NHS BLOOD AND TRANSPLANT

28th March 2019

UK Organ Donation and Transplantation beyond 2020: a strategic discussion document

Status: Official

Executive Summary

The attached document describes the key strategic areas which need to be addressed if the UK is to continue to save and improve more lives through organ donation and transplantation after 2020. Using as its starting point a review of the data from the current service, it proposes five strategic aims for consideration namely:

1. We will miss no opportunity for donation and transplantation
2. We will make the most of new legislation, increasing support for donation
3. We will improve kidney transplant opportunities for our Black and Asian citizens.
4. We will reduce the wait for a transplant.
5. We will work to secure a sustainable donation and transplant service across the UK

Developing the strategy

This document will provide the basis for widespread engagement with: people working in the fields of organ donation and transplantation (both those providing the service and those commissioning it); the voluntary sector; patients and the general public; the four UK governments. NHSBT will facilitate this engagement to confirm: whether the aims are right; how the aims can best be delivered and how progress should be measured.

The intention is to have developed a strategy that has widespread support by January 2020 and then to seek final agreement from all four UK Health Departments and the NHSBT Board by March 2020. A key feature of the donation and transplantation service in the UK is the many organisations and people who need to work together to deliver a successful strategy. Once the strategy is agreed a detailed plan will need to be developed ascribing actions and accountabilities for each element. Further work will also be needed to assess whether the current Oversight Group is the right mechanism for scrutinising progress in the future.

Action: **The Board is asked to approve the document as the basis for discussion with all stakeholders in the organ donation and transplantation pathway.**

Author: Sally Johnson, March 2019

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Introduction

Following the publication of the Organ Donor Taskforce Report *Organs for Transplant in 2008* and the subsequent strategies *Taking Organ Transplantation to 2020* and *the Living Donor Kidney Transplant 2020 Strategy,* the UK has made great progress in increasing the number of organs available and transplanted and thus given hope to everyone needing a transplant to save and improve their life.

Since 2008 the number of deceased organ donors has risen from 809 (2007/8) to 1574 (2017/18) and the number of transplants from these donors has grown from 2384 to 4039. During this time, the number of people coming forward as living donors has also increased from 858 to 1051 although the peak of 1148 achieved in 2013/14 has not been sustained. Annually around 90 people donate a kidney altruistically while living. As a result of these increases, there are fewer people overall waiting for a transplant. However, 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 this success there remain immense challenges in securing a suitable organ for everyone who needs a transplant. The overall number of people who die in circumstances[1] where organ donation is possible is relatively static at about 6,000 people each year (about 1% of deaths). However, these people are now older, have greater co-morbidities and a higher BMI than in the past, making a successful transplant less likely. Although there are 25 million people registered to donate on the NHS Organ Donor Register and the consent rate in the UK has risen, it still does not match the best in the world. There are particular challenges in securing consent from people in our black and Asian citizens where the need is greater but there is little tradition of donation, either deceased or living.

In hospitals, tremendous progress has been made in identifying potential donors and ensuring their families are approached for donation and supported through the process by a specially trained professional. The donor characterisation, offering and retrieval have changed so that more transplants take place at night, increasing the challenges for the surgical team and stretching resources further. There is growing evidence that new perfusion technology would give surgeons greater confidence to implant more organs successfully. Enabling routine adoption of these technology 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.

[1] Patient is intubated and ventilated, generally on an Intensive Care Unit

From a public perspective, the biggest change since the publication of the 2020 strategies, is the change in legislation in Wales. In December 2015 Wales changed their consent legislation so that if you haven't made a decision about organ donation before your death, you are deemed to have made a decision to donate. Families continue to be closely involved in the process and are always asked about the last known decision of their relative and whether there are any faith requirements that need to be considered. Families are also asked for medical and social history to ensure that any donated organs would be safe to transplant. After a relatively slow start, the change in legislation together with the accompanying public information campaign, have begun to bear fruit with the consent rate rising significantly. Scotland, England and a number of the Crown Protected Territories are pursuing similar legislation in an effort to increase the number of organs available for transplant. Making the most of this new opportunity will be critical over the coming years.

1. Miss No Opportunity for Donation, Retrieval and Transplantation

In 2017/18 NHSBT initiated a new approach to organ donation with the Clinical Leads, Donation Committee Chairs and Specialist Nurses. Rather than setting and focussing on specific targets, every donor hospital was asked to make sure that they missed no opportunity to make a transplant happen. This required leadership supported by policy and good processes at each step of the organ donation pathway and contributed together with other initiatives to an 11% boost in the number of organ donors in a single year.

With so few people dying in circumstances where organ donation is an option it is essential that hospitals strive to get it right 100% of the time. NHSBT will continue to audit all deaths under the age of 80 in Intensive Care and Emergency Departments to assess whether every potential donor has been identified, brain stem tested (where appropriate), referred and the donor family approached in line with the national legislation. The Potential Donor Audit may benefit from development to provide the best data to hospitals in the future as the basis for learning and improvement.

Increasingly potential donors are older with increasingly complex health and disease problems making their organs harder to transplant. As a result, the number of deceased donor transplants is not keeping pace with the increases in donors. Whilst NHSBT will continue to support donor hospitals in their work to miss no opportunity, over the next 5 years the focus will move to the transplant centres.

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

Transplantation is inevitably a risky form of surgery. Even with the most effective donor characterisation and careful offering schemes, ultimately it is the transplant team, together with their patient, who have to decide whether an available organ is suitable at that particular time. There are several areas for development so transplant teams to miss no opportunity to transplant organs safely, building on NHSBT's existing organ utilisation strategy published in 2017.

◊ **Improved data/processes to support learning and decision-making**

- 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.
- Develop tools to support patients and clinicians as they agree consent for transplantation so both can make a fair assessment of the risks involved.
- NHSBT will support transplant centres with individual and comparative data on organ utilisation as a tool for learning and will develop Transplant Collaboratives (similar to Regional Collaboratives in organ donation) which provide a safe environment for clinicians to discuss opportunities to improve practice, learn from other centres and make the best use of limited resources).

◊ **Improving organ assessment and functioning**

Key to assessing organ risk is good clinical data to inform the transplant team. Following a Donor Characterisation Review, and dependent on the outcome of the PITHIA trial, it is proposed to extend donor characterisation to provide clinicians with better information to support acceptance decisions.

There are a range of interventions that are undertaken in many other countries to increase the number and quality of organs from donors. For example, heparin (a drug to reduce the chance of blood clots forming in the organs) is routinely given to donors prior to death. There should be research and service evaluations undertaken in the UK to assess the impact and efficacy of donor management and drug therapies.

In October 2018 a UK Summit on Innovation in Perfusion and Preservation strategies in solid organ transplantation concluded that novel methods of Preservation and Machine Perfusion are highly likely to transform organ donation and transplantation in clinical management, logistics and outcome. One aspect of this, also agreed, is the likely need for a few Organ Assessment and Reconditioning centres. It is anticipated that donated organs, especially those with higher risk profile, would be transported to these centres for investigation and, if possible, intervention to improve function prior to onward transplantation. Only a few such centres, by common consent, will be required across the UK and these are likely to be situated separate from transplant centres but within easy reach of a number of such centres.

Assessment will allow triaging of organs, identifying those that need little intervention, those higher risk organs that require a lot, and those that should never be transplanted. In the future, such interventions are likely to include novel drugs and cells 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 although this is outside the scope of this strategy.

The UK has poor rates of both lung and heart transplantation compared with international comparators with 20% of people waiting for a lung transplant and 15% of people waiting for a heart transplant[2] die or are removed from the list within a year of being listed for a transplant. Finding affordable technological solutions to increase the use of hearts and lungs from both DBD and DCD donors will be important to give hope to patients waiting for transplants.

2. Make the most of new legislation

Following Wales's lead, other jurisdictions (England, Scotland, Jersey, Guernsey, Isle of Mann[3]) are now developing legislation which expects citizens to record a decision to 'opt out', preferably on the NHS Organ Donor Register if they have decided not to donate their organs after death. People who do not 'opt out' will be deemed to have consented to or authorised donation. It will still be possible for citizens to record their decision to donate on the NHS ODR: 25 million people have already done this.

Wales implemented their legislation on 1st December 2015 and since then have seen considerable increases in consent, especially for DBD donors. The challenge will be to ensure that similar gains are seen in all areas with changed legislation. This will require:

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

Making the most of the opportunities presented by new legislation is possibly the best chance to increase the size of the donor pool with more individuals, supported by their families, becoming donors. It will probably take the full period of the strategy to realise all the benefits of opt out with citizens expecting to donate their organs unless they have decided not to.

[2] Excluding urgent heart patients

[3] Northern Ireland have chosen to remain with their present opt in system where the government is responsible for promoting organ donation.

The impact of the new legislation on tissue donation (particularly cornea, heart valves and large osteochondral grafts) is being considered. There is a shortfall of these tissues within the UK which is filled by imports, mainly from the USA. The changes to the legislation provide an opportunity to increase the number of UK citizens who donate these tissues.

3. **Improving kidney transplant opportunities for our Black and Asian citizens**

Black and Asian citizens needing a kidney transplant are doubly disadvantaged. More black and Asian people need transplants than the rest of the population because of their susceptibility to diabetes and hypertension (high blood pressure). A third of the people (1487 in the UK waiting for a kidney transplant are black or Asian.

Donated kidneys need to be from a donor who matches the recipient. This means they need to have the same blood group and be a human leukocyte antigen (HLA) match too. This is more likely if donor and recipient are from the same ethnic group. The number of people from our black and Asian communities who die in circumstances where donation is possible is around 550 a year, i.e. not enough even if every kidney were able to be used to meet the need. Furthermore, black and Asian citizens are less likely to give consent for organ donation (White DBD Consent – 78.2% compared with BAME DBD consent rate of 43.8%).

Much work has already been done to engage with black and Asian citizens about the importance of donation but progress is slow. The opportunities presented by Opt Out legislation to change behaviour in these communities are important. Just as important, given the shortage of potential donors, is to maximise the opportunity presented by living donors, finding family or friends who can help.

4. **Reduce the wait for a transplant**

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 (about 3 a day on average) who die or who become too sick to transplant before an organ is available for them. Sadly, although the absolute number listed for a transplant has fallen and the waiting time for a kidney transplant has reduced, still too many people wait too long or die before transplantation.

With the increase in deceased donor kidney transplantation, we have seen a slow decline in the numbers of people coming forward as live donors despite the benefits of living donation, including better graft function, reduced delayed graft function and transplantation before dialysis. Approaching family and friends to ask them to consider live donation is a daunting prospect for most people seeking a kidney transplant and it seems that as the number of

deceased kidney donors increases, many people would prefer to wait for a deceased donor.

If the UK is to increase the total number of kidney transplants and reduce the waiting time, then living donor kidney transplants will be a key component, especially for people who are hard to find a match for. Living donors may be: friends or family of the recipient; part of the pooled and pairing scheme (where a willing donor cannot give to the recipient of their choice and instead gives to another recipient in return for a reciprocal donation); or altruistic.

NHSBT will continue to work with all governments to promote living kidney donation and to provide information to patients on the waiting list which will help them weigh up the options for achieving a transplant sooner. Transplant centres should explore all donor options at the time of considering transplantation, being open about which option is likely to lead to transplant fastest.

Work will continue to support pooled, paired and chains of donors to increase the number of transplants.

Living liver donation is also possible but the risks to the donor are much greater than for kidney donation. Transplant centres are therefore only likely to discuss the option for carefully selected patients.

5. A sustainable world class service

The UK's success in growing donation and transplantation since 2007/8 has resulted in a system which is under considerable strain. The most optimistic forecasts suggest that the UK could achieve 600 more deceased donors each year and 1600 more transplants (950 kidneys, 450 livers, 100 pancreases, heart & lung). Already there are 50,000 people with transplants being cared for and this could increase to around 65,000 by 2025.

This cannot be achieved with the current infrastructure. The specialist nursing service is close to capacity, there is growing evidence that transplant capacity is inhibiting organ acceptance, retrieval teams are now operating at 75% of capacity and struggle when there are several days with high donor numbers. The timing or the entire donation process has extended so that it takes a median of 53 hours from referral to implantation for a DBD donor and 41 hours for a DCD donor. Donor families are impacted and increasingly do not give consent/authorisation because of the length of the process. This occurred in 151 cases or 13.1% of the total family refusals (1148) in 2017/18. To address these issues, the whole donation and transplant system will need to take action in five areas:

- ◊ Workforce
- ◊ Digital
- ◊ Processes

- ◊ Capacity
- ◊ Funding

- ◊ **Workforce**

Recruitment of nursing, scientific and medical staff to work in the organ donation and transplant system is increasingly challenging. The nature of transplantation with much of the activity happening at night, can make achieving a good work/life balance challenging. Many of those in the system have come from outside the UK and there are areas where fewer people in the UK are being trained. NHSBT has started to address nursing workforce issues by ending 24-hour working and broadening the criteria for entry. Covering rotas out of hours for scientific staff (in H&I services for example) is getting harder and over the next five years technological and collaborative solutions will need to be explored to maintain the service. The British Transplantation Society is already leading work to consider how best to promote careers in transplantation and the peer reviews lead by NHS England identified recruitment challenges. This work should be revisited and transplant centres should work together regionally to ensure they develop the capacity to match the predicted service growth. Specialist training for the workforce, particularly with the introduction of novel technologies, will continue to be important.

- ◊ **Digital**

The service has implemented new digital solutions to support donor characterisation and controlled document access for specialist nurses, to assist with donor referral and triage, to digitise regulatory forms (HTA B form with HTA A form to follow) and to transform the donor/recipient offering algorithms. These developments, under the umbrella of the ODT Hub, have sought to make the working life of colleagues in organ donation and transplantation simpler, safer and more supportive. This transformation needs to continue so that information access and data transfer throughout the donation and transplantation pathway is increasingly automated. Key objectives will be to enable digital acceptance of offers and digital transfer of testing results.

The new NHS Organ Donor Register (developed 2015) is being linked to the NHS App to simplify and promote public access and if successful, we can expect the other UK nations to expect similar developments. During the period of this strategy NHSBT should review whether partnerships such as those with the DVLA and Boots, linking citizens to the Register remain valuable.

In an ‘opt out’ environment, it will remain important to engage more frequently with citizens to ensure that they are aware of their rights and responsibilities with regard to organ and tissue donation. Increasingly this engagement will be digital, speeding up response times and making personally tailored communication simpler.

◊ **Processes**

The journey from donor referral to organ implantation has increased in length and certain activities happen at times which are sub-optimal (long waits overnight for donor families before the organ retrieval operation commences; during day time impacting on hospital operating schedules; resulting in transplant operations at night when evidence suggests this is less safe). Work has already started to reduce redundant effort through donor referral and triage and to shorten and change the timing of the donation journey with pilots in major hospitals to match timing to resources. This work needs to continue so that the stress on the system and the people within it is reduced. A particular area of challenge is how best to follow up and support the growing number of people living with a transplant. Transplant centres and other hospitals who undertake this work will collaborate to find new ways of supporting their patients in future so that everyone who has had a transplant has the best quality of life they can achieve.

◊ **Capacity**

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

Commissioners of transplant services will want to consider how they best secure the capacity to undertake increasing numbers of transplant. A British Transplantation Society Summit in 2018 has initiated thinking and some kidney transplant centres in London are collaborating to consider how best to network their resources to boost capacity at times of peak demand. The introduction of I NHS England regional structures with responsibility for specialist commissioning should facilitate this approach across renal centres. Commissioners will need to keep under review demand and capacity for liver transplantation and should consider whether the predicted levels of demand for cardiothoracic transplantation merits further collaborative review.

◊ **Funding**

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

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

the number of deceased donors has increased by 12.3% and the number of transplants by 10.6%.

Currently the relevant health departments are reviewing business cases for investment in public education programmes and operational capacity to support opt out and at the possibility of supporting new perfusion technology to make sure that the fullest benefit of increased number of donors results in more transplants.

The intention is that this high-level strategy will be supported by a strategic plan and an assessment made of the costs associated with this across the health system before the strategy is agreed by the Health Departments and commissioning bodies with funding responsibility.

UK Organ donation and transplantation beyond 2020: strategic aims		
1	We will miss no opportunity for donation and transplantation.	Measurable reduction in missed opportunities
2	We will make the most of new legislation, increasing support for donation.	More registrations, higher consent rates
3	We will improve kidney transplant opportunities for our Black and Asian citizens.	More deceased donor consents & high living donation
4	We will reduce the wait for a transplant.	Reduced waiting time
5	We will work to secure a sustainable donation and transplant service across the UK	No evidence that capacity or process is a barrier to a transplant.