisation Review, and dependent on the outcome of the trials of pre-implantation (“PITHIA”) histopathology trial, donor characterisation will be extended to provide clinicians with better information to support acceptance decisions.

NHSBT will ensure that each transplant centre is only offered organs which meet pre-selected centre and patient specific criteria, reducing the potential for delays in the process. Tools will be developed to support patients and clinicians as they agree consent for transplantation, so both can make a fair assessment of the risks involved.

NHSBT will support transplant centres with individual and comparative data on organ acceptance and utilisation as a tool for learning and driving improvements in performance. Transplant Collaboratives (similar to Regional Collaboratives in organ donation) will be developed to provide a safe environment for clinicians to discuss opportunities to improve practice, learn from other centres and make the best use of limited resources.

We will also build upon the international networks in organ donation and transplantation to facilitate the exchange of ideas and comparative data, to learn from best practice around the world.

Objective 5: As donation numbers increase due to new legislation, we will secure a sustainable service across the UK, making the most of every opportunity for a donation or a transplant

	Action	**Impact**	**Who**
5.1	Strengthening of transplant outcomes through a greater role for NHSBT in the commissioning process	Integrated system planning, improved sustainability	NHSBT
5.2	Digital and IT-enabled support to NHS	Maximise use of NHS resources, cost avoidance	NHSBT
5.3	Increase organ retrieval capacity as donation activity grows: through selective service re-design	Best use of NHS resources via collaboration Additional NORS capacity where needed No missed opportunities	NHSBT
5.4	Provide individual and comparative data on organ acceptance and utilisation to transplant centres	Increase learning and drive improvements in performance. Minimise unwarranted variation in practice.	NHSBT Transplant Centres
5.5	Develop Transplant Collaboratives	Create an organ specific platform for sharing learning and best practice. Build a framework for organ sharing and coordination to better cope with peaks of activity.	NHSBT Transplant Centres
5.6	Action to change transplantation timing	Increased daytime transplantation, as a %	NHSBT
5.7	Addressing NHSBT workforce sustainability by carefully examining future roles and role requirements	Reviewed recruitment criteria enable a wider, more diverse talent pool to be accessed. NHSBT is a popular career choice.	NHSBT
5.8	Length / timing of the ODT process	Reduced length, more predictable timing	NHSBT

5.9	Further development of ODT operating model	New target operating model More clinicians' time spent on clinical activities Safer, responsive co-ordination	NHSBT
5.10	Strengthen leadership and engagement of Transplant Co-ordination	Improved technology solutions, improved donation and transplant process	NHSBT
5.11	Strengthen leadership and engagement of Living Donation	Improved technology solutions, improved donation and transplant process	NHSBT
5.12	Responding to changes in transplantation	Respond effectively to new organ types	NHSBT
5.13	Pathway optimisation	Length and / or timing of the donation and transplant pathway improved	NHSBT
5.14	Donation and Transplantation Academy	Integrated approach to practice development and education of colleagues across NHS Income generation later in development	NHSBT
5.15	Benchmarking, co-operation and international comparators	More comparative data about organisations to inform future actions Continued collaboration with neighbouring European and international colleagues Charter agreed between Commonwealth nations	NHSBT
5.16	ODT Foundation (charity)	Ability to accept financial support and to commission initiatives supportive of our mission	NHSBT
5.17	*Integrating ODT and Tissue & Eye Services*	*Maximising donation and transplant opportunities*	NHSBT

6. Research and Innovation

Objective 6: *We will build further support for the world-leading, pioneering culture of research and innovation for the UK*

Research and innovation provide an opportunity to maximise the altruistic gift of every donor through research participation, for their family, recipients and those of the future. This in turn improves the evidence base for UK donation practice by embedding research in service delivery and quality improvement.

Over the duration of the previous strategy, the UK developed a strong foundation for research and innovation in organ donation and transplantation. Through horizon scanning and evidence gathering, a set of research priorities were established to address the clinical challenges being faced by Organ Donation and Transplantation. To facilitate research performed by NHSBT, clinicians and scientists and in collaboration with academic partners several initiatives have been delivered. These include:

- Establishing a national biobank of samples from deceased organ donors (Quality in Organ Donation (QUOD));
- Creation of a successful partnership with the National Institute for Health Blood and Transplant Research Unit in organ donation and transplantation;
- Funded 5-year research programs on donor assessment and organ reconditioning
- Developing a public and patient involvement and engagement platform;
- Establishing the RINTAG committee which assesses and reviews novel technologies in organ donation and transplantation;
- Expanded the NHSBT portfolio of informative National trials in organ donation and transplantation (e.g. PITHIA);
- Expanded the NHSBT research team to support further growth in ODT research.

Looking forward to this strategy, the main challenge in organ donation and transplantation is bridging the gap between access to life-saving transplants and the number of patients waiting on the transplant list. Five evidence-based initiatives are planned in this strategy to bridge this gap.

Behavioural research

Review of published evidence and engagement with the public and patients has shown that access to transplantation is not equitable for all patients. Black, Asian and minority ethnic groups have a high need for organ transplantation, while donation rates are generally lower. Barriers to organ donation in BAME communities restrict the availability of well-matched organs and results in relatively long waiting times for transplantation, with an increased risk of death on the transplant list. Understanding

the barriers to donor registration and family consent among the BAME groups, is essential to match demand for transplantation and availability of suitable donor organs.

Essential infrastructure

The donor organ pool is scarce. Increasing utilisation of the donated pool of organs will continue to be a priority throughout this strategy. The QUOD National BioBank will continue to be a valuable resource of samples collected from deceased organ donors. As more organs are offered from older and sicker deceased donors it is essential to make sure that every donor organ counts as a transplant while the longevity of the transplanted grafts is extended. Improving the assessment of donor organs prior to offering as transplants will enable us to better match the donor organ to each recipient, improve transplant outcomes and limit the need for re-transplantation. To date more than 4,300 donors have consented to provide samples and these are being used in 50 world-leading research studies.

Similarly, the NHSBT research team and Specialist Nurses – Organ Donation provide essential support for the successful delivery of a broad portfolio of research studies[8]. These studies span the entire donation & transplantation pathway and will shape future clinical practice. The infrastructure provided through this strategy to enable Research and Innovation in ODT is essential to transform future patient outcomes.

Stimulating increased investment in the highest priority areas

Constraints on Grant-in-Aid funding for organ donation and transplantation restrict NHSBT's ability to directly fund research and innovation through this strategy, however, in order to stimulate increased investment in relevant R&I NHSBT will work with research funders, charities and academics to ensure that Organ Donation and Transplantation remains a high priority area for funding. We will achieve this through a co-ordinated national approach consisting of:

- Subject to available funding, prioritising organ donation and transplantation as a future NIHR BTRU when the current funding cycle comes to an end;
- Funding a series of James Lind Alliance Priority Setting Partnerships across the donation and transplantation pathway;
- Providing a source of pump-priming to generate preliminary data to support funding applications to external funders;
- Supporting the newly established National Research Network in Organ Donation and Transplantation;
- Ensuring that the Research and Novel Technology Advisory Group continues to provide strategic oversight to and assessment of developing technologies that will transform transplantation.

The main barrier in achieving excellence and realising innovation is working in isolation. Aiming to improve patient care and save more lives by transplanting more organs that last for longer, NHSBT will actively engage with national and international,

[8] https://www.odt.nhs.uk/odt-structures-and-standards/research/current-odt-research/

clinical and academic partners within ESOT and BTS, to ensure research priorities are aligned with the current clinical challenges.

Data sharing and data capture

The UK has one of the best transplant registries in the world, the use of which has driven significant improvements in transplantation practice. The approach to data collection, analysis and insight will be transformed during this strategy, to ensure that it continues to utilise state-of-the art approaches to data capture and interrogation. The potential of automated data capture, machine learning, artificial intelligence and integration of data from external sources at-scale will all be investigated over the lifetime of this strategy. The ambition will be to leverage the UK's donation and transplantation data to generate and answer research questions.

Translational research and service developments

Assessment of donor organ quality, monitoring organ recovery during donor management or the successful regeneration of marginal organs during perfusion all have the potential to maximise the utility of donated organs.

NHSBT will continue to support research in this area and strengthen collaborations with academic partners, the pharmaceutical industry and diagnostic and therapeutic services to accelerate translation of biomarkers to the point of care.

Specialist national and international research networks will provide the ability to investigate new discoveries of novel pharmaceutical interventions that have the potential to optimise donor organs during donor management. In collaboration with the ICUs and the clinical trial units NHSBT will partner in prospective studies to test the efficacy of novel interventions in increasing utilisation improving transplant outcomes in recipients.

In recent years there has been an enormous expansion in the development of novel perfusion technologies. The next step will be the implementation of these technologies. The key role of R&I will be to support the assessment of these potential perfusion applications through the service development of biomarkers, and functional parameters as tools to monitor improvements of donor organ quality during perfusion.

Objective 6: We will build further support for the world-leading, pioneering culture of research and innovation for the UK			
	Action	**Impact**	**Who**
6.1	Initiate and support behavioural research	Provides evidence on impactful interventions that increase consent / authorisation levels for BAME donors in both deceased and living donation	NHSBT
6.2	Continued support for essential infrastructure	Underpin high-quality research and innovation to advance clinical practice and improve outcomes	NHSBT

6.3	Stimulate increased investment in the highest priority research and innovations	Improve patient care and more lives saved by transplanting more organs that last for longer	NHSBT
6.4	Enable enhanced data sharing and automated data capture	NHSBT will foster an environment of transparent and convenient data sharing, to maximise the opportunities afforded by advances in healthcare data science and big data	NHSBT
6.5	Support for emerging service developments	Increased translation of research and service developments to quantify organ quality prior to transplantation (e.g. Assessment & Recovery)	NHSBT

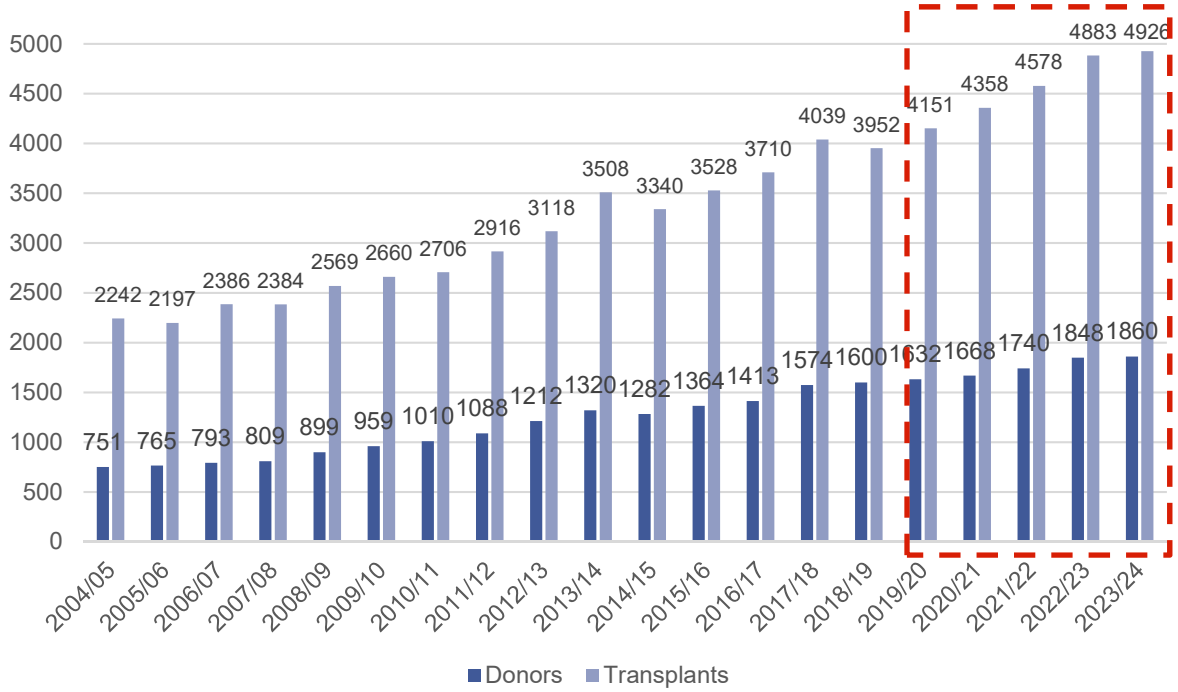
Impacts

The first 5 years All TBC

In the first five years of this Strategy to 2025, our projections suggest that the collective impact of the actions described here will lead to:

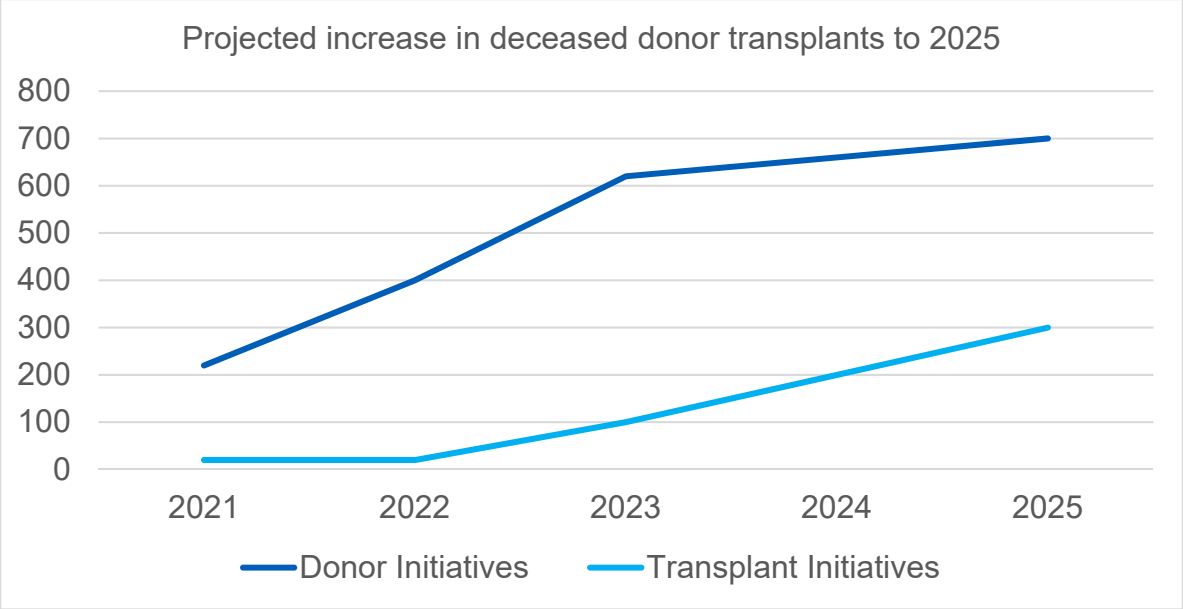
- 16% increase in the number deceased donors
- 25% increase in the number of living donors
- 25% increase in the number of deceased donor transplants (c.1,000 per year, by 2025)
- 25% increase in the number of living donor transplants (c.250 per year, by 2025)

Projection for deceased donors and deceased donor transplants



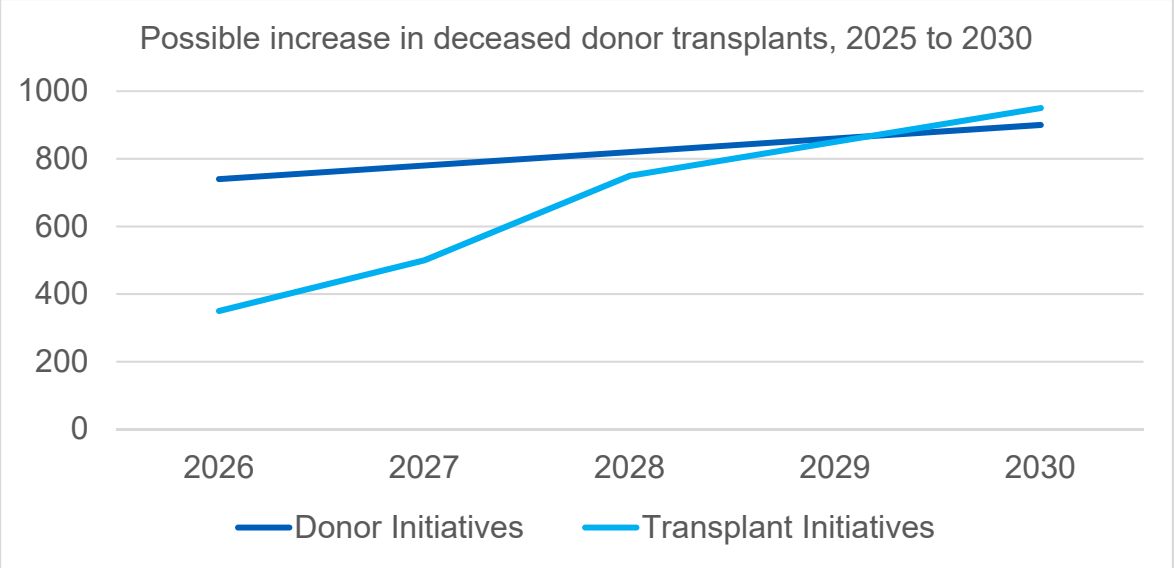
Within these first five years, donor initiatives – most notably the implementation 'pot-out' legislation – will progressively see an increase in the rate of consent or authorisation from donor families for deceased organ donation increase to an overall average of 80%. It is envisaged that this will account for about 65% of the first five years' gains.

Addressing the challenges of organ utilisation and harnessing the potential of new transplantation technologies and techniques will take time. It is estimated that the advances will contribute c.35% of the additional transplants by 2025 – but importantly also to higher quality, longer lasting transplants.



Years 5 to 10

We believe that transplant utilisation initiatives are more likely become impactful from years 3-5 of the strategy. There is the potential for these initiatives to become the greatest source of additional transplants from years 5-10.



Planning, Funding and Review

Taken as a whole, transplantation is a highly cost-effective intervention when compared with supporting and treating patients with organ failure in other ways, largely due to the cost of treatments such as renal dialysis and left ventricular assist devices. In terms of efficiency and human need, the NHS should prioritise securing increased numbers of transplants over less effective modes of treatment.

NHSBT have worked closely with the four home nations' NHS delivery bodies to ensure that there is a common understanding of donor and transplant activity in the

first five years of this strategy and the actions required to support this looking ahead to ten years hence.

The overall cost of organ donation and transplantation is difficult to assess given the number of organisations involved across the 4 nations of the UK. A high-level assessment of the investment in the service over the last 3 years shows funding to NHSBT has been flat at £74 million since 2016/17. During this time the number of deceased donors has increased by 13% and the number of transplants by 11%.

Relevant government Health Departments will be asked to review business cases for investment in public education programmes and operational capacity. Primarily, it is anticipated that these will support opt out, operational capacity and the possibility of supporting new perfusion technology. These will ensure that the fullest benefit of increased number of donors results in more transplants.

This high-level strategy will be supported by detailed plans, developed under the view of the NHSBT supported Sustainable Funding Group. An assessment will be made of the costs associated with these plans across the health system, to support decision-making by the Health Departments and commissioning bodies with funding responsibility.

Work will take place with NHS funders and stakeholders to set out detailed plans to achieve the strategy's aim and outcomes, systematically reflecting on the progress over each year or period of delivery.

Measuring Success

Mechanisms for review of this strategy and the engagement of stakeholders will be developed. This will principally involve the development of the *Taking Organ Transplantation to 2020* Oversight and Stakeholder groups.

Taken together, the impact of this strategy will be measured by its outcomes for patients: progressively improving rates of all organ donation, organ utilisation and transplantation.

Action by	Measure	2018/19	2025	2030
Individuals and donor hospitals	Total, deceased & living donors PMP	40	48	51
Transplant centres, commissioners and NHSBT	Utilisation rate (organs per donor)	2.6	2.8	3.1
Transplant centres, commissioners and NHSBT	Total, deceased & living transplants PMP	79	93	102

Supporting these ambitions, a more detailed set of measures is being developed (all TBC):

Objective	Measure	2018/19	2025	2030
Living and deceased donation are an expected part of care	• Consent / authorisation rate • Living donors per million population	67% 15.6	80% 20	80% 23
A step change in organ utilisation	• An increase in organs utilised from actual, donating deceased organ donors in each organ group	-	5%	>5%
Recipient outcomes among the in the world	• Recipient outcome measure TBC	TBC	TBC	TBC
People of all backgrounds have access to the organ they need, at the time they need it	• A reduction in the median kidney waiting time (including a greater reduction for black patients)	24 (32) mth	TBC	TBC
Making the most of every opportunity for a donation or a transplant	• Organ declines due to capacity • % organ offers accepted	110 TBC	Nil TBC	Nil TBC
Pioneering culture of research and innovation for the UK	• Organs provided for research	TBC	TBC	TBC