Organ Donation and Transplantation 2030: Meeting the Need

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

Acknowledgements

To be added at publication

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Page to be added in final version, to include

Foreword

The last decade has seen significant progress in organ donation and transplantation in the UK, during which deceased organ donation rates have increased by 56%. Through the selflessness of organ donors and their families, combined with the generosity of living donor 56,000 patients are currently alive with a functioning transplant.

These incredible achievements were made possible through the NHS, patient groups, commissioners and Governments working in collaboration and sharing a commitment to deliver improvements. Our work is not yet done. As of February 2020, there were 6138 people on the transplant waiting list, and lives lost every day, due to a lack of available organs. *Organ Donation and Transplantation: Meeting the Need* sets the vision and focus for the next 10 years, to build on the successes of the past and deliver further improvements.

The strategy will only be a success if it supports and benefits everyone in need of a transplant. Whilst progress has been made, an unacceptably large number of people from a Black, Asian, Mixed Race and Minority Ethnic (BAME) background still spend far too long on the transplant waiting list because of a lack of suitable organs. We will do more to engage with the diverse populations across the UK, empowering them to lead the promotion of living and deceased organ donation.

One of the key foundations for *Meeting the Need* is the strength of the public support for organ donation. To reflect this support, three of the Governments in the UK have already changed the law on consent or authorisation for deceased donation to one of 'opt out', rather than 'opt in'. The fourth is consulting on the change.

The anticipation is that these law changes could lead to hundreds of additional lives saved or improved every year, through increasing the number of organs available for transplantation. The challenge for the coming years is to make sure that the transplant service can keep pace with this increase.

This strategy therefore sets out the aims to ensure that every organ that can be safely transplanted is used to save or improve someone's life. It also sets out the actions to support and maximise the potential for living donation, which is vital for ensuring that as many people as possible receive the transplant they need.

Research and innovation are vital components of this strategy. The UK is a pioneer in developing and adopting new techniques and technology in donation and transplantation and we will continue to look to the future and lead the way, so that the benefits of this strategy will be felt well beyond the next decade.

The improvements of the last ten years have taken commitment, passion and hard work to deliver. There is no sign of this dedication to delivering improvements wavering. The actions set out in this strategy are ambitious, but through continuing to

work together, even more lives will be saved every year through the gift of organ donation.

Health Secretaries signatures x 4

Executive Summary (include relevant hyperlinks)

Twelve years of progress

The publication of the Organ Donation Taskforce report on deceased donation 'Organs for Transplant' in January 2008, gave subsequent strategies the mandate to focus on its 14 specific recommendations, which have resulted in a revolution in deceased organ donation activity and practice across the UK.

Together, these strategies, supported by all four UK nations' governments, NHSBT, professional societies and patient organisations, have delivered a 95% increase in deceased donors and a 58% increase in deceased donor transplants, since 2008. This amounts to 1580 donors and 3760 transplants in the last year.

Alongside the strategy for deceased donor transplantation, 'Taking Organ Transplantation to 2020', the 'Living Donor Kidney Transplantation 2020' strategy has consistently delivered around 1000 transplants per year, accounting for 21% of overall transplant activity and 29% of all kidney transplants. The overall stability in living donation activity, masks the change in approach to living donor kidney transplantation and the patient benefit that has been realised through increasing numbers of non-directed (altruistic) living donors and the UK Living Kidney Sharing Scheme. Collectively, these world-leading programmes have benefited 1852 kidney transplant recipients, including those who wait longest due to difficulty in matching them to a suitable donor.

Additional strategies focusing on organ utilisation and paediatric and neonatal deceased donation have contributed to these considerable achievements, which are testament to the commitment of everyone involved in the donation and transplantation pathway, but particularly to organ donors and their families.

Meeting the Need

Significant positive steps have been taken, but there remains a mismatch between donation and transplantation. We now need to build on the success of the past to deliver the future. To close the gap for patients waiting for a transplant, we need an additional 2400 transplants every year for the duration of the strategy.

To achieve our ambition, it is estimated that baseline funding from UK Governments to NHSBT will need to rise by £22 million in 2021/22 and to £30 million by 2024/25, allocated in accordance with the Barnett formula. In addition, NHSBT will require approximately a further £10 million per annum over the same period to deliver the Directorate of Organ and Tissue Donation and Transplantation's (OTDTs) responsibilities with respect to the strategic objectives detailed in this document.

The success of the strategy is dependent on further investment from Transplant commissioners to support provider Trust/Board capacity and service sustainability.

This vision can only be delivered with investment and collaboration between key stakeholders.

Our shared vision brings together both living and deceased donation and their concurrent strategies. We are aiming to balance the evolution of current best practice initiatives with a revolution in organ utilisation using new technologies, digital solutions and research and innovation to deliver real improvements for people in need of a transplant.

The strategy takes into account two of the most significant events that have occurred in 2020 and in the history of organ donation and transplantation: firstly, the introduction of 'opt-out' legislation across the UK; secondly the impact of the COVID-19 pandemic.

The pandemic has brought both opportunity and threat to organ donation and transplantation: opportunity to understand how we can work together and differently for the benefit of patients with a common purpose in the face of adversity, and threat in terms of the uncertainty about the impact on waiting lists, donation behaviour and individuals within society, who may have been disproportionately disadvantaged in ways that we have yet to fully understand.

Building on the work of previous strategies, achieving diversity and inclusion and addressing health inequalities in donation and transplantation are key ambitions within this strategy.

This is particularly pertinent at a time when issues of inequalities for people from a Black, Asian, Mixed Race and Minority Ethnic (BAME) backgrounds have been brought to the fore across society and, in general, more people across society are disadvantaged by the socio-economic situation. The abbreviation 'BAME' will be used with reference to people from Black, Asian, Mixed Race and Minority Ethnic backgrounds throughout the document.

Context

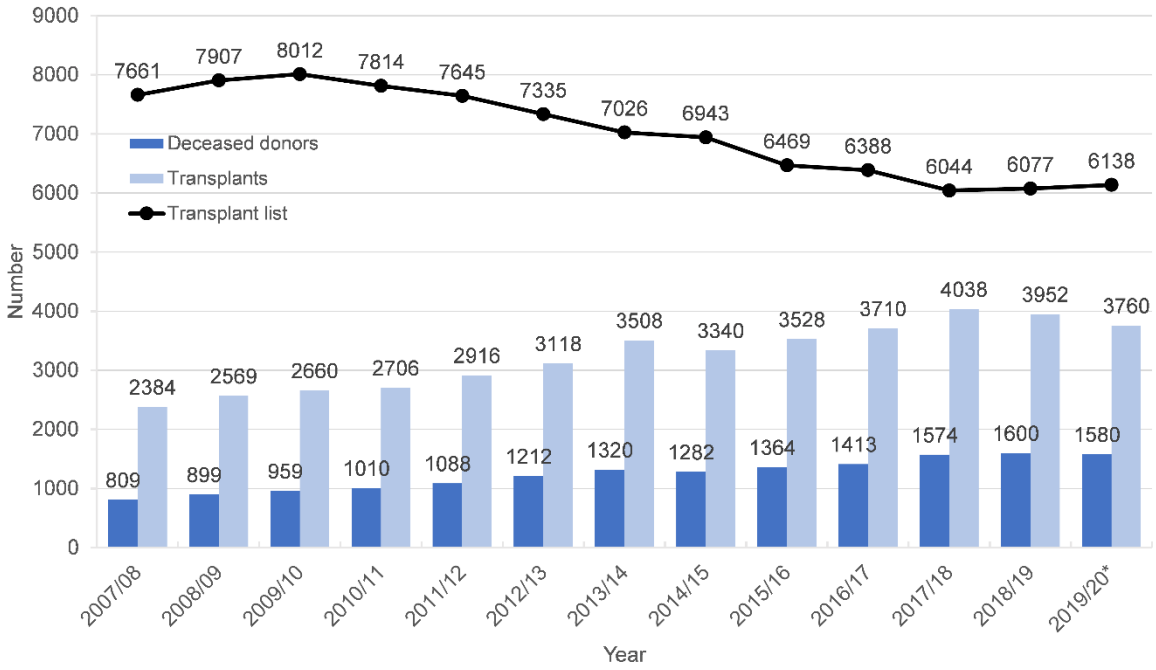
For more than fifty years, the United Kingdom has made great progress and developed world-leading expertise in organ donation and transplantation medicine and surgery, giving hope to everyone in need of a transplant that their life may be saved or improved.

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

In this era the number of deceased organ donors has almost doubled from 809 (2007/08) to 1,580 (2019/20) and the number of transplants from these donors has increased by 58% from 2,384 to 3,760 (See Figure 1).

In 2019/20, living donor transplantation represented 29% of the UK kidney transplant programme and 21% of overall transplant activity. 98% of living donors donate a kidney, with 1024 people donating a kidney and 22 a lobe of liver in 2019/20.

Figure 1 Deceased donors and transplants in the UK, 1 April 2007 to 31 March 2020 and active transplant list at 31 March



*Transplant list as at 29 February 2020

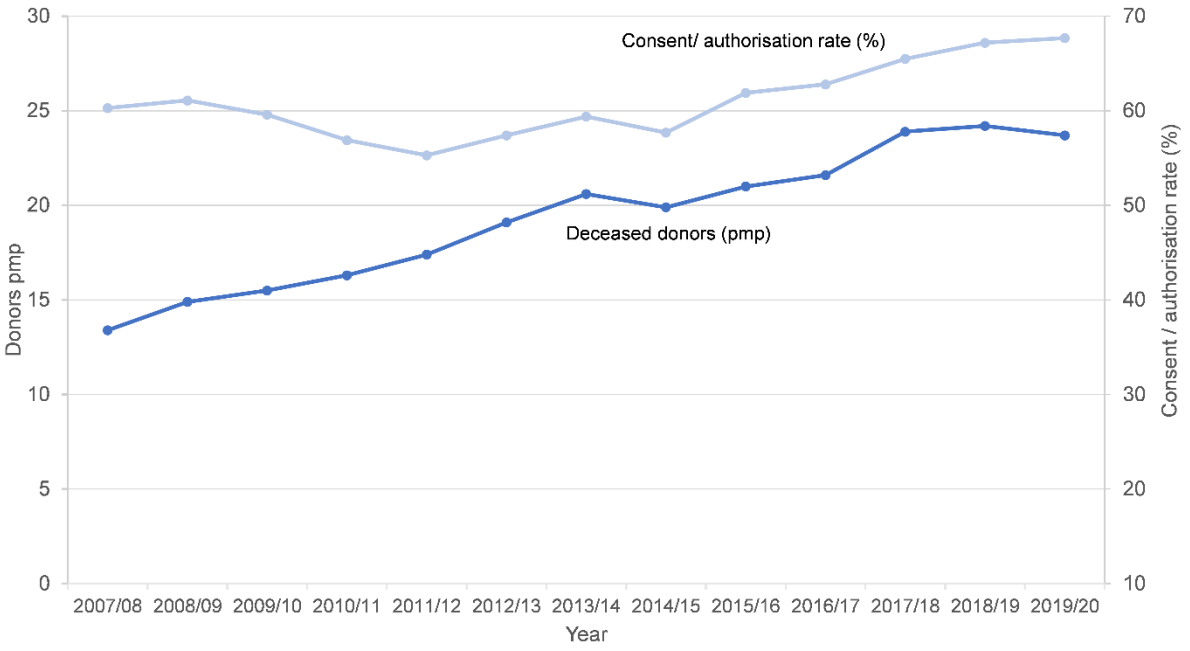
** 2019/20: Many patients became suspended from the active transplant list as transplant centres reacted to the COVID-19 pandemic in March 2020. Therefore, 29 February 2020 has been used as a more representative date for the number of patients on the active transplant list at year end in 2019/20.*

The achievements in deceased donation stem from 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 sustained effort on increasing consent or authorisation for deceased organ donation (Figure 2).

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 resulted in their consent rate rising significantly. England, Jersey and Guernsey have already implemented similar legislation, Scotland will do so in March 2021 and Northern Ireland is in consultation about the possibility of a future change from the current ‘opt-in’ system. Making the most of this opportunity remains vital to progress in the coming years.

Figure 2 Overall consent / authorisation rate and donors per million population (pmp) in the UK, 1 April 2007 to 31 March 2020



During the same period, the overall number of living donors has remained relatively stable at approximately 1,000 each year – partly due to an increase in the availability of organs from deceased donors. However, the contribution of non-directed altruistic donors (donation to a stranger) and paired/pooled (kidney exchange) donations in the UK Living Kidney Sharing Scheme (UKLKSS) has increased the quality and number of transplant opportunities available for people waiting for a kidney transplant, thereby reducing the demand for more complex transplant options for long-waiting patients. Of the 1046 living donor transplants performed in 2019/20, 95 non-directed altruistic donors enabled 146 patients to benefit from a kidney transplant and a further 96 were made possible by paired/pooled donations. As a result of these increases in organ availability, more people have benefited from a transplant.

Kidney transplantation, both living and deceased, has the greatest health economic impact of all solid organ transplantation due to savings to the NHS in dialysis costs. Based on figures from the Department of Health and Social Care (DHSC) in England in 2015, the estimated cost of a kidney transplant in the first year is £55,288, reducing to £8,526 for follow up. The costs of dialysis were estimated to be £29,841 per annum.

Therefore, the NHS costs reduce per patient from year three post-transplant. The average transplant survival following deceased donor kidney transplantation is approximately 13 years and for living donor transplantation approximately 20 years. In addition, living donor transplantation maximises the opportunities for pre-emptive transplantation (avoidance of dialysis). In comparison with dialysis, quality of life and survival for patients with a successful transplant are significantly improved.

The health economics for other organs are more difficult to evaluate because the availability of comparative treatment options is organ specific and variable. However, a successful organ transplant with the potential to restore health and well-being in the recipient, is likely to have a positive impact on hospital admissions, length of stay per patient and costs to the wider NHS.

Health economics require on-going evaluation for all organ groups throughout the next strategic era to demonstrate the value of new technologies and initiatives to increase organ utilisation and successful transplantation.

Previous Strategies (DN: 2020 strategies outcome report to be referenced/added as footnote or appendix)

Our **'Taking Organ Transplantation to 2020'** strategy was published in 2013 with an over-arching aim 'to match world-class performance in deceased organ donation and transplantation' through four key outcomes:

Who	Outcome
Society and Individuals	Attitudes to organ donation will change and people will be proud to donate, when and if they can.
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.
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.
NHSBT and commissioners	Better support systems and processes will be in place to enable more donations and transplant operations to happen.

The 2010 strategy for living donor kidney transplantation was updated in 2014 to the **'Living Donor Kidney Transplantation 2020'** strategy, which matched the ambitions of the deceased donation strategy through five key outcomes:

Who	Outcome
NHSBT, commissioners and all UK health departments	There are no financial disincentives to support a fully integrated UK- wide LDKT programme
NHSBT, commissioners and clinicians	Appropriate infrastructure, systems and processes are in place to maximise the number of transplants achieved from all suitable living kidney donors
NHSBT, clinicians, commissioners and other authorities	Outcomes of LDKT are monitored and that information is accurately interpreted and utilised to support state of the art donor and recipient care
NHSBT and clinicians	All suitable recipients have an opportunity to consider the option of LDKT before dialysis or to minimise waiting time if dialysis is unavoidable, regardless of where they live in the UK
NHSBT, society and individuals	Awareness of LDKT is effective across all sectors of society in all four UK countries

A strategy for Organ Utilisation was later published, in addition to a Strategic Plan for Paediatric and Neonatal Deceased Donation. All these aspects are now incorporated in this new strategy.

More people could benefit from a transplant

The UK has achieved significant progress in all areas since 2013, overcoming many challenges to give more people the life-changing benefit of a transplant. However, there remains a substantial unmet need. True demand for an organ transplant is unknown but, taking current waiting list size and rate of new registrations into account, it is estimated that another 2,400 transplants per year are needed to meet current demand.

Despite our collective achievements, there remain inequities across areas of the UK and in types of organ transplant. For example, 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 from a BAME background are also still disproportionately affected by shortfalls and longer waits for a suitable kidney for transplantation and lower rates of organ donation amongst these communities[1].

Impact of COVID -19

The lessons learnt during the 2020 global pandemic will be shared as we continue to work collaboratively across the donation and transplantation pathway to develop resilient implementation plans to deliver this strategy. At the time of writing, the second wave of COVID-19 was advanced and such plans were already being implemented to maintain donation and transplantation activity across the UK.

[1]NHSBT BAME Annual Report https://www.odt.nhs.uk/statistics-and-reports/bame-annual-report/.

The first wave of the pandemic had an immediate impact on all forms of donation and transplantation. Due to the uncertainty associated with COVID-19, deceased donor criteria were adjusted to minimise risk, living donor kidney transplantation was paused and all centres limited transplantation to selected patients; where the risk-benefit ratio of transplantation could be justified.

In the immediate aftermath of the first wave, deceased donation and transplantation activity recovered quickly to pre-COVID-19 rates. Consent / authorisation rates exceeded pre-COVID-19 levels for reasons that need further study but the impact of opt-out in England, introduced in May 2020, and increased goodwill towards the NHS may be contributory factors.

Living donor kidney transplantation was slower to restart and for normal activity to be resumed due to the complete pause. Consequently, preventing closure of programmes through a subsequent surge of the pandemic became a priority. The UKLKSS was reinstated in October 2020.

Whilst the impact of the COVID-19 pandemic was profound, the system leadership role undertaken by NHSBT, working closely with clinical and commissioning communities across the UK, brought the whole community together. This underpinned an effective and flexible response, which mitigated the risks involved and facilitated a rapid and successful recovery, including:

- Rapid, flexible response to changes in the environment and to needs of the donation and transplantation community
- Effective and regular communication
- Willingness to engage from all parties
- Shared ownership of critical decisions
- Focused, time-limited meetings with clear outcomes
- Timely submission and review of data
- Appropriate reflection on decisions made and lessons learned

The long-term impact of COVID-19 on numbers of patients waiting for a transplant and on the overall waiting list is not yet understood and will continue to be evaluated. An early comparison of the UK kidney waiting list in February 2020 (pre-COVID) with October 2020 indicated no significant difference in the proportion of patients waiting for a transplant by age or ethnicity, despite concerns to the contrary. Patient selection for transplantation continued throughout the first and into the second wave of COVID-19. This has impacted on the number and characteristics of listed patients and, as yet, we do not have the evidence to show long-term impact on waiting lists for individual organs.

In addition, the impact of Long COVID is not yet fully understood. It is too early to understand how this will impact demand for transplantation. What is clear is that COVID-19 will have a long-term impact on the implementation of this strategy and we must be responsive and flexible in our approach.

Our Vision

Evolution and Revolution

Despite significant progress, there remain substantial challenges – and enormous opportunities – to securing a suitable organ for everyone who needs a transplant. This Strategy represents both evolution and revolution: some of our existing initiatives will continue, while some will be new. These will be balanced to deliver real improvements for people in need of a transplant.

We have two propositions, supported by actions across the organ donation and transplantation pathway.

1. **To increase organ donation and**
2. **To increase organ transplantation**

Previous strategies have delivered by focusing mainly on organ donation initiatives. While there remains great potential for increases in donor numbers in both living and deceased organ donation, there are also opportunities for the UK to increase organ utilisation using new technologies and techniques.

We will focus on addressing organ utilisation challenges common to all organ groups, and each group individually. We will also develop models of organ recovery – where organs can be assessed and treated with precision medicine prior to transplantation. The ambition is that the UK will deliver a step-change in transplantation, which will reduce the wait for a transplant and improve outcomes for those who receive this life-changing gift.

The importance of a strategic approach to addressing issues related to BAME communities and other disadvantaged groups was highlighted throughout our stakeholder events. This has been brought into sharper focus because of the disproportionate impact of COVID-19 amongst people from a BAME background and the greater awareness of systemic racism in society and efforts to address it through the Black Lives Matter movement. The fastest growing demographic in the UK is people of mixed race; although the definition of who is included in this group needs clarification, we must be mindful of this shift in ethnicity. Any developments will be underpinned by a focus on diversity and inclusion, ensuring that we deliver the best possible outcomes for all, irrespective of ethnicity or social circumstances.

We will transform the UK's donation and transplantation services to provide a sustainable service that is well-prepared for the future and engenders public and patient confidence. We will further develop the UK's pioneering culture of research and innovation in donation and transplantation.

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 partners 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 (NBTA), focused specifically on diversity.

The events contributed to nearly 5,000 ideas, questions and suggestions. We have used these to develop our evidence base and plans.

In addition, we undertook an International Peer Review in September 2020, with input from colleagues across the world. This event provided valuable feedback and support for the strategy, with further ideas for collaboration with NHSBT as world leaders in research and development.

Our Ambition

Our ambition is to be a world-leading organ donation and transplantation system. This will be achieved by working in partnership across the UK and the NHS and in collaboration with international colleagues to increase the number of organ donors and the number of successful transplants.

The emphasis on increased action in transplantation in this strategy will require organisations to work together – those with a focus on donation and those with accountability for transplantation services - to achieve our ambitious objectives for patients.

We will focus on six key areas of action:

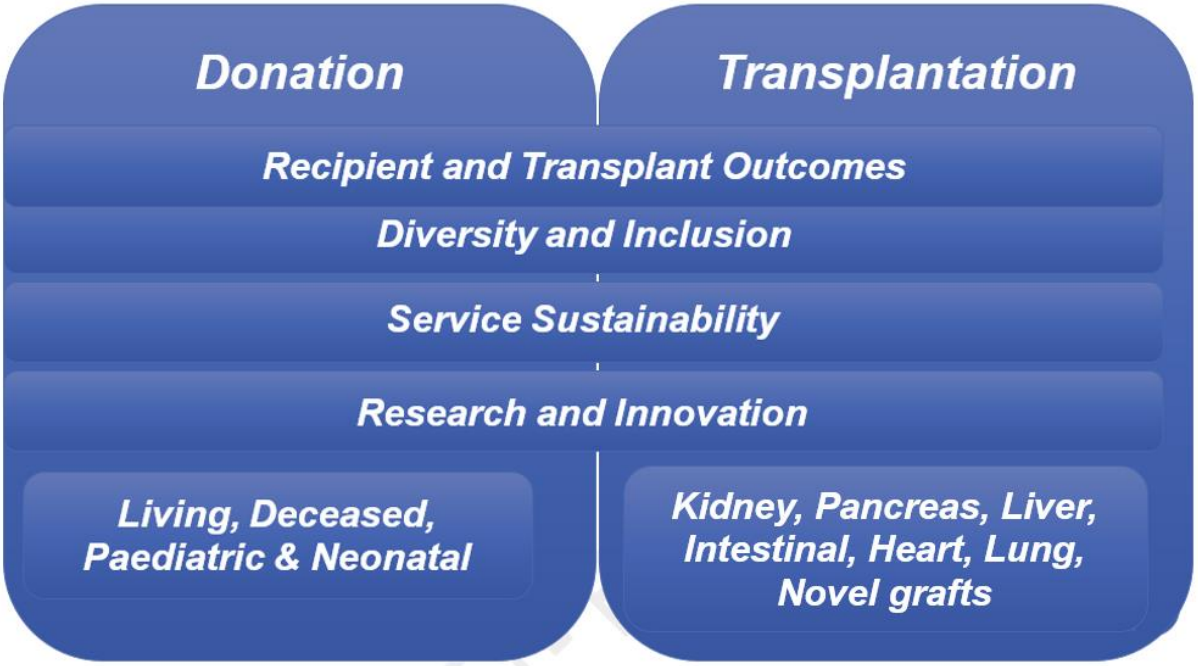
Action by	Aims	
Primary Objectives		
Individuals, donor hospitals and NHSBT	**1**	Living and deceased donation will become an expected part of care, where clinically appropriate, for all in society
Transplant centres, commissioners and NHSBT	**2**	We will aim for optimal organ utilisation in every organ group, benefitting from new technologies and techniques
Enabling Objectives		
Transplant centres, commissioners and NHSBT	**3**	To make the most effective use of a precious donor organ, we will ensure that recipient outcomes are amongst the best in the world
Transplant centres, commissioners,	**4**	People of all backgrounds and circumstances have timely access to the organ they need

community and National partnerships, and NHSBT		
Transplant centres, commissioners and NHSBT	**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 and a transplant
Transplant centres, researchers and NHSBT	**6**	We will build a pioneering culture of research and innovation in donation and transplantation in the UK

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

Our Approach

This detailed strategy describes the areas that need to be addressed as the UK continues to save and improve more lives through organ donation and transplantation after 2020



1. Increasing Donation

Objective 1: Living and Deceased Donation will become an expected part of care, where clinically appropriate, for all in society

This strategy sets out how the UK will move to a position where the public can expect organ donation to be explored and discussed.

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. Further innovation in the practice of organ donation and realising the opportunities of changes to the law will be essential if we are to honour the gift of donation.

Only one percent of us will die in circumstances where organ donation is currently considered possible.[2] The UK has advanced by identifying more potential donors, referring for assessment and obtaining consent or authorisation from donor families. In our intensive care and emergency departments, the consideration of organ donation is now a usual part of end of life care.

While other countries have experienced declines in living donation, we have maintained activity and improved outcomes for patients thanks to the generosity of non-directed (altruistic) donors and the success of the UKLKSS.

Although there are 26 million people registered to donate on the NHS Organ Donor Register and the consent rate for deceased donation in the UK has risen (currently 69%), it still does not match the best in the world (Spain, Poland and Republic of Ireland are all greater than 80%).[3]

There are inequalities in terms of age, gender, and ethnicity for living and deceased donation from BAME people. We need to improve engagement, to overcome the obstacles for both deceased and living donation and address these inequalities.

This is particularly relevant to Black or Asian people, who are more likely to need a transplant but are less likely to agree to donate an organ[1].

1.1 Deceased Donation

A revolution in support for organ donation

The biggest change since the publication of the previous strategies is the introduction of opt-out legislation.

- Since December 2015 in Wales, July 2019 in Jersey and May 2020 in England, consent legislation has changed so that people are considered to be organ donors after their death, unless they have decided not to donate or are in one of the excluded categories.[4]
- Scotland will be introducing deemed authorisation in 2021 and Northern Ireland, Guernsey and Isle of Man are also moving to introduce opt-out.[5]

The decision about organ donation rests with the individual. People are encouraged to make a decision, record that decision on the NHS Organ Donor Register[6] and tell their families about what they would want to happen. Families will always be closely involved in the process. They provide information regarding the last known decision of

[2] A patient who is intubated and ventilated, generally on an Intensive Care Unit or Emergency Department, without an absolute medical contraindication to organ donation.
[2] Pedder-Jones C, Papadopoulos C, Randhawa G (2019) Who's opting-in? A demographic analysis of the U.K. NHS Organ Donor Register. PLoS One. 2019 Jan 2;14(1):e0209161. doi: 10.1371/journal.pone.0209161).

[4] Link to Website https://www.organdonation.nhs.uk/uk-laws/
[5] Northern Ireland currently operates an opt-in system, where the Devolved Government is responsible for and leading on, promoting organ donation.
[6] NHS Organ Donor Register: By November 2020, 28.2 million people had recorded a decision on the ODR, of whom 1.8 million recorded a decision not to donate.

their relative, whether there are any faith requirements that need to be considered and medical and social history to ensure that any donated organs would be safe to transplant.

To achieve a revolution in consent / authorisation for deceased organ donation we will need:

- Highly visible public information campaigns in a wide range of settings[7], encouraging people to make an organ and tissue donation decision and share it with their family.
- To promote organ donation through community and national partnerships and through NHSBT's Donor Ambassador programme leading to increased diverse community advocates for the benefits of organ donation.
- Further train NHS staff involved in the donation process so that families can expect to receive the care and support they need during the donation process.

Making the most of the opportunities presented by opt-out legislation is our best chance to increase the number of individuals, supported by their families, becoming donors.

Maximise donation potential

There can be no transplantation without donation. With so few people dying in circumstances where organ donation is an option it is essential that we maximise the number of donors and the number of organs from each donor and look for new potential donors outside intensive care and hospitals.

We will:

- Strive to get processes right 100% of the time and drive improvements and innovations through the UK's model of local Clinical Leads, Specialist Nurses and Organ Donation Committees.
- Use the UK Potential Donor Audit, a world leading audit tool, to provide the best data to hospitals as the basis for learning and improvement and for comparing donation activity internationally.
- Further improve donor selection, management and drug therapies, to expand the number of donor organs considered suitable to transplant, learning from best international practice.
- Explore the potential for donation both inside and outside the traditional hospital settings of intensive care and emergency medicine, supporting those initiatives that show the best potential.
- Establish a forum for addressing ethical issues associated with innovative new practices.
- Continue to implement the recommendations and actions from the 2019 UK Paediatric and Neonatal Deceased Donation Strategic Plan.

[7] NHSBT has conducted a feasibility trial of whether GP practices may be a suitable forum for discussing organ donation Jones C, Papadopoulos C, Asghar Z & Randhawa G (2020) Improving access to organ donor registration in general practice – A feasibility study. British Journal of General Practice. https://doi.org/10.3399/bjgp20X709601

The length of the donation process is now a frequent reason for families to withhold or withdraw their consent / authorisation for organ donation. Progress has been made to ensure that suitable recipients are sought for every organ generously offered by deceased donors and their families. However, this has had the unintended consequence of making the donation process longer and more complex. The time required for donor characterisation, organ offering and retrieval has increased so much that transplantation is becoming a night-time procedure - increasing the challenges for the surgical team and stretching resources further.

We will:

- Improve the donation experience for families by reducing delays in the process.
- Act together with colleagues across the donation and transplantation pathway to address the issues of the length and timing.
- In those hospitals which have a transplantation centre, expand our established Organ Donation Committees to become Organ Donation and Transplantation Committees, so that there will be a whole pathway approach.

Recognise donors and donor families

Donors and their families make the generous decision every day to save and improve the lives and inspire others to donate.

We will:

- Provide the highest level of ongoing support to donor families. This will include developing NHSBT's family after-care programme which provides information, by request, about the donation outcome, facilitates correspondence and provides referrals for grief support.
- Strengthen the public recognition of the gift of organ donation, including continuing the posthumous Order of St John Award for Organ Donation
- Recognise the gift of donors and donor families who participate in research and tissue donation.
- Increase the visibility of donor families within UK society so that organ donation becomes a societal norm.

Objective 1:1 Deceased Donation will become an expected part of care, where clinically appropriate, for all in society

Deceased Donation

	Action	Impact	Who
1.1.1	Maximise the number of donors and number of organs from each donor and look for new potential donors outside intensive care and hospitals	Widened donor selection and donor management procedures to realise additional donors and donor organs.	NHSBT NHS Commissioners Organ Donation Committees

		Expanded possibilities for donation from new settings.	
1.1.2	Public visibility and promotion of the benefits of organ donation and awareness of the change of legislation; engagement with BAME people and faith groups	A revolution in support for organ donation. Public decides about organ donation, recorded via the NHS Organ Donor Register.	NHSBT Governments. Public Community and National partnerships
1.1.3	Continue to improve training for NHS staff involved in the donation process	Improve the donation experience for families. Families can expect to receive the care and support they need through the donation process. Improved donor management leading to the donation of more organs.	NHSBT Acute hospitals
1.1.4	Develop the Potential Donor Audit	Evidence to inform new practices and identify the greatest potential for more donors	NHSBT
1.1.5	Establish a forum for ethical discussions as donation practice continues to innovate	Ethical issues associated with innovative new practices are addressed and endorsed	NHSBT
1.1.6	Continue to implement the recommendations and actions from the 2019 UK Paediatric and Neonatal Deceased Donation Strategic Plan.	Assure health care professionals, families, children and society, that every gift of donation from children is precious and will be sensitively explored and discussed. Maximise donation and transplantation	NHSBT Transplant Centres

		opportunities from every paediatric donor.	
1.1.7	Establish Organ Donation and Transplantation Committees in hospitals with transplant centres	Integrated, local action planning to address cross-pathway issues. Improve donor family experience by reducing length of the donation process.	NHSBT NHS
1.1.8	Recognise and support donors and donor families who have made the generous decision to save and improve lives.	Donor families will be provided with the highest-level of support during and after donation. The gift of donors and donor families, including those who participate in research and tissue donation, will be visibly recognised so that donation for transplantation and research increases and becomes a societal norm.	NHSBT Community and National partnerships Organ Donation Committees

1.2 Living Donation

Maximising the benefit

Living donation makes a unique contribution to organ donation and transplantation by offering more patients the possibility of a successful transplant - often one that they may never have had from a deceased donor- whilst adding to the overall supply of organs for all those who are waiting for a kidney or liver transplant.

The safety and welfare of the person who chooses to donate is paramount; their physical and emotional suitability must be carefully assessed and the decision to donate fully informed, voluntary, with consent freely given. Although there are legitimate concerns about surgical and life-long risks for living donors, evidence suggests that careful individual assessment before donation mitigates against such risks.

Living donors may be friends or family members who donate directly to their recipient or through the paired and pooled kidney 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 within the UKLKSS); or non-directed altruistic (anonymous donation to a stranger).

Overall rates of living kidney donation trebled between 2000 and 2010 due to excellent reported outcomes for both recipients and donors and in response to patient and family choice. Activity in the UK peaked in 2014 due to a steady increase in non-directed donation since 2011. However, in common with other countries, overall donation rates have stabilised and fallen short of predicted activity in the 2020 strategy. In 2019/20, living donor transplantation represented 21% of overall transplant activity and 29% of the total UK kidney transplant programme. Kidney donations are 98% of all living donations, with 1024 kidney and 22 liver donors in the last year. In total, living donation contributed 28% of all transplants in 2019/20.

Living donor kidney transplantation is well established in the UK. Despite the benefits of immediate and long-term transplant function and the opportunity for planned transplantation before dialysis (pre-emptive transplantation), the increase in deceased donor organs and reduced waiting times during this period, has had an impact on living donation.

For people in need of a transplant, approaching family and friends to ask them to consider living donation can be a difficult conversation. As the number of deceased donors has increased and waiting times improved, more people may have either chosen to wait for a deceased donor or the conversation about living donation has not been raised. This is also evident in other countries where there has been an increase in deceased donation, although the UK has been more successful in sustaining activity and developing innovative approaches to maximise the gift of living donation. The increase in BAME living donors (1% in 5 years) now exceeds BAME deceased donors, and the reasons for this need further exploration. However, there have been notable achievements in raising awareness about living donor kidney transplantation through targeting modest resources within BAME communities. These offer templates for future initiatives.[8]

Living donor liver transplantation currently makes up a small proportion of living donation activity in the UK and has typically focused more on children than adult recipients. This strategy will build on the experience from previous strategies to include living donation as one of a range of options for suitable recipients.

The impact of strangers

Through the 'Living Donor Kidney Transplantation to 2020 strategy', more 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 exceeded expectations and made a unique contribution to the success and impact of living donor kidney

[8] Final Report of the Living Transplant Initiative, November 2019 https://www.nbta-uk.org.uk/wp-content/uploads/2019/11/LTI-FINAL-REPORT-Nov-2019.pdf

transplantation by creating transplant opportunities within the UKLKSS and for recipients on the UK transplant list who may not have a living donor of their own.

Transplants achieved through the UKLKSS particularly benefit long-waiting patients who are immunologically complex and / or from BAME backgrounds. The UK is an international leader in kidney exchange and has reduced the need for higher risk antibody removal treatments to facilitate transplants between incompatible donors and their recipients. As a result, the UK has improved its ranking in living donation by international comparison despite limited expansion of overall activity.

Taken together, the benefits of living donation and the potential for future development, extend the opportunities for patients waiting for a transplant

If the UK is to increase the total number of transplants and reduce the waiting time (for kidney in particular), non-directed altruistic kidney donors will be 'game changers' and living donor kidney transplantation 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. For this reason, non-directed donation is less common. Transplant centres currently discuss this option for paediatric recipients and for carefully selected adult patients. Living donor liver transplantation will be offered as one of a range of options for people who need a transplant.

In this strategy, we will:

- Continue to work with all governments to promote living donation, improve engagement and access to it across society and safeguard the interests of people who are willing and suitable to donate
- Provide tailored information and support for people considering living donation and to patients waiting for a transplant to help them make the best decision
- Explore all transplant and donation options at an early stage and in the context of other available treatment options to ensure that all suitable recipients have the opportunity of a transplant with the best outcome at the time they need it
- Create a digital platform to underpin development and expansion of the UKLKSS, maximise utilisation of non-directed altruistic donors and increase the number of successful transplants for all patients who are waiting for a kidney
- Collect comprehensive self-reported Donor Report Outcome Measures (DROM) and Donor Reported Experience Measures (DREM) for living donors within the UK Living Donor Registry to enhance donor care and inform people who are considering donation about the donation process
- Continue to recognise the gift of donation from every living donor through the Living Donor Pin Recognition Scheme

Objective 1:2: Living Donation will become an expected part of care, where clinically appropriate, for all in society			
	Action	**Impact**	**Who**
1.2.1	Maximise transplant opportunities in the UK through the UKLKSS	Innovative sharing scheme, to maximise transplant opportunities. Updated IT platform to support best clinical practice	NHSBT, Transplant and Non-transplant Centres, Commissioners
1.2.2	Ensure that the option of "transplant first" is considered for **all** suitable kidney recipients, especially pre-emptive transplantation	Avoiding unnecessary or extended time on kidney dialysis, improving recipient well-being and experience, saving NHS resources. Addresses health inequalities e.g. BAME, socio-economic	NHSBT, Transplant Centres Community and National partnerships
1.2.3	Make it as easy as possible for people to give or receive a living donor kidney or lobe of liver by removing unwarranted barriers to donation	Overcoming barriers (including financial), resulting in more access to donation and maximising transplant opportunities	NHSBT, Transplant and non-transplant Centres, Commissioners
1.2.4	Promote public and patient awareness and engagement in living donation across all sectors of society and develop the Living Transplant Initiative.	Increased transplant opportunities for patients who are currently disadvantaged (including liver recipients; people with whom we could engage more effectively; increasing proportion of non-directed living kidney donors)	Governments NHSBT Transplant and Non-transplant Centres Community and National partnerships NBTA
1.2.5	Address unwarranted variation in clinical practice by strengthening	Living donation is part of a "range of choices" for potential transplant recipients and their	NHSBT Transplant and non-transplant Centres Commissioners

	leadership and providing clear polices and guidelines	families, resulting in more kidney and liver living donor transplantation for suitable recipients and improved access to transplantation	
1.2.6	Ensure that the experience, safety and welfare of living donor transplantation is the best it can be for all donors and recipients and that donors are recognised for their gift of donation	Improved donor and recipient clinical pathways and data quality via existing UK Registry and donor self-reported outcome and experience tools (digital infrastructure. Enhanced quality of donor and recipient outcomes	NHSBT Transplant and non-transplant Centres Commissioners
1.2.7	Use innovative solutions to offer more recipients the option of a living donor transplant (e.g. antibody depletion techniques)	Improved access to transplantation and outcomes for patients who are unlikely to benefit from other interventions	Transplant and Non-transplant Centres, Commissioners

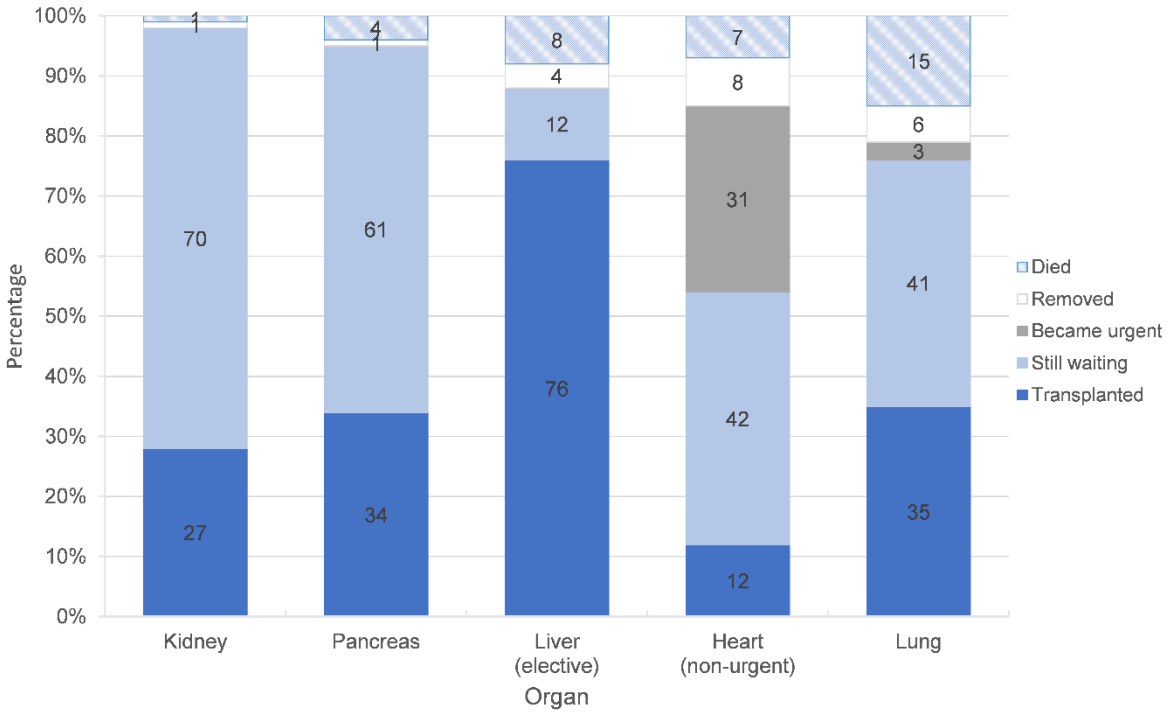
2. Increasing Transplantation

Objective 2: We will aim for optimal organ utilisation in every organ group, benefitting from new technologies and techniques

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. This has largely been very successful.

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 all patients who could benefit from a transplant, may not currently be on the transplant waiting list.

Figure 3 One year post-registration outcome of patients registered for an organ transplant*



These factors underline the need for a further transformation, which will now see additional advances in technology used to help assess, retrieve and if necessary, repair organs prior to transplantation. This will be in addition to actions to improve deceased donor 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 the intended recipient, who decide whether an available organ is suitable at that time.

The delivery of 'Taking Organ Transplantation to 2020' has led to challenges. 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.

Utilisation describes maximising the use of available organs for transplant to achieve the best outcomes. 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 deliver the ambition to meet unmet demand for transplantation.

Liver transplantation rates are competitive by international standards, although in the UK approximately 20% of livers donated from DBD donors are not utilised. 70% of livers donated from DCD donors are not used but, not all of these livers may be suitable for transplantation.

The UK has comparatively poor rates of both lung and heart transplantation compared with international colleagues, with 21% of people waiting for a lung transplant and 15% of people waiting for a heart transplant[1] dying or being removed from the list within a year of being listed for a transplant.

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 which will be important to give hope to patients waiting for transplants.

NHSBT will also continue to encourage the UK-wide adoption of donor utilisation initiatives and maintain scrutiny of emerging developments through our Research, Innovation and Novel Technologies Advisory Group (RINTAG) and other structures.

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 deceased organ donation and transplantation in clinical management, logistics and outcome. The UK has a decade of practical experience in this field, which uses machines and technology to enable organs, that might otherwise be discarded, usable for transplantation.

There is growing evidence that new perfusion technology would give clinicians greater confidence to implant more organs successfully by enabling focused organ assessment, reducing ischaemic damage during organ transport, and if necessary, providing a mechanism to repair and recover donated organs. 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, such as normothermic regional perfusion (NRP) of DCD donors to improve liver outcomes and facilitating the transplantation of hearts from DCD donors, are working. We will seek to build on our world-wide leadership in this area of transplantation and take advantage of emerging international developments.

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 UK model of organ Assessment and Recovery (AR). It is anticipated that deceased donor 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 the UK could investigate.

Assessment will allow triaging of organs, identifying those that need little intervention, those higher risk organs that require more intervention, 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.

NHSBT will work with other organisations in the NHS, and beyond, to pilot Assessment and Recovery approaches. The aim is to understand which approach delivers the best returns in terms of increases in the number and / or quality of organs utilised as a result of these technologies. Currently, NHSBT is performing an in-house assessment

to explore the feasibility of a centralised approach to AR in the form of Assessment and Recovery Centres (ARCs).

NHSBT will 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, international collaboration) and NHSBT will, in parallel, encourage bids for complementary research.

Possible approaches to organ perfusion and preservation

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 necessary vascular reconstructions would 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 perfusion machines to the donor hospital, which would remove the urgency of transporting donor organs within a certain timeframe. This model may preclude more advanced interventions for some organs.

Some of the possible approaches to organ perfusion and preservation may work in parallel with one another. NHSBT will continue to co-ordinate and to establish infrastructure where it does not yet exist to enable experts to decide which 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 organs that may otherwise by discarded for transplantation).

Objective 2: We will aim for optimal organ utilisation in every organ group, benefiting from new technologies and techniques

	Action	Impact	Who
2.1	Deliver organ utilisation	Clear plans for improving utilisation for each organ	NHSBT Transplant Centres

	improvement plans for each organ group, working with colleagues across the UK	group, contributing to overall increases in utilisation	Commissioners
2.2	Establish a sustainable service for *in situ* Normothermic Regional Perfusion (NRP) for DCD donors of all abdominal organs	Increase in utilisation of livers with improvement of outcomes and similar benefits for kidney and pancreas transplantation	Governments Commissioners NHSBT Transplant Centres
2.3	Establish a sustainable service for transplantation of DCD hearts	Increase in donation of hearts from DCD donors	Governments Commissioners NHSBT Transplant Centres
2.4	Investigate the utility of new technology for utilisation of all organs	Increase in use of all organs for transplantation	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 (within legislative boundaries)	Increase in use of organs from donors who are unstable	NHSBT Transplant Centres Commissioners
2.6	Clarify custodianship of deceased 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	Governments NHSBT Transplant Centres Commissioners
2.7	Implement UK guidelines and policy on which extended criteria organs could be	Clarifies the role of perfusion in overcoming logistical issues that would otherwise prevent transplantation. Standards for acceptance	NHSBT Commissioners

	subject to *ex situ* perfusion	and utilisation of organs as technology becomes more widespread.	
2.8	Work with regulators, to define how the introduction of new technologies to assess and improve organs will 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 and parallel evaluation	Clarity about which models provide greater utilisation and ensure that previously discarded organs are transplanted. Safe, “non-inferior” organs; predictable timings. High quality outcome-based data, to assess service and progress further developments	NHSBT

3. Recipient and Transplant Outcomes

Objective: Recipient and transplant outcomes will be amongst the best in the world

Timely access to transplantation and excellent post-transplant outcomes (quantitative and qualitative) are vital to excellence in organ donation and transplantation services. NHSBT is well placed to deliver such excellence, facilitated by a world-leading UK organ donation and transplantation registry and comprehensive and robust analysis providing an evidence base for interventions that benefit patients. There is more to do, however, as improvement requires a continuous cycle of review and innovation.

NHSBT has collected data on transplant patients for the UK Transplant Registry for over 40 years. The data include clinical and demographic information from the time of joining the waiting list, through to receiving a transplant and then cover post-transplant follow-up. The UK Transplant Registry has proved invaluable in providing an evidence base for developing new or revised organ offering schemes, understanding factors that impact waiting times and post-transplant outcomes, comparing and monitoring transplant centre performance as well as allowing data to be appropriately shared for a wide range of patient-benefitting research.

NHSBT continued to develop the UK's organ offering schemes following the publication of 'Taking Organ Transplantation to 2020' and has delivered new offering schemes and important developments for kidney, pancreas, liver, heart, lung and intestinal transplantation since 2016. Through the 'Living Donor Kidney Transplantation 2020 strategy', the development of the UKLKSS and the contribution of non-directed altruistic donors has created additional donation and transplant opportunities for kidney patients. Collectively, these schemes have demonstrated benefits to patients, including a better chance of an organ offer for those who have historically been harder to match with a suitable organ donor.

There is more to be done with organ offering and there are other key areas for development that will help us to reach our aspiration of becoming the world's best organ donation and transplantation service.

We will:

- Seek to **enhance understanding of post-transplant outcomes** that are important to patients, by looking beyond simply quantifying the life of a patient or graft, to increasingly consider quality of life factors that are not currently captured on a routine, UK basis. NHSBT will develop relevant outcomes based on patient perspectives, with the aim of introducing self-reported quality measures for patients' life experiences - Patient Reported Experience Measures (PREM) and Patient Reported Outcome Measures (PROM) after transplantation. Self-reporting of donor outcomes and experiences after living donation will also enhance quality and completeness of data and understanding. (see objective 1.2).

- Increase our focus on **long-term outcomes after transplant and re-transplantation**. There is less evidence of improvement over time in long-term outcomes, and we know that the UK does not always have world-leading results[9] [10]. We want to increase the longevity of functioning transplants and reduce the need for re-transplantation (around 800-900 patients per annum return to the transplant waiting list after a failed graft). When re-transplantation is required, patients should have access to appropriately matched organs that will provide good outcomes. Our actions and further research need to address the burden on patients and the wider NHS.

- Continue to **refine organ offering schemes** by NHSBT working with clinical, scientific, patient and other collaborators from across the UK to improve overall effectiveness and equity of access to transplantation. There is some evidence of inequity of access by ethnicity and class, among other factors, and we know that patients of ethnic minorities wait longer for kidney transplant than white patients[1]. Kidney waiting times are falling across the board with some evidence of the gap in waiting times becoming smaller, and the revised kidney offering scheme (2019) should further reduce the gap and will continue to be monitored for effectiveness. Access to living donor kidney transplantation will also be considered, with this option being facilitated for as many patients as possible. Offering of organs on a named patient basis enables allocation to be transparent and equitable and we will seek to consider extending named patient offering to all heart and lung patients if deemed clinically appropriate (where currently there are only named offers for clinically urgent patients).

- We will improve the collection of follow-up data in the UK Transplant Registry to maintain its world-leading reputation by developing a digital-first model, to facilitate tracking up to 65,000 transplant recipients in the next 5 years. NHSBT will focus on **digitising data collection**, exploring the most effective means of capturing relevant information in an automated way from existing data sources, driven by the benefits to the wider NHS. Options for patients to self-report information will also be developed as required.

- **Enable appropriate data linkage / sharing, and further promote and practise effective use of data**. NHSBT registry data are linked with other relevant data sources but only on an *ad hoc* basis (e.g. cancer registry data, Hospital Episode Statistics), and we want to exploit new opportunities for seamless data linkage to enable relevant research for patient benefit. We will refine existing analysis of Registry data, e.g. to further examine geographic variations in practice regarding organ acceptance and post-transplant care and explore the benefits of artificial intelligence / machine learning approaches. NHSBT will develop its data and information capabilities and, working with commissioning partners across the UK, seek to challenge any unwarranted variations in practice.

[9] Kidney transplant graft outcomes in 379 257 recipients on 3 continents. Merion RM, Goodrich NP, Johnson RJ, McDonald SP, Russ GR, Gillespie BW, Collett D. Am J Transplant. 2018;18:1914-1923. DOI: 10.1111/ajt.14694
[10] Causes of renal allograft failure in the UK: trends in UK Renal Registry and National Health Service Blood and Transplant data from 2000 to 2013, Hannah Burton et al., Nephrol Dial Transplant (2019)

Objective 3: Recipient and transplant outcomes will be amongst the best in the world			
	Action	**Impact**	**Who**
3.1	Implement new outcome metrics, including a focus on quality of life indicators (experience and outcome measures)	New understanding of outcomes and complications to develop best practice for living donors and transplant recipients	NHSBT Transplant centres Community and National partnerships
3.2	Undertake analysis of long-term post-transplant outcomes and re-transplantation	Generate new evidence about long-term outcomes to increase longevity and reduce the need for re-transplantation	NHSBT Transplant centres
3.3	Refine effectiveness and equity of access to transplantation in organ offering schemes	Further improved equity of access to transplantation, especially for minority ethnic, socio-economically deprived and hard-to-match people; extend named-patient offering where clinically appropriate	NHSBT Governments Public Transplant centres Community and National partnerships NBTA
3.4	Transform data collection to a digital model, including options for patient reported experience and outcome measures (PREM and PROM)	Safeguard and extend robust, contemporary data collection and reduce the burden on NHS colleagues	NHSBT Transplant centres Governments
3.5	Enable appropriate data linkage / sharing and promote and practise effective use of data	Accessible donation and transplantation data (to link to other sources) for novel and relevant research and analysis	NHSBT Transplant centres Public

4. Diversity and Inclusion

Outcome 4: People of all backgrounds and circumstances will have timely access to the organ they need

The COVID-19 pandemic has had disproportionate effects on certain groups. Individuals from BAME background are more likely to be admitted to hospital and intensive care with a diagnosis of COVID-19, compared with the general population. Similar observations have been made about people from lower socio-economic backgrounds.

For twenty years, important research and reports have noted that people from a BAME background needing a transplant are disadvantaged and that the NHS Organ Donor Register is not as diverse and inclusive in terms of age, gender and ethnicity[2] [11]. Proportionately, more BAME people need transplants than the rest of the UK population, partly explained because of higher rates of diabetes and hypertension (high blood pressure). In 2020, a third of the people – approximately 1,900 – in the UK waiting for a transplant are BAME[12] while together they comprise approximately 14% of the UK population.

There is now greater recognition of the potential for systemic racism in our society which has been highlighted through the Black Lives Matter movement as well as the disproportionate effect of COVID-19 on people from a BAME background in the UK[13]. It is essential that this strategy addresses these issues in the context of organ donation and transplantation.

Donated organs, particularly kidneys, need to be from a donor who 'matches' the recipient by both blood group and human leukocyte antigen (HLA) type.[14] 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, which is not enough to meet demand, even if every organ could be used.

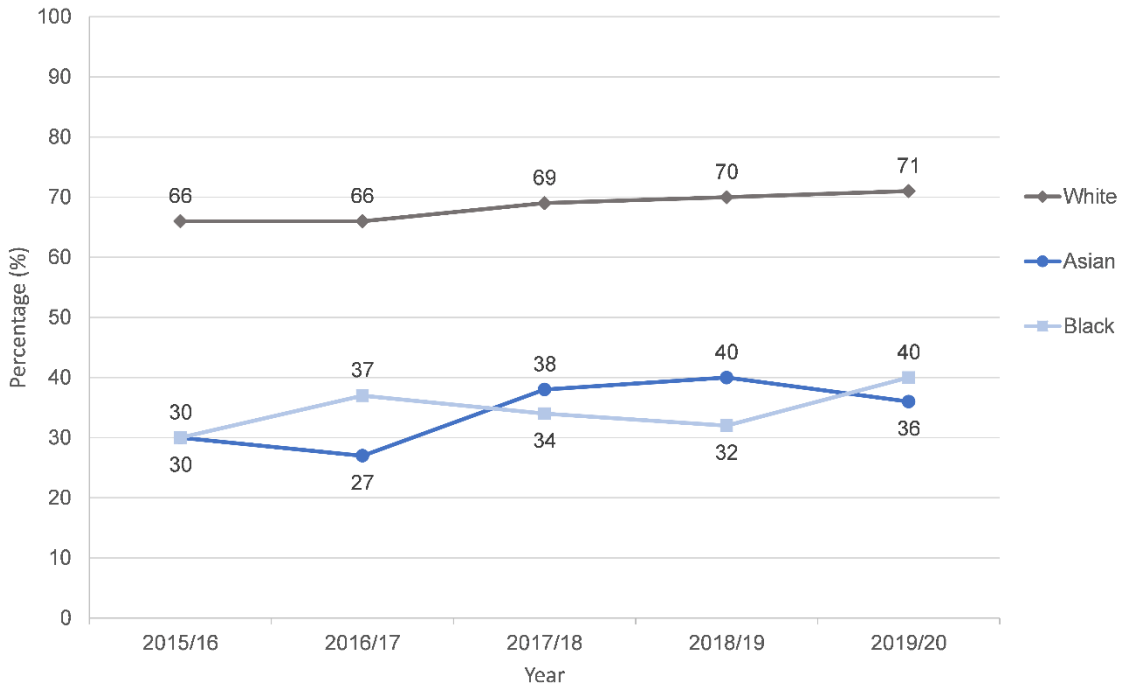
Furthermore, despite progress in recent years, people from a BAME background are less likely to give consent/authorisation for organ donation (Figure 4). Data has shown that the decision of BAME individuals to become an organ donor has a higher chance of being overturned by the individual's family.[15] This challenge is not unique to the UK

[11] For example: Preventing kidney disease: the ethnic challenge, Prof L. Lightstone, 2001
[12] Organ Donation and Transplantation data for Black, Asian and Minority Ethnic (BAME) communities (2018-2019-2020)
[13] Bamrah JS, Randhawa G, Chand K, Basi J (2020) The NHS is 72 this year, covid-19 has taught us some tough lessons. BMJ Opinion 31 July. https://blogs.bmj.com/bmj/2020/07/31/the-nhs-is-72-this-year-covid-19-has-taught-us-some-tough-lessons/
[14] HLA is an immunological marker dictated by genetics
[15] The Rule of Threes: three factors that triple the likelihood of families overriding first person consent for organ donation in the UK. J Intensive Care Soc 2018; 19:101-106.

and has been experienced and tackled through a variety of interventions across the world[16].

Surveys show that BAME 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[17]. 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. This means that opportunities for lifesaving transplants are being missed because families are reluctant to discuss the topic of organ donation.

Figure 4 Organ donation consent/ authorisation rate by ethnicity



In the UK, there has been progress. NHSBT recognised the role of faith as a potential facilitator and / or barrier towards organ donation and developed a Faith Action Plan to engage communities in important and sensitive issues. This was the world's first such plan[18]. Although not fully implemented, it has helped develop our approach to engaging with faith communities.

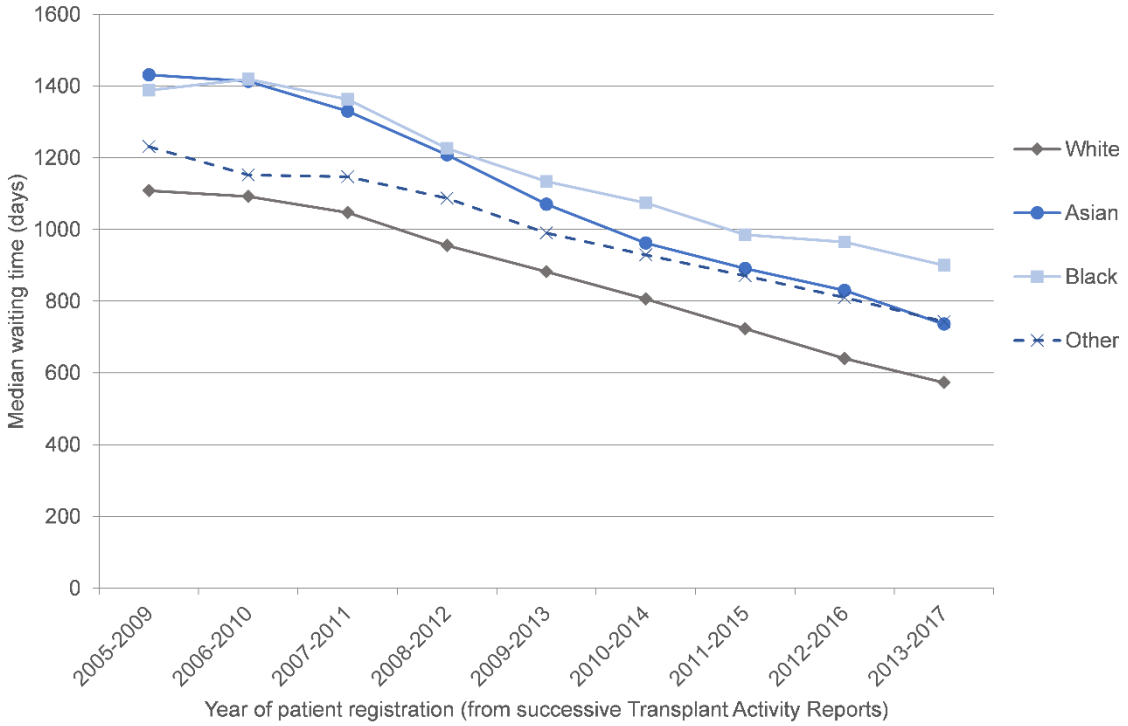
Positive outcomes are visible in living donation, where people from a BAME background are now more likely to donate than the general population. Much work has also been done to engage with BAME people about the importance of donation, both deceased and living. The establishment of the National BAME Transplant Alliance (NBTA) and its work in co-establishing, monitoring and evaluating the

[16] Organ Donation: Breaking Taboos Amongst British BAME Communities, Nishtha Chugh, 2016
[17] Morgan M, Kenten C, Deedat S; Donate Programme Team. Attitudes to deceased organ donation and registration as a donor among minority ethnic groups in North America and the UK: a synthesis of quantitative and qualitative research. Ethnicity and Health. 2013;18(4):367-90. doi: 10.1080/13557858.2012.752073. Epub 2012 Dec 19.)
[18] Randhawa G & Neuberger J (2016) The role of religion in organ donation - Development of the UK Faith and Organ Donation Action. Transplantation Proceedings. 48: 3, 689–694.

innovative Living Transplant Initiative and Community Investment Scheme projects in collaboration with NHSBT has also enabled people from a BAME background to take the lead in addressing the challenges and provided opportunities for partnership working with NHSBT and others. Both initiatives empower local BAME and faith groups to promote organ donation in their targeted communities through the development of culturally appropriate resources and organised community events. [7] [19]

While waiting times have reduced for BAME patients (Figure 5), this is often due to the donation of an organ from a white person, either deceased or living. There remains **significant unmet need**. 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 through family and friends who may be willing to donate and by realising the potential for BAME recipients within the UKLKSS initiated by non-directed and paired/pooled donations from non BAME donors.

Figure 5 Median waiting time (days) to kidney only transplant, by ethnicity



While we have some insight into aspects of diversity and inequality and where they exist, further research and exploration is needed to completely understand the issues. Engagement is constrained by the failure to build trust with communities by healthcare organisations and is influenced by religious and personal beliefs and fears about

[19] Community Investment Scheme Progress Evaluation report, June 2020 https://www.nhsbt.nhs.uk/how-you-can-help/get-involved/community-investment-scheme/community-investment-scheme-report/

health-related issues[20],[21],[22],[23]. A commitment to improving communication and engagement with people from a BAME background to engender trust and confidence in organ donation and transplantation programmes must be a priority if we are to achieve the ambition of genuine diversity and inclusion in delivering our strategy.

NHSBT will support action to improve insights and increase the number of organ donors from BAME communities, including research where there are evidence gaps (e.g. consent / authorisation behaviour).

Improving the collection, analysis and publication of data

NHSBT publishes a BAME data report on organ donation and transplantation each year with the last report for 2019/2020 was published in September 2020[1] .While this is a very helpful report, which provides annual data as well as trends, there are areas that could be improved with more granular reporting of data. Most of the data on the background of organ donors and recipients uses general categories such as Asian or Black. We need granular data by ethnicity so that we can better understand the trends and target action accordingly[17]. There is little information published by religion at present and we know that for some faith groups, religion is a very important consideration for organ donation. It is important, therefore, that we consider feasibility and means of improving the collection, analysis and publication of data by ethnicity and religion.

Promoting organ donation

We will build upon the existing models of the Community Investment Scheme and the Living Transplant Initiative to support community and faith-based organisations to promote organ donation. Work will continue in partnership with the NBTA and other partners to ensure that all BAME people, 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.

Listing and outcomes

There is evidence that rates of listing and successful transplantation are lower for BAME 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, including continuing to develop organ offering schemes that take into account people who are harder to match with a suitable donor. Any disparities in listing for a transplant will be explored and addressed to ensure parity of access.

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[20] Incentives and reciprocity in deceased organ donation from a UK Polish migrant perspective, Sharp C & Randhawa G (2014) Organ donation as an 'altruistic gift': Annals of Transplantation. 19, 23-31.

[21] Attitudes towards organ donation and kidney disease among Black African, Black Caribbean and Asian population in Lambeth, Southwark and Lewisham, London, United Kingdom. Clarke-Swaby S, Sharp C, Randhawa G (2012) Organs, Tissues and Cells – Journal of the European Transplant Co-ordinator's Association. 15, 17-20.

[22] Meeting the needs of multi-ethnic and multi-faith populations Randhawa G (2012) Death and organ donation. British Journal of Anaesthesia, 108, 88-91.

[23] The Influence of religion on organ donation and transplantation among the Black Caribbean and Black African population - A pilot study In the UK Davis C. & Randhawa G. (2006). Ethnicity and Disease. **16**, 281

Diversity and inclusion in the workforce

Following heightened awareness of the potential for systemic racism, the NHS organ and donation community must reflect on these issues and ensure that appropriate actions are embedded in the implementation of the strategy. There have been previous efforts from the NHS to diversify its workforce and we need to ensure that we learn from those affected.[24]

The need for equality in all aspects of life and work, including health, is paramount. However, the convergence of societal events, for example: COVID-19, BAME risk, the Black Lives Matter Movement and evidence of organisational systemic racism, provides a unique and unprecedented opportunity to make significant positive change. This will enable more trust, confidence and engagement with BAME people across society.

In the meantime, NHSBT will continue to develop diversity and inclusion plans to ensure that, within 5 years, patient-facing services such as Specialist Nurses for Organ Donation (SNODs) are representative of the population served. OTDT will aim for an average of 14% (up from 6%) of SNODS to be from a BAME background, recognising that some teams will have different requirements. Organisations across the NHS will need to maximise the opportunities to attract and retain a diverse, representative workforce within the donation and transplantation community.

Action Plans and Partnerships

The main challenge in delivering partnership-based action plans is that NHSBT has supported schemes through annual funding arrangements. As a result, partners tell NHSBT that this not sustainable and longer term budgets are 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 NBTA and other partners will continue, ensuring that these are productive and deliver measurable benefits to patients.

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 and annual UK Transplant Games present ideal opportunities to do this.

We will also consider using a community champion or specialist peer-educators, in different settings, to raise awareness, which should help improve consent/authorisation rates for deceased donation.

[24] Barriers and Enablers for UK 'Home Grown' South Asian Prospective Students Choosing Nursing and Midwifery Courses and Careers Ali, N, Qureshi I, Sidika T, Mondokova A, Mahmmod S, Jan A, Garcia R, Cook E, Burden B, Reid C, Randhawa G. (2018). Diversity and Equality in Health and Care 15(4): 190-197.)

Objective 4: People of all backgrounds and circumstances will have timely access to the organ they need			
	Action	**Impact**	**Who**
4.1	Improve collection, analysis and publication of data by ethnicity, religion and social class	Targeted promotion and action planning, based on higher quality data and insights into systemic barriers	NHSBT NBTA Community and National partnerships
4.2	Empowering BAME communities to lead on promoting or raising awareness of organ donation e.g. by developing the Community Investment Scheme and the Living Transplant Initiative	Increased number of living and deceased donors from BAME people and others	NHSBT Governments Public NBTA Community and National partnerships
4.3	Tackle disadvantage in listing and outcomes	Improved outcomes for BAME recipients	NHSBT NBTA Community and National partnerships
4.4	Increase the diversity of OTDT's workforce	Representative patient-facing workforce within 5 years	NHSBT NBTA Community and National partnerships
4.5	Develop and sustain long term diversity and inclusion action plans	Confidence that action plans for delivering priorities are effective, through a multi-year approach	NHSBT NBTA Community and National partnerships
4.6	Improve partnerships between NHSBT and external supporters	Productive partnerships, leading to measurable benefits to patients	NHSBT NBTA Community and National partnerships External organisations
4.7	Support efforts towards a Commonwealth Memorandum of Understanding for the sharing of knowledge and expertise in support	Coinciding with 2022's Commonwealth Games, a mutually agreed approach to promotion and visibility for organ donation and	NHSBT External organisations

	of organ donation and transplantation	transplantation providing an ongoing framework for the sharing of knowledge and expertise across Commonwealth nations.	
4.8	Examine potential and benefits of a community champion/ peer-educator model	Establishes the viability and impact of such a model	NHSBT NBTA Community and National partnerships External organisations

5. A Sustainable, Responsive UK Service

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

Our success in increasing donation and transplantation in the UK since 2007/8 has resulted in a system which must expand and reform to be sustainable.

By 2025, this UK strategy plans to deliver up to:

- 260 more deceased donors each year resulting in 1,000 more transplants
- 300 living donor transplants
- 70,000 people with a transplant being cared for in the NHS. Further increases will be promised by 2030 if the full potential is realised.

These ambitions can only be achieved if there is investment in the infrastructure to provide the capacity and capability to deliver both deceased and living donation and transplantation services across the NHS. This includes development of the multi-professional workforce and addressing ways of working across the whole pathway.

Such developments require action by NHSBT and all other NHS partner organisations. This includes commissioners and health departments working together to ensure 'end to end' resilience and sustainability across the whole donation and transplantation pathway by focusing on key areas of transformation.

Deceased Donor Organ Retrieval

It has already been identified that deceased donor organ retrieval capacity and capability (people and infrastructure) will need further support to meet demand at peaks of activity and will be kept under review. A review of retrieval activity in 2018 led to a review of the abdominal team capacity within the National Organ Retrieval Service (NORS) resulting in an additional recurrent investment of £1.78 million from April 2019. As new perfusion technologies are introduced and donor numbers increase, new models of retrieval will be considered for abdominal and cardiothoracic organs.

Deceased and Living Donor Transplantation

Future capacity planning for transplantation must allow for a predicted increase in deceased donor transplants and living donation activity, particularly within the UKLKSS due to the contribution of non-directed altruistic kidney donation and increasing uptake of paired/pooled donation. All centres must be able to provide timely transplantation during peak periods of deceased donation activity to maximise best organ utilisation and successful outcomes. Within kidney centres, once transplants are identified in the UKLKSS matching run, delays in scheduling dates of surgery between 'matched' centres presents the highest risk of transplant 'exchanges' being unable to proceed, impacting on all patients across the UK.

Commissioning across the donation and transplantation pathway is complex and results in multiple organisations with competing priorities being involved in any service development. If this were simplified, changes in capacity requirements could be reviewed in a more timely, responsive manner. We already have examples of strong co-working across organisational boundaries, such as the Joint Innovation Fund (NHS England (NHS E) & NHS Improvement (NHS I), NHSBT) supporting DCD Heart Retrieval and Transplantation and this collaborative style must be continued.

To deliver this strategy, NHSBT will work with commissioners of transplant services across the UK, in consultation with key stakeholders (patients and professionals), to agree how best to secure the essential capacity and capability to undertake increasing numbers of living and deceased donor transplants and to safely monitor and care for transplant recipients and living donors.

Some kidney transplant centres (London, Midlands, North of England, Scotland) are collaborating to consider how best to network their resources and make best use of infrastructure to manage peak demand. The response to the COVID-19 pandemic has encouraged greater collaboration and joint working between centres, providing a foundation for new models of care delivery to be considered.

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 heart and lung transplantation merit further review.

Our People

Emerging NHS workforce planning initiatives across the UK identify that the recruitment and retention of allied health professionals, scientific and medical colleagues to work in the NHS is increasingly challenging. In addition, the nature of transplantation, with much of the activity happening at night, can make it difficult to achieve a work / life balance.

NHSBT is committed to addressing issues within the specialist nursing workforce by reviewing the working pattern and broadening the criteria for entry. There is also a commitment to increase the diversity of the workforce, ensuring that it is representative of the population it serves. Future roles and role requirements will be carefully examined, to attract the best talent available. This approach is being replicated throughout the NHS.

The British Transplantation Society (BTS), NHSBT and transplant commissioners, through summits and NHS E Peer Review processes, have identified recruitment challenges in surgical support for transplantation in all organ groups. BTS and other specialist professional societies are leading on work to address these issues.

Covering rotas out of hours for scientific support staff and in diagnostic and testing services is a challenge. Technological and collaborative solutions will be explored to build a sustainable service.

NHSBT will develop a Donation and Transplantation Academy to deliver education and training about donation, retrieval and transplantation for health care professionals.

This will include exploring the cost-effectiveness of building a world-leading education facility and / or network. We will also explore ways of how we can work with our colleagues across the system, within the UK and internationally, 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 SNODS, to assist with donor referral and triage, to digitise some regulatory forms and to transform organ offering algorithms. These developments, under the umbrella of the ODT Hub programme, have sought to make the working life of colleagues in deceased organ donation and transplantation simpler, safer and more supportive.

The new NHS Organ Donor Register (developed 2015) has been linked to the NHS App to simplify and promote public access in England. During the life of this strategy there will be a review of the important role external partnerships, such as those with the DVLA and Boots, have in linking people to the Organ Donor Register. In a deemed consent / authorisation environment, it is essential to engage frequently with people 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.

Despite the progress made, much remains to be done and this transformation needs to continue so that information access and data transfer throughout the living and deceased donation and transplantation pathway is increasingly automated. Areas of focus include:

- Digitisation of the living donation pathway to enable the growth of this highly successful programme and the continued delivery of a robust service to transplant centres.
- Enable the digital transfer of donor testing results from a network of national laboratories to NHSBT systems.
- Introduce digital patient management enabling transplant centres to register and update patient data in real time.
- Further development of the organ allocation schemes to enable more frequent and timely updates.
- Transition of the existing organ offering solution to a new platform allowing us to improve the experience for clinicians reviewing organ offers. This will incorporate the addition of new data sets, which are currently on paper, the inclusion of images and video and the ability to accept and decline offers digitally.
- The development and hosting of patient-facing content and tools helping potential organ recipients to understand the benefits and risks of an organ transplant.

Working in partnership with the Digital, Data and Technology Directorate to introduce a new Product Centre for ODT, our over-riding aims are to ensure that solutions are focused on user needs, to develop and future-proof systems to support our strategic

aims and, ultimately, ensure the best possible digital experience in support of the donation and transplantation process.

Processes

The deceased donation pathway from referral to organ transplantation has increased in length. This results in long delays for donor families, organ retrieval during the day and transplantation at night, disruption to hospital operating schedules and concerns about safety and work/life balance.

Work will be done to improve processes for donor referral and triage and to shorten the donor pathway. Pilots will take place in major hospitals to match timing to resources. We will examine the current system of organ offering and interaction with transplant centres. Initiatives will be developed to reduce stress on the system and the people working within it.

In the post COVID-19 era, there will be an opportunity to consider the role of technology in the monitoring, follow up and support of the growing number of people living with a transplant and living donors. Transplant and non-transplanting centres are best placed to share expertise and find new ways of supporting their recipients and living donors, so that everyone who has had a transplant or who has donated an organ has the best care available. NHSBT, in collaboration with transplant centres, will continue to collect follow-up data, (clinical and self-reported outcomes and experience measures) from recipients and living donors with a renewed focus on digital data collection.

NHSBT, through the new OTDT Directorate, will maximise the opportunities for donation and transplantation by working closely between organ donation and transplantation and tissue and eye services.

Support for learning and decision-making

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

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 discuss 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 supportive 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, 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	Improve transplant outcomes through a strengthened collaborative model for commissioning across the UK	Integrated system planning, improved sustainability	NHSBT NHS commissioners
5.2	Digital and IT-enabled support to NHS	Maximise use of NHS resources, cost avoidance	Commissioners NHSBT NHS
5.3	Increase organ retrieval capacity as donation activity increases: through selective service re-design	Best use of NHS resources via collaboration Additional NORS capacity where needed No missed opportunities	Governments 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 and workforce sustainability to support transplantation activity (transplant and non-transplanting centres)	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 Development of a sustainable workforce	Commissioners NHSBT Transplant Centres and non-transplanting centres Professional societies

		to deliver a UK wide transplantation service	
5.6	Address NHSBT workforce sustainability by carefully examining future roles and role requirements and further development of ODT operating model	Improved recruitment criteria to enable a wider, more diverse talent pool to be accessed. NHSBT is a popular career choice. New target operating model More clinicians' time spent on clinical activities Safer, responsive co-ordination through digital platforms	NHSBT
5.7	Automate data collection and information transfer between NHSBT and providers for (transplant/non-transplanting centres, H&I laboratories)	Completeness and accuracy of data collection/information transfer between external providers and NHSBT Improved processes and technology solutions, leading to an improved experience and maximised opportunities for donation and transplant	Commissioners NHSBT Transplant Centres Non-transplanting centres H&I laboratories
5.8	Optimise deceased donation pathway	Length and / or timing of the donation and transplant pathway improved, maximising the opportunities for donation and transplantation	NHSBT Transplant Centres
5.9	Establish Donation and Transplantation Academy	Integrated approach to practice development and education of colleagues across NHS Income generation later in development	NHSBT

5.10	Integrate ODT and Tissue & Eye Services	Maximising donation and transplant opportunities	NHSBT

6. Research and Innovation

Objective 6: We will build a pioneering culture of research and innovation in donation and transplantation in the UK

Research and innovation across the devolved administrations is critical to delivering long-term improvements in donation and transplantation. The research carried out today will provide the evidence base for future clinical practice.

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 in organ donation and transplantation. The donation and transplantation research community has delivered essential initiatives including:

- Establishing a national biobank of samples from deceased organ donors (Quality in Organ Donation (QUOD))
- Establishing the Increasing the Number of Organs Available for Research (INOAR) platform so that more donated organs not accepted for transplantation are available for research
- Creation of a successful partnership with the National Institute for Health Research's Blood and Transplant Research Unit (NIHR BTRU) in Organ Donation and Transplantation
- Developing a public and patient involvement and engagement platform
- Establishing RINTAG which assesses and reviews novel technologies in organ donation and transplantation
- Expanded the portfolio of informative UK trials in organ donation and transplantation (e.g. PITHIA)
- Expanded the NHSBT research team to support further growth in organ donation and transplantation research
- Established the UK Organ Donation and Transplantation Research Network (UKODTRN)

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.

We will respond to this challenge by ensuring that a pioneering culture of research leads UK organ donation and transplantation practices. We believe that every donation and transplant offer a potential research opportunity which can improve patient outcomes. Five evidence-based initiatives are planned in this strategy to bridge this gap and deliver our vision.

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. People from a BAME

background 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 that lead to donor opt-out registrations and family consent among people from a BAME background is essential to match demand for transplantation and availability of suitable donor organs[25].

Essential infrastructure

The donor organ pool is limited. Increasing utilisation of donated organs will continue to be a priority throughout this strategy. The QUOD National BioBank and INOAR will continue to enable research providing a valuable resource of whole organs and clinical samples collected from deceased donors. As of 1st November 2020, 91,601 samples have been collected from 5,045 deceased donors. 59 research applications have been approved by the QUOD Steering Committee and 13,878 biobanking items have been issued for research. Utilisation of the QUOD and INOAR research infrastructure will offer opportunities to develop better donor and organ assessment protocols to support decision making prior to transplantation.

Similarly, the NHSBT research team and Specialist Nurses – Organ Donation provide essential support for the successful delivery of a broad portfolio of research studies[26]. 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. In order to stimulate increased investment in relevant research and innovation we 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 UK approach consisting of:

- Making the case for a future NIHR- BTRU in organ donation and transplantation 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 grants to generate preliminary data to support funding applications to external funders
- Supporting the newly established UK Research Network in Organ Donation and Transplantation

[25] *Randhawa G (2011) Achieving equality in organ donation and transplantation in the UK - Challenges and solutions. Better Health Briefing 23, Race Equality Foundation & Department for Communities and Local Government.*
[26] https://www.odt.nhs.uk/odt-structures-and-standards/research/current-odt-research/

- Ensuring that the RINTAG continues to provide strategic oversight to and assessment of developing technologies that will transform donation and transplantation.

The main barrier to 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, we will actively engage with UK and international, clinical and academic partners within the European Society of Transplantation (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 (as referenced in Objective 3), 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 important 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 these areas 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 UK and international research networks will provide the ability to investigate novel pharmaceutical interventions that have the potential to optimise organ quality during donor management. In collaboration with critical care colleagues 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 (see Objective 2). The key role of research and innovation will be to support the assessment of these potential perfusion applications through the development of biomarkers, and functional parameters as tools to monitor improvements of donor organ quality during perfusion.

Objective 6: We will build a pioneering culture of research and innovation in donation and transplantation in the UK

	Action	Impact	Who
6.1	Undertake behavioural research	Provide evidence on impactful interventions that increase consent / authorisation levels for BAME donors in both deceased and living donation	NHSBT NBTA Community and National partnerships
6.2	Sustain essential infrastructure	Underpin high-quality research and innovation to advance clinical practice and improve outcomes	NHSBT UKODTRN
6.3	Stimulate increased investment in the highest priority research and innovations	Improve patient care and save more lives by transplanting more organs that last for longer	NHSBT UKODTRN Community and National partnerships Research funders Governments
6.4	Enable enhanced data sharing and linkage (see also Objective 3)	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 Transplant Centres
6.5	Invest in service development	Increased translation of research and service developments to quantify organ quality prior to transplantation (e.g. Assessment & Recovery programmes)	NHSBT
6.6	Co-ordinate an associated research programme for Assessment & Recovery	Accelerate implementation of Assessment and Recovery programmes Lead to service developments	NHSBT
6.7	Evaluate emerging technologies and techniques	Early identification of potential for new methods, through RINTAG and other structures	NHSBT

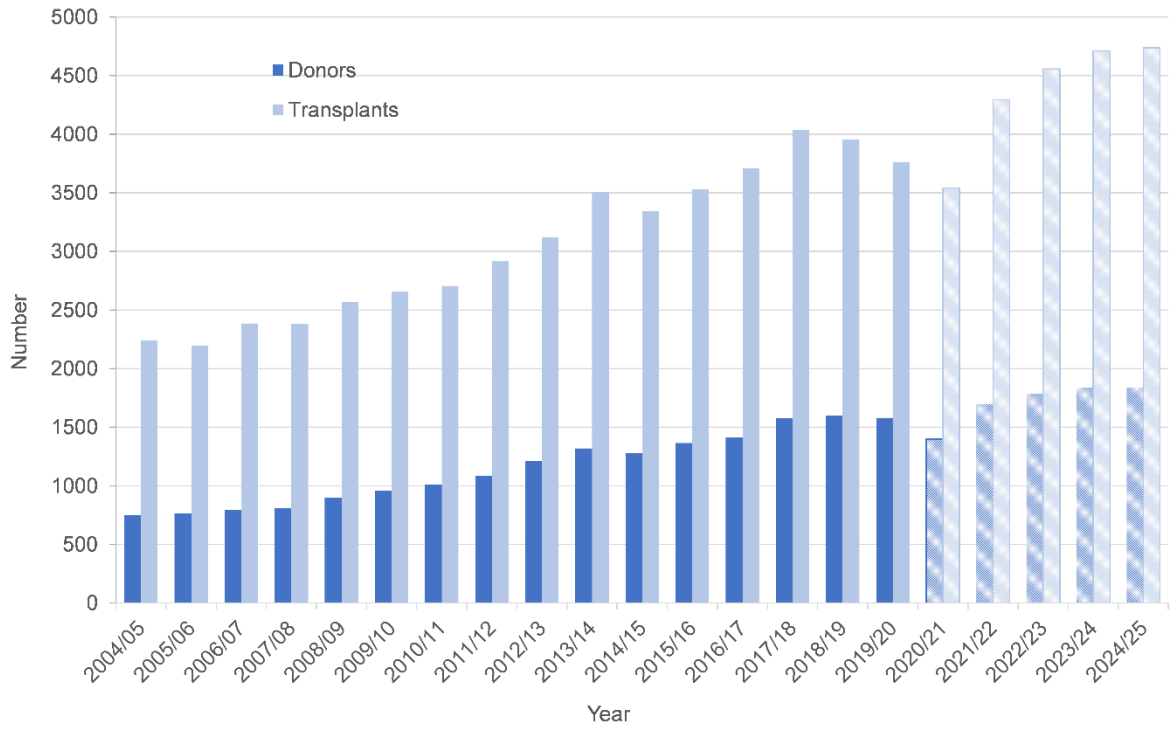
Impacts

The first 5 years

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

- 16% increase in the number deceased donors
- 31% increase in the number of living donors
- 26% increase in the number of deceased donor transplants (approximately 1,000 per year, by 2025)
- 26% increase in the number of living donor transplants (approximately.300 per year, by 2025)

Figure 6 Number of deceased donors and transplants, with projections for next five years.



Within these first five years, deceased donor initiatives – most notably the implementation of 'opt-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% (Figure 6). It is envisaged that this will account for about 60% 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 approximately 40% of the additional deceased donor transplants by 2025 – but importantly also to higher quality, longer lasting transplants.

For living donation, the ability to develop new initiatives within the UKLKSS, underpinned by a robust digital platform, will directly impact on the number of transplants that can be achieved for both adults and children over the next 5-10 years. This is likely to result in a further reduction in the need for antibody incompatible transplantation, resulting in better outcomes for patients and transplants and improved cost effectiveness.

Investment in digital technology to support the scheme will be critical to realising these ambitions but, assuming that this is funded, it is expected that an additional 300 living donor transplants could be performed in the first 5 years and a further 250 in the next 5 years.

Initiatives to address access to living donor transplantation due to health inequalities and a focus on living donor liver transplantation within this strategy will contribute smaller increases in activity but significant impact on health and patient outcomes.

Years 5 to 10

We believe that transplant utilisation initiatives are more likely to 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. We do not yet have the evidence to make informed projections beyond 5 years but have included aspirational targets for activity and performance in our projections.

Once this strategy has been agreed, we will set out our plans for the first five years, starting 2021.

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 high cost of treatments such as renal dialysis and left ventricular assist devices. In terms of efficiency and human need, the NHS should prioritise increasing numbers of transplants over less effective modes of treatment.

NHSBT has worked closely with NHS delivery bodies of the four home nations' to ensure that there is a common understanding of donor and transplant activity in the first five years of this strategy and the actions that are required to support this looking ahead to ten years.

The whole service cost of organ donation and transplantation is difficult to assess given the number of organisations involved across the four nations of the UK. Funding of the organ donation service within ODT has been flat at £74 million/per annum since 2016/17. During this time, the number of deceased donors has increased by 12% (from 1,413 in 2016/17 to 1,580 in 2019/20) and the number of transplants by 1% (from 3,710 to 3,760), which demonstrates greater efficiency in the service provided by ODT.

By maximising the potential of the UKLKSS and the non-directed altruistic donor pool within existing resources, the proportion of living donor transplants achieved through the scheme increased substantially during the same period by 63% (from 134 in

2016/17 to 218 in 2019/20) with 55% (696 of 1249 transplants) of total UKLKSS activity achieved in this 4 year period.

Government Health Departments will be asked to review business cases for investment in public education programmes and operational capability and capacity to underpin both living and deceased donation. Primarily, it is anticipated that these will support opt out, operational capability and capacity, new perfusion technologies and digital transformation requirements. These will ensure that the fullest benefit of increased number of donors results in more successful transplants.

This high-level strategy will be supported by detailed plans, developed under the oversight 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.

NHS funders and stakeholders will work together to set out detailed plans to achieve the strategy's aim and outcomes, systematically reflecting on progress throughout delivery.

Measuring Success

Mechanisms for review and oversight of this strategy and the engagement of stakeholders will be established as part of the implementation plan. NHSBT has already begun to develop a clear roadmap for the targets that will be measured internally that are within its remit.

These measures will be shared with other organisations as part of the overall performance management of the strategy, together with the targets and measures developed by all stakeholders individually.

All measures for this strategy will be guided by outcomes for patients, improving rates of all organ donation, organ utilisation and transplantation.

Risks to Delivery

This is an ambitious strategy which is dependent on substantial financial investment and multi-agency commitment across all 4 UK nations to deliver it. The main risks to delivering the strategy include:

Risk	Impact	Mitigation
Unable to build capacity and capability - different organisations responsible for funding donation and transplantation	• Inability to realise full potential numbers of transplants from living and deceased donors (transplant capacity) • Inability to achieve optimal organ utilisation (no new technologies/centre capacity) • No development of the UKLKSS (without digital platform for manual processes and ability to develop matching algorithm) • Increased waiting lists (if fewer transplants) • Reduced progress in research and development	Delivery of strategy signed off by all 4 UK countries Scrutiny by ODT Sustainable Funding, Oversight and Stakeholder Groups
Unable to address systemic issues in health inequalities in donation and transplantation	• Inability to improve equity of access to organ donation and transplantation	Training in equality matters for **everyone** involved in delivering the strategy
Lengthy and unpredictable deceased donation and transplantation process	• Barrier to recruitment and retention of staff • Reduced donation rates (family refusal/withdrawal of consent/donor hospital unable to accommodate) • Safety concerns about transplantation at night • Poorer transplant outcomes due to prolonged cold ischaemic time (CIT)	Work to optimise length and predictability of process and investment to make required changes Collaborative working/new ways of working for transplant teams
COVID-19 pandemic (subsequent surges)	• Possibility of increased numbers of patients on the transplant waiting list	Contingency plans in place and enacted during 2nd surge

	• Unknown impact of long COVID • Reduced donation and transplantation activity (suitable donors/recipients and staff sickness/self-isolation/centre closures) • Fluctuations in workforce (short and long-term) • Safety concerns- risk of recipient death	NHSBT COVID Transplant Registry (monitoring) Policies and guidelines in place (NHSBT/professional societies/commissioners) Government policies to control spread of virus Expanding research capacity in infectious diseases Vaccine 2021
Complexity of digital solutions required to support strategic aims/activities	• Risk of serious untoward events due to manual processes and paper forms • Unable to deliver UKLKSS activity (as above) • Incomplete data collection • Lack of completeness of clinical registry data and self-reported measures (recipients and living donors)	Sustainable IT funding resource

Abbreviations

AR – Assessment and Recovery

ARC- Assessment and Recovery Centre

BAME – Black, Asian, Mixed Race and Minority Ethnicity

BTS – British Transplantation Society

CIT - Cold Ischemic Time

COVID - 19 - Coronavirus Disease 2019

DBD – Death after Brain Stem Death

DCD – Death after Circulatory Death

DHSC – Department of Health and Social Care

DROM- Donor Reported Outcome Measure

DREM- Donor Reported Experience Measure

ESOT - European Society for Organ Transplantation

HLA – Human leukocyte antigen

HTA – Human Tissue Authority

INOAR- Increasing the Number of Organs Available for Research

LDKT - Living Donor Kidney Transplantation

MHRA - Medicines and Healthcare products Regulatory Agency

NBTA - National BAME Transplant Alliance

NHS – National Health Service

NHSBT – NHS Blood and Transplant

NHS E- NHS England

NHS I NHS Improvement

NIHR BTRU - National Institute for Health Research Blood and Transplant Research Unit

NORS – National Organ Retrieval Team

ODT – Organ Donation and Transplantation

OTDT- Organ and Tissue Donation and Transplantation

PITHIA - pre-implantation histopathology trial

PREM- Patient Reported Experience Measure

PROM- Patient Reported Experience Measure

QUOD – Quality in Organ Donation

RINTAG - Research, Innovation and Novel Technologies Advisory Group

SNOD – Specialist Nurses for Organ Donation

UKLKSS - UK Living Kidney Sharing Scheme