OTDT 2030 Strategy and OUP/G

Professor D M Manas

Who am I?

- Surgeon (Transplant and HPB) for 30 years +
- Trained – Cape Town, Johns Hopkins and Paris
  - Pittsburgh and Kyoto
- Spent most of my UK career in Newcastle
  - Institute of Transplantation
- Past President of BTS
- Past president of BLTG
- Deputy chair of LAG
- AMD – Governance (Retrieval and transplantation)
- MD - OTDT

Why another strategy?

Who is it for?

How will it help?

Why do we need it?

Who wrote it?

Is it clinically relevant ?

Who will fund it?

Patients

Waited 3 years

3rd Kidney (cRF 90%)

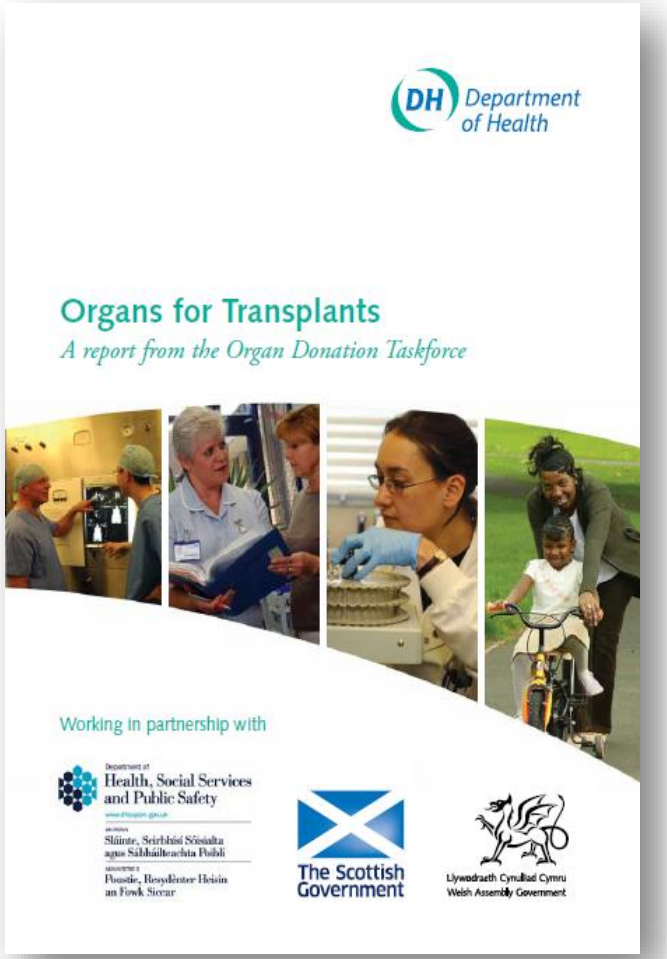
3 false starts

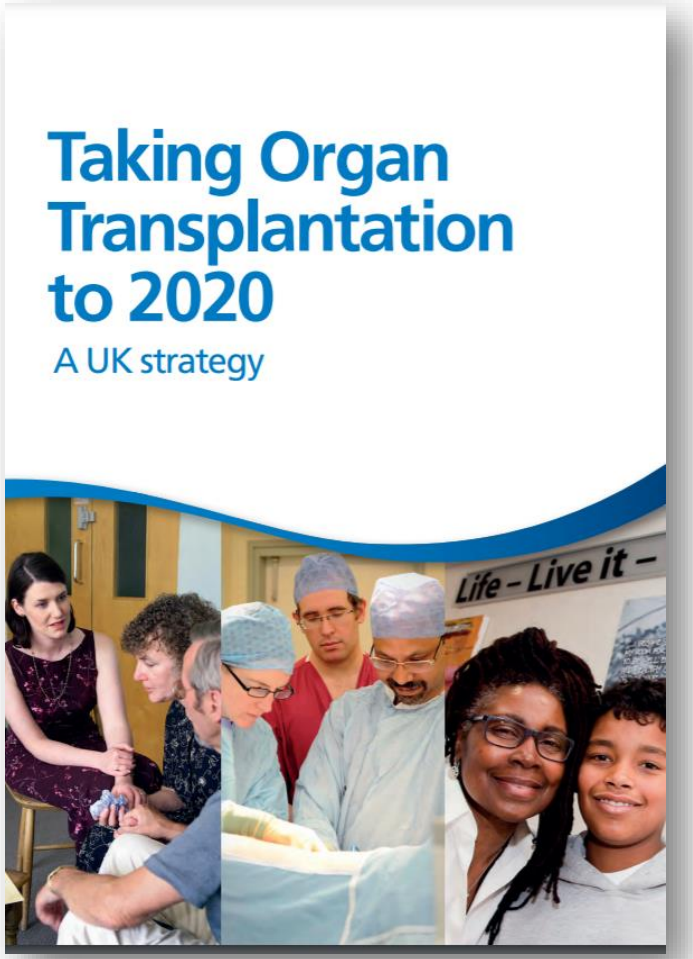
Donate his R L Lobe

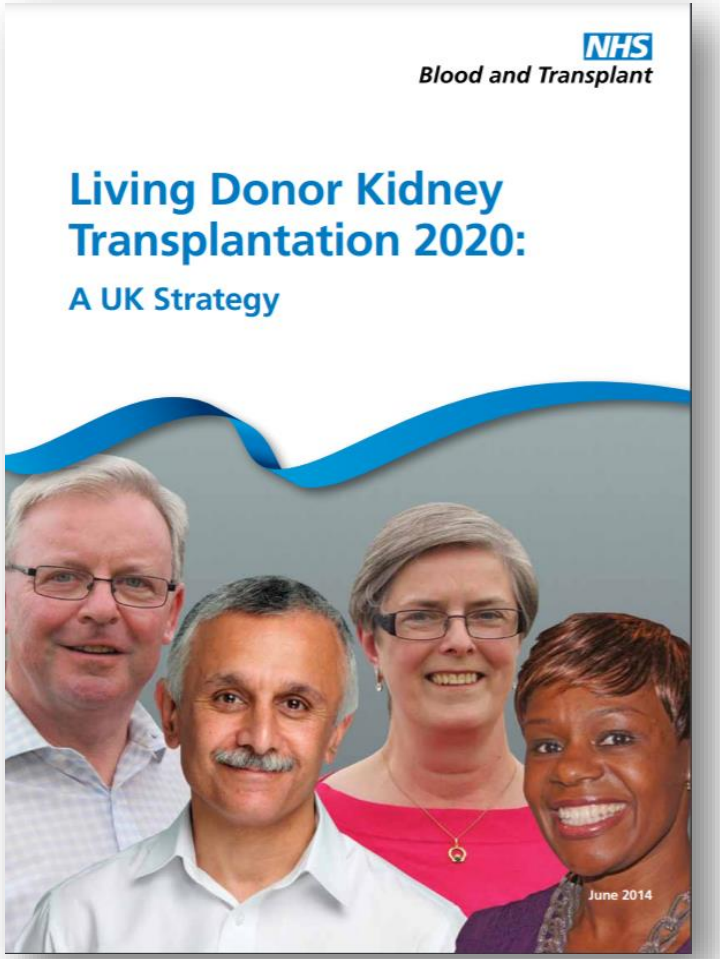
Who else could benefit?

- Commissioners
- Clinicians
  - By clinicians – for clinicians
- Stakeholders
- International collaborations
- Researchers

Previous UK Strategies



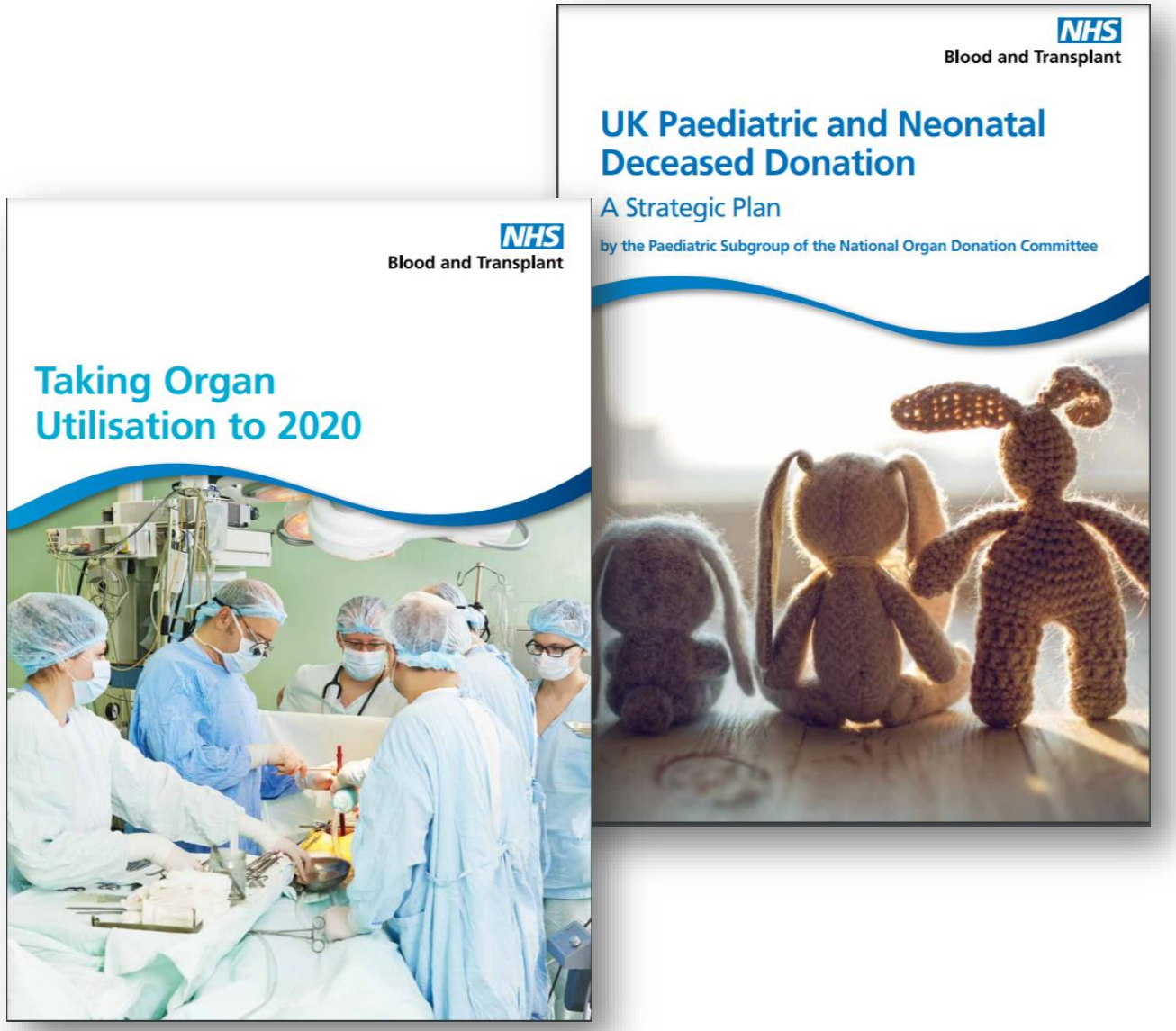




Twelve years of progress

- **Organ Donation Taskforce report on deceased donation 'Organs for Transplant' in January 2008, gave 'birth' to 'Taking Organ Transplantation to 2020',**
  - focused on its 14 specific recommendations
  - resulted in a revolution in deceased organ donation activity and practice across the UK.
  - 95% increase in deceased donors and a 58% increase in deceased donor transplants, since 2008.
    - 1,580 donors and 3,760 transplants in the last year.
- **'Living Donor Kidney Transplantation 2020' strategy has consistently . . .**
  - 1,000 transplants per year, (21% of overall transplant activity and 29% of all kidney transplants).
    - The overall stability in living donation activity, masked the change in approach to living donor kidney transplantation
    - Focussed on patient benefit - realised through increasing numbers of non-directed (altruistic) living donors and the UK Living Kidney Sharing Scheme.
    - World-leading programmes have benefited 1,852 kidney transplant recipients, including those who wait longest due to difficulty in matching them to a suitable donor.

Additional Strategies

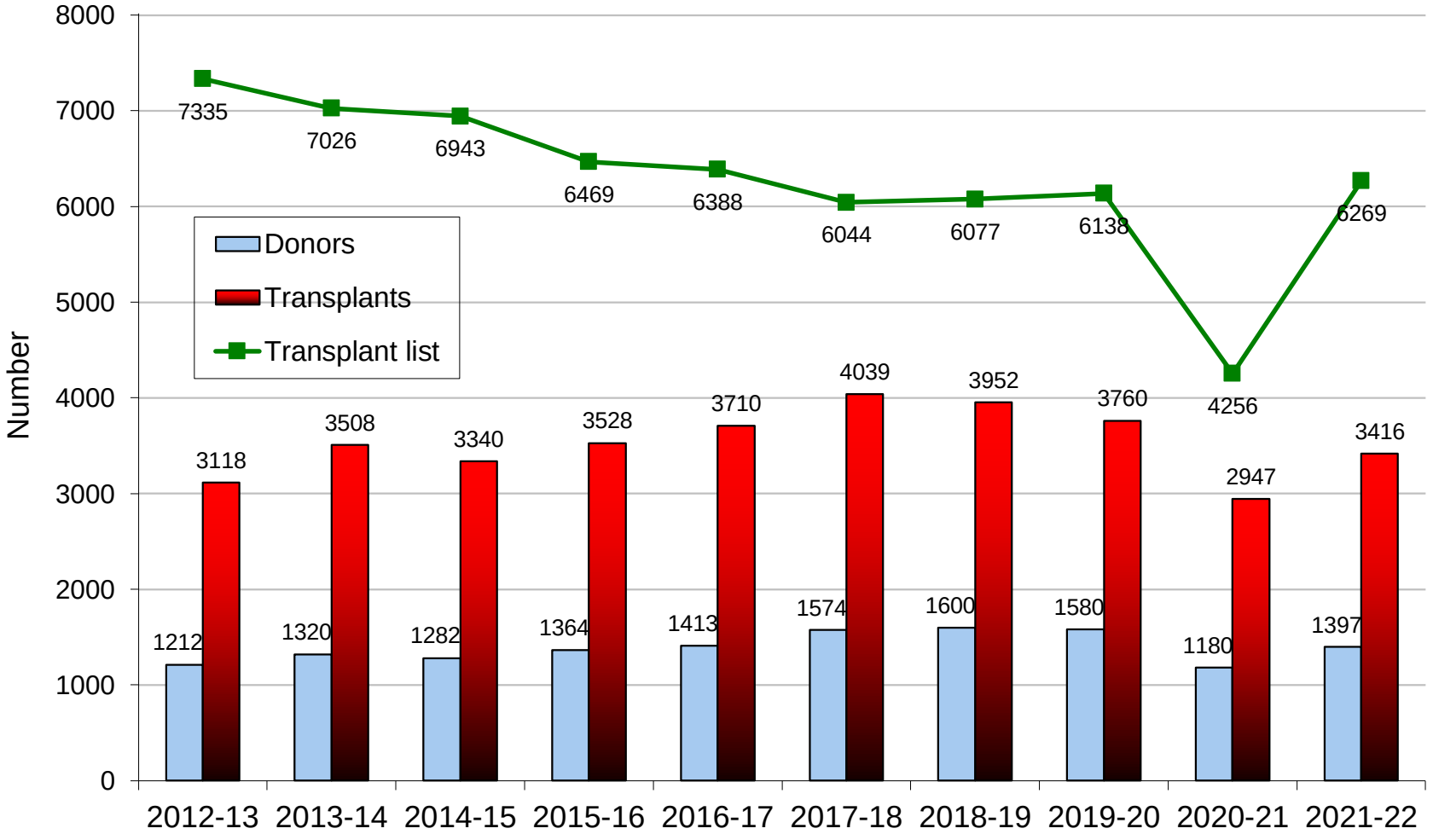


Additional strategies have focused on organ utilisation and paediatric and neonatal deceased donation

Have contributed considerably . . .

Deceased organ donation and transplantation

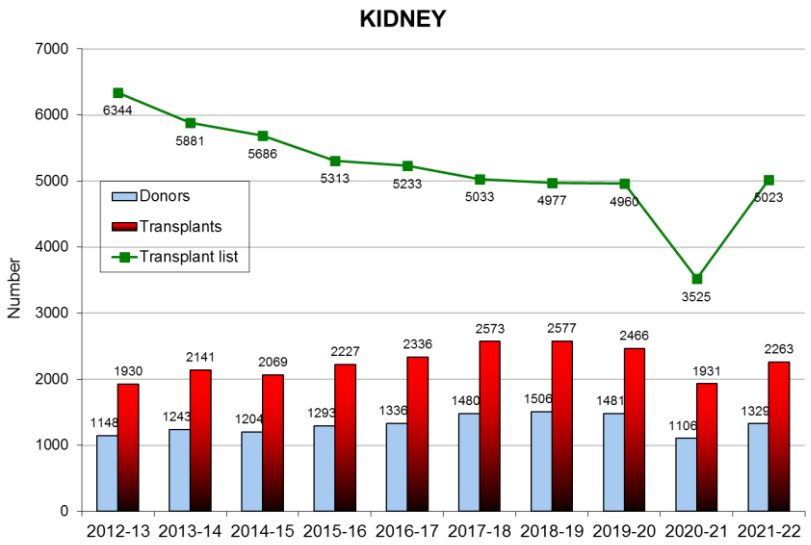
Deceased donors, transplants and transplant waiting list

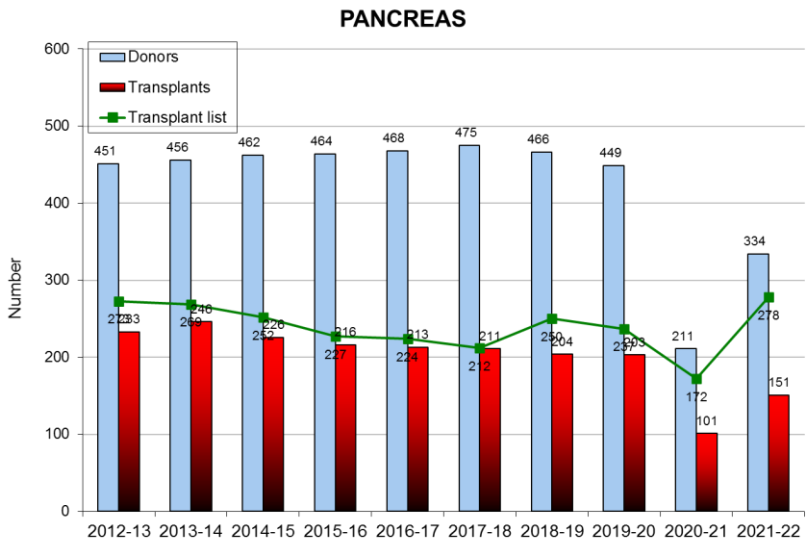


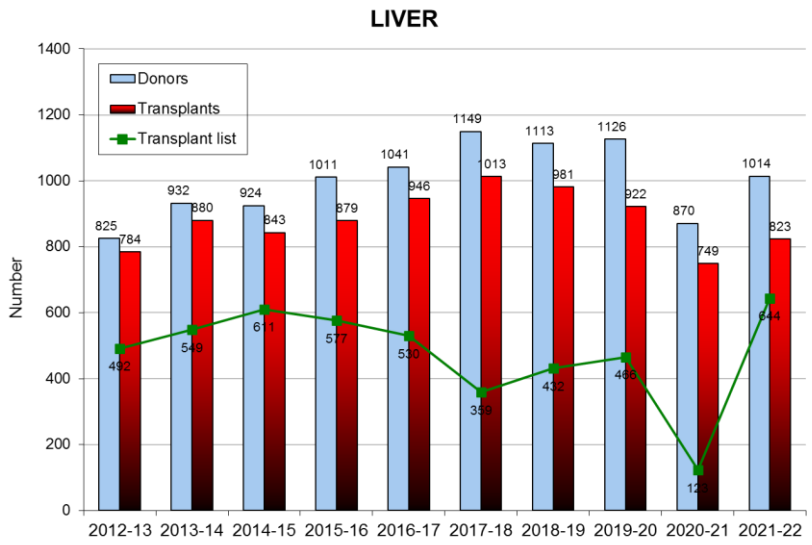
Over the last ten years	Over the last year
15% fall in waiting lists	47% increase in waiting lists
9% increase in transplants (all organs)	16% increase in transplants (all organs)
15% increase in deceased organ donors	18% increase in deceased organ donors

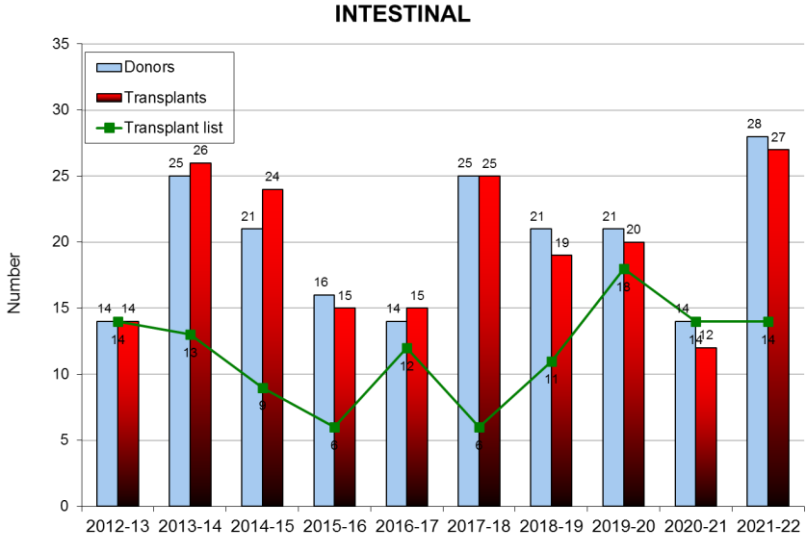
Yes I donate
ORGAN DONATION

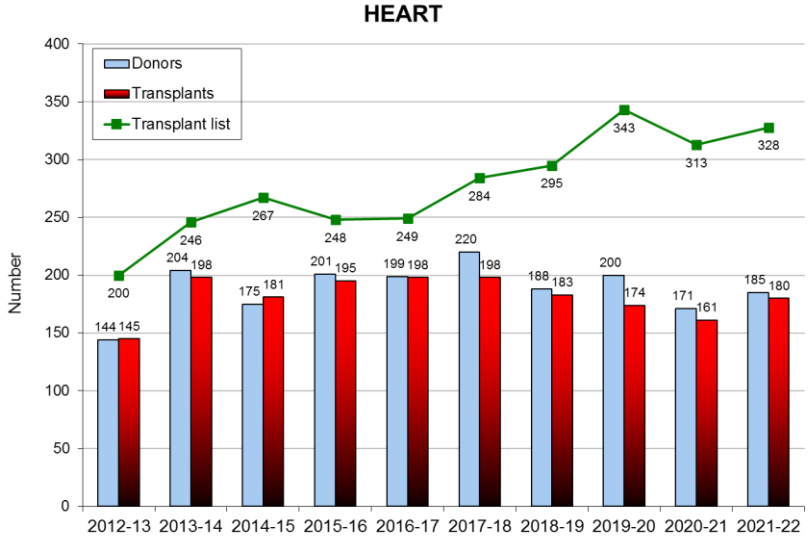
Deceased donors, transplants and transplant lists

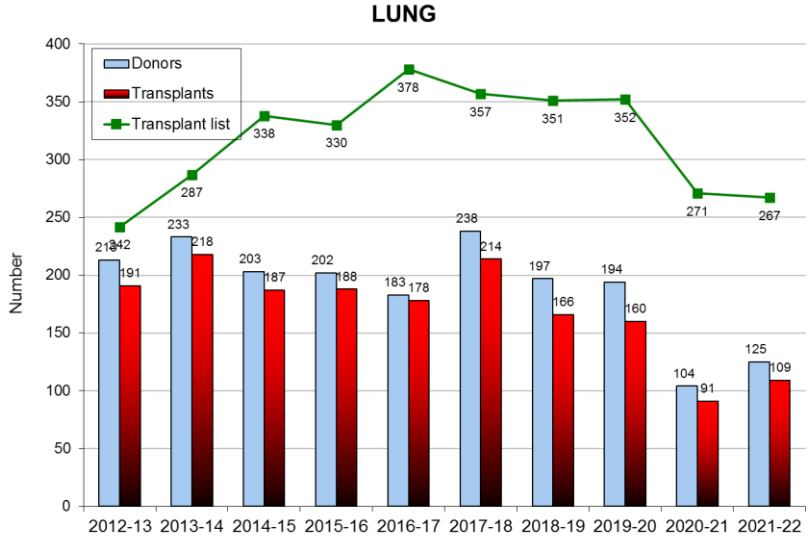






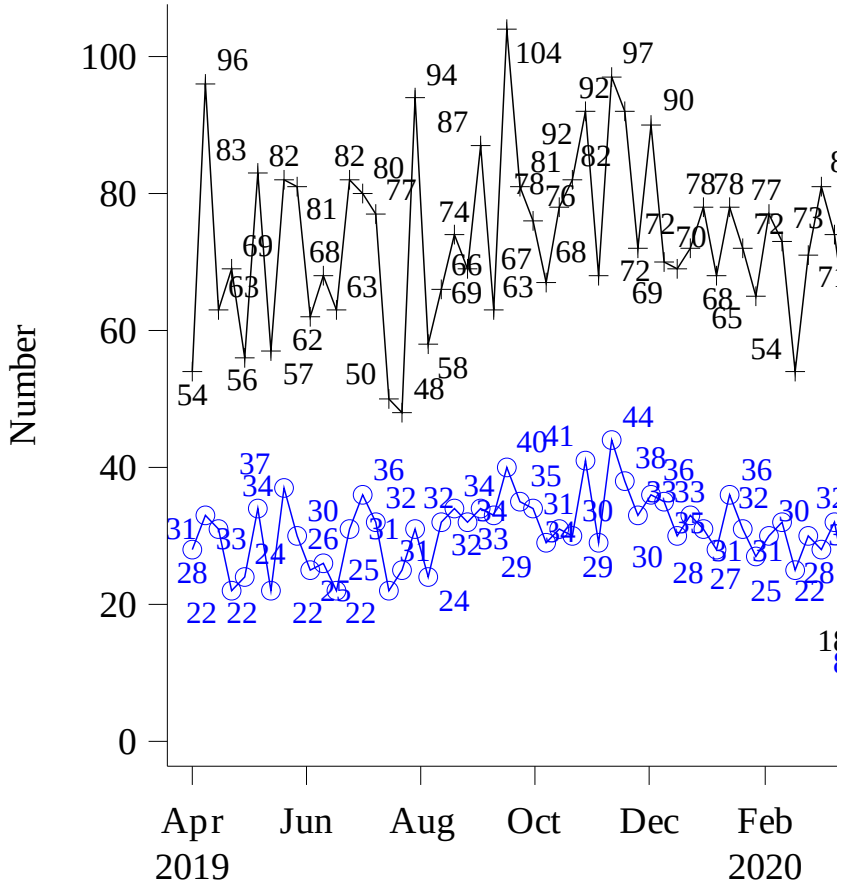




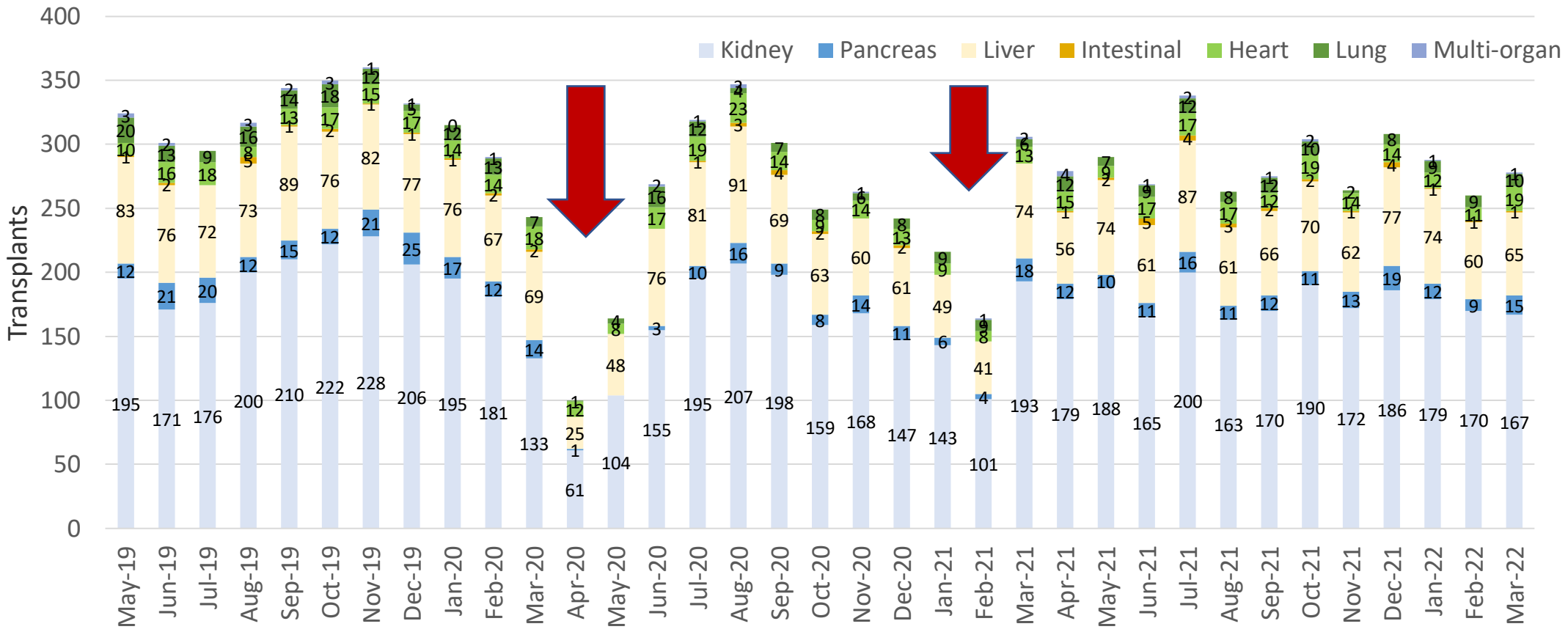


COVID effect on weekly activity

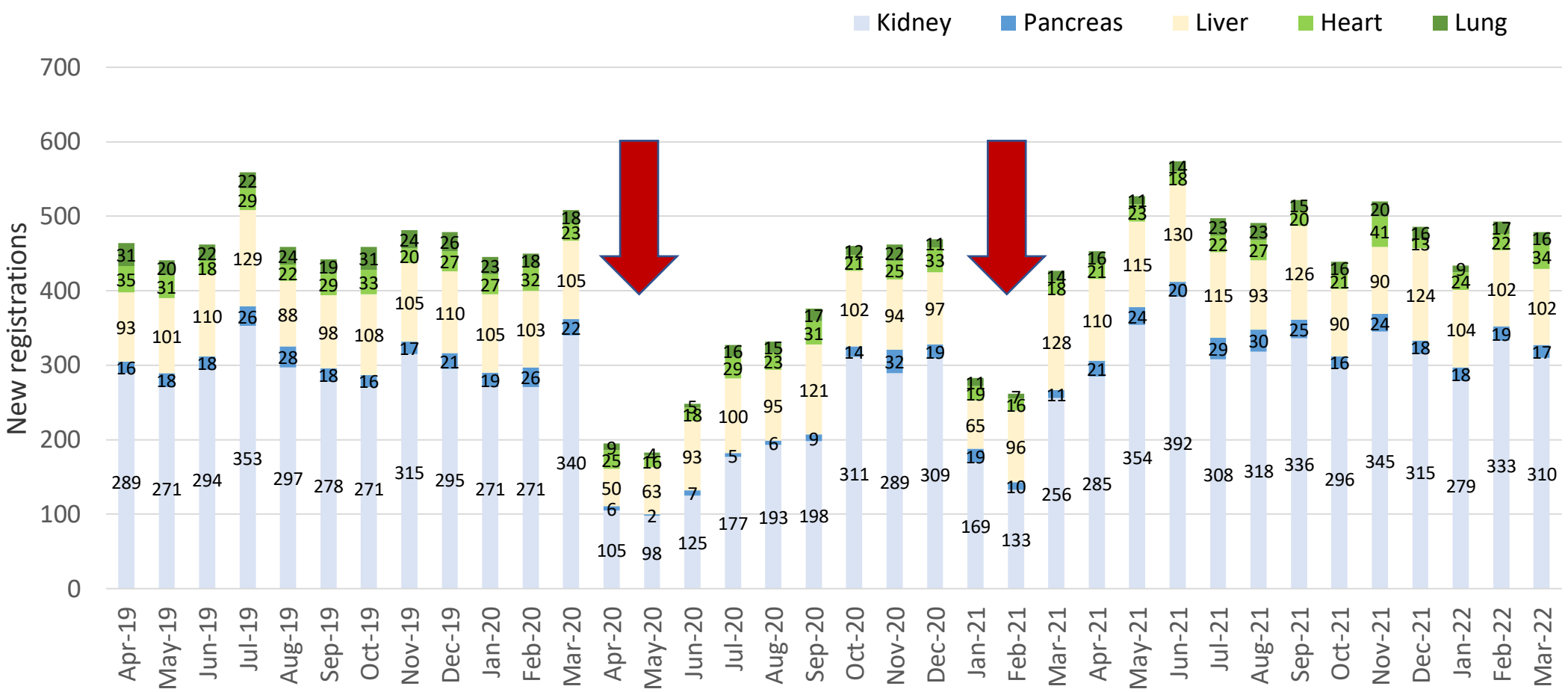
Figure 1 Effect CoVID-19 has on Deceased Donation and Transplantation
Number of deceased donors and transplants by week since 1 April 2019



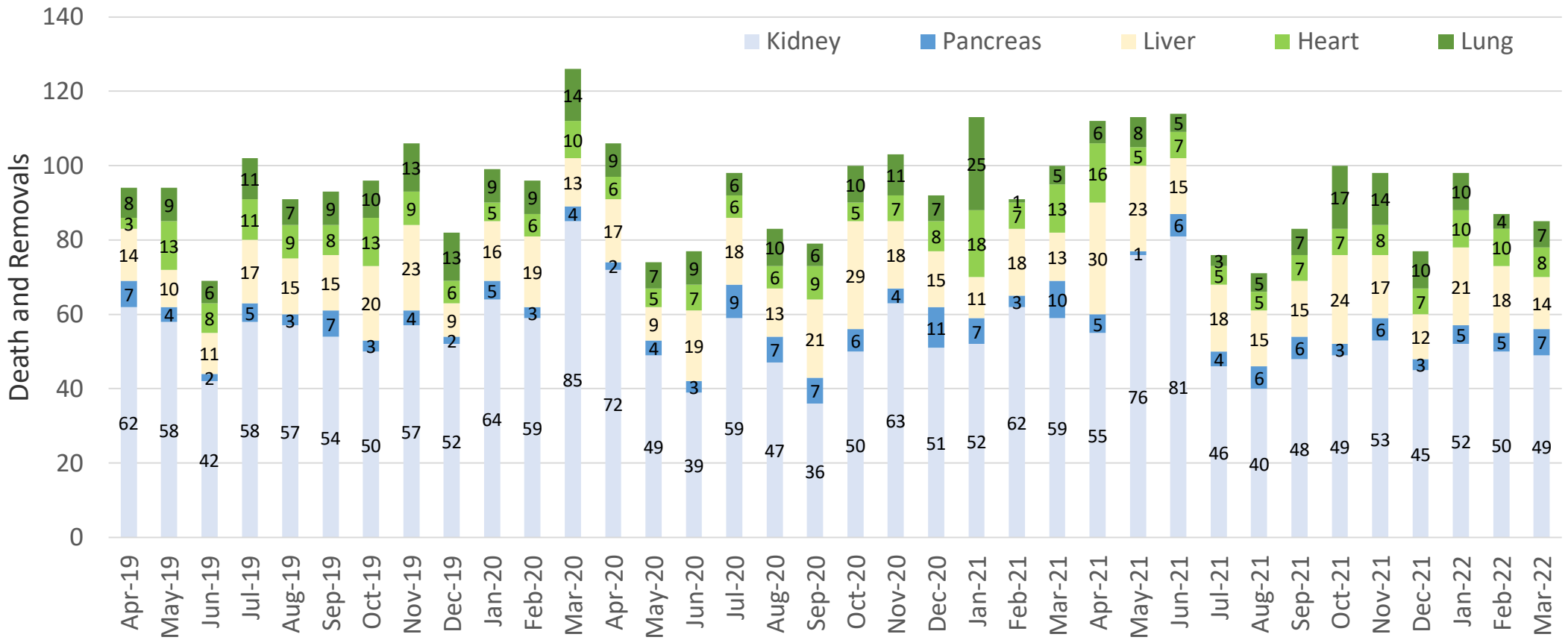
Transplants by month and organ



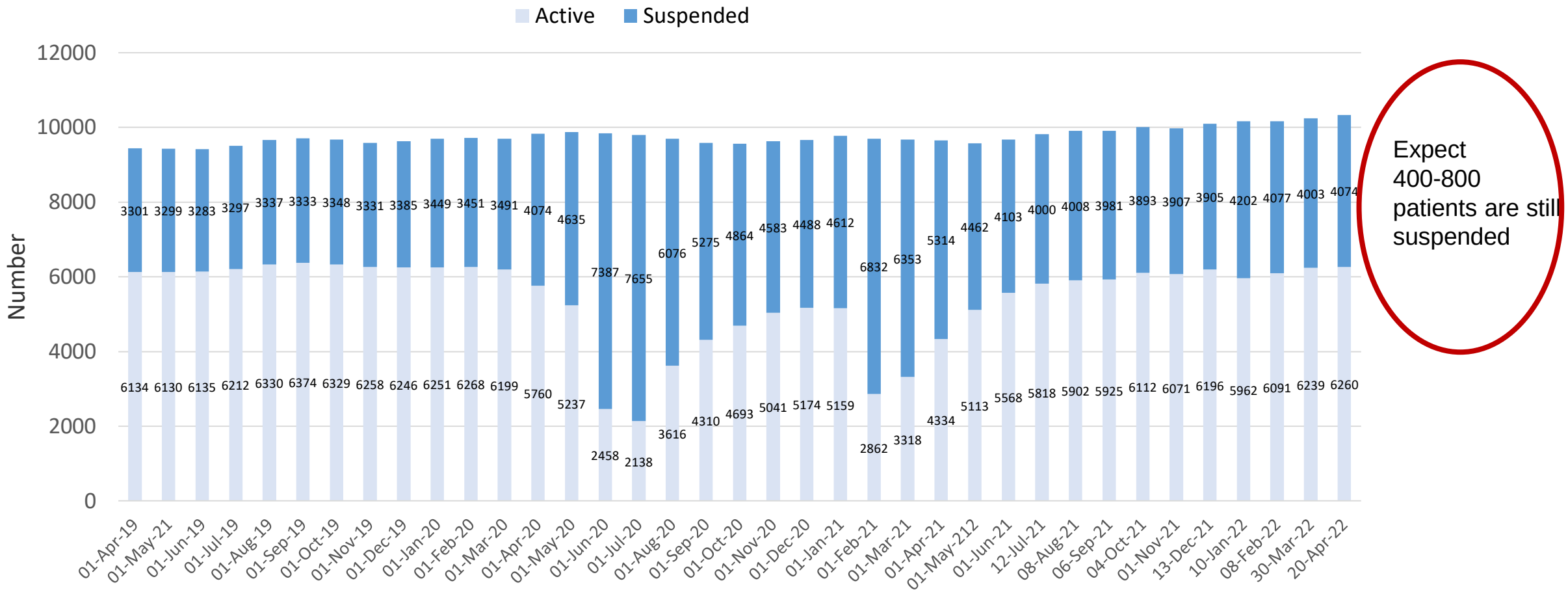
New registrations by month and organ



Deaths and Removals by month and organ



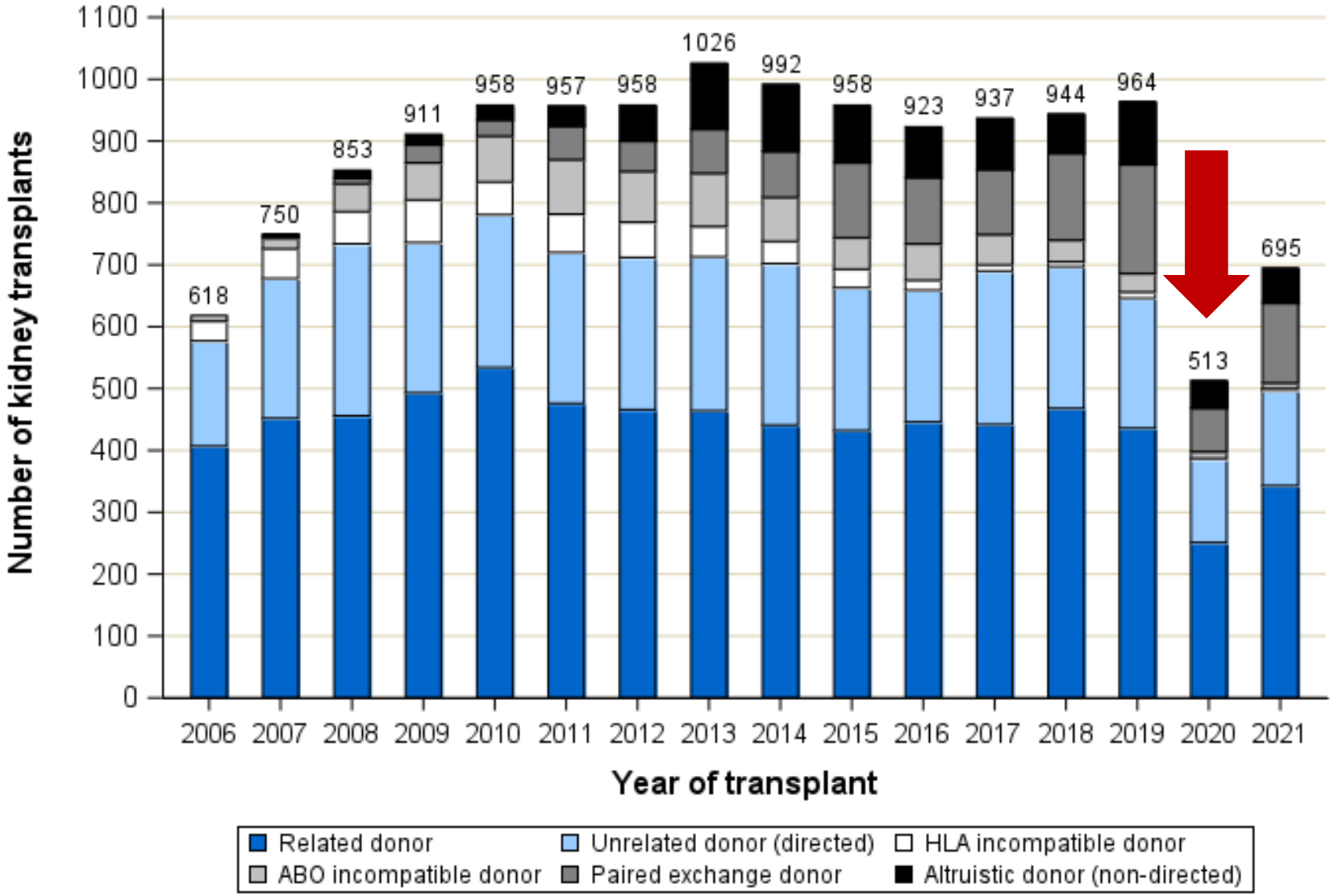
Waiting list by month



Expect 400-800 patients are still suspended

Living organ donation and transplantation

Adult living donor kidney transplants



In 2020

2/4 UKLKSS matching runs performed

Living transplants ceased between 21 Mar and 27 Apr 2020

In 2021

Jan UKLKSS matching run not performed

Yes I donate
ORGAN DONATION

We now need to build on the success of the past to deliver the future

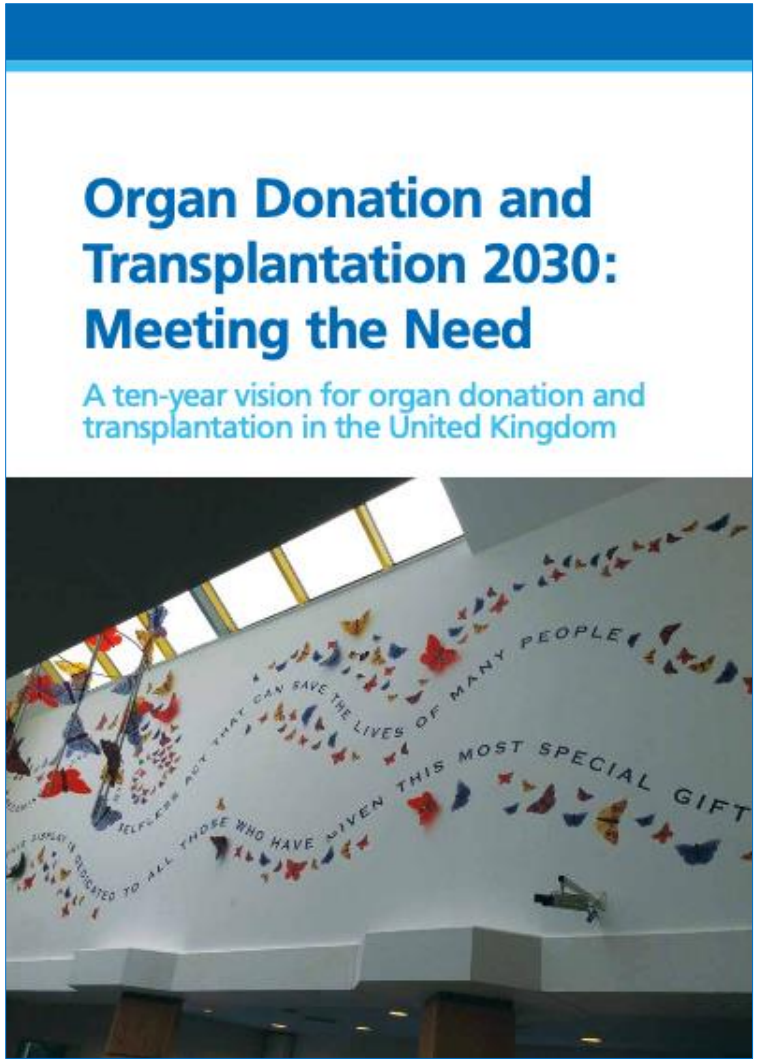
- Current vision brings together both **living and deceased donation** and their concurrent strategies.
- Aiming to balance the **evolution** of current best practice initiatives with a **revolution** in organ utilisation
  - new technologies
  - digital solutions
  - research and innovation
- In the hope - deliver real improvements for people in need of a transplant

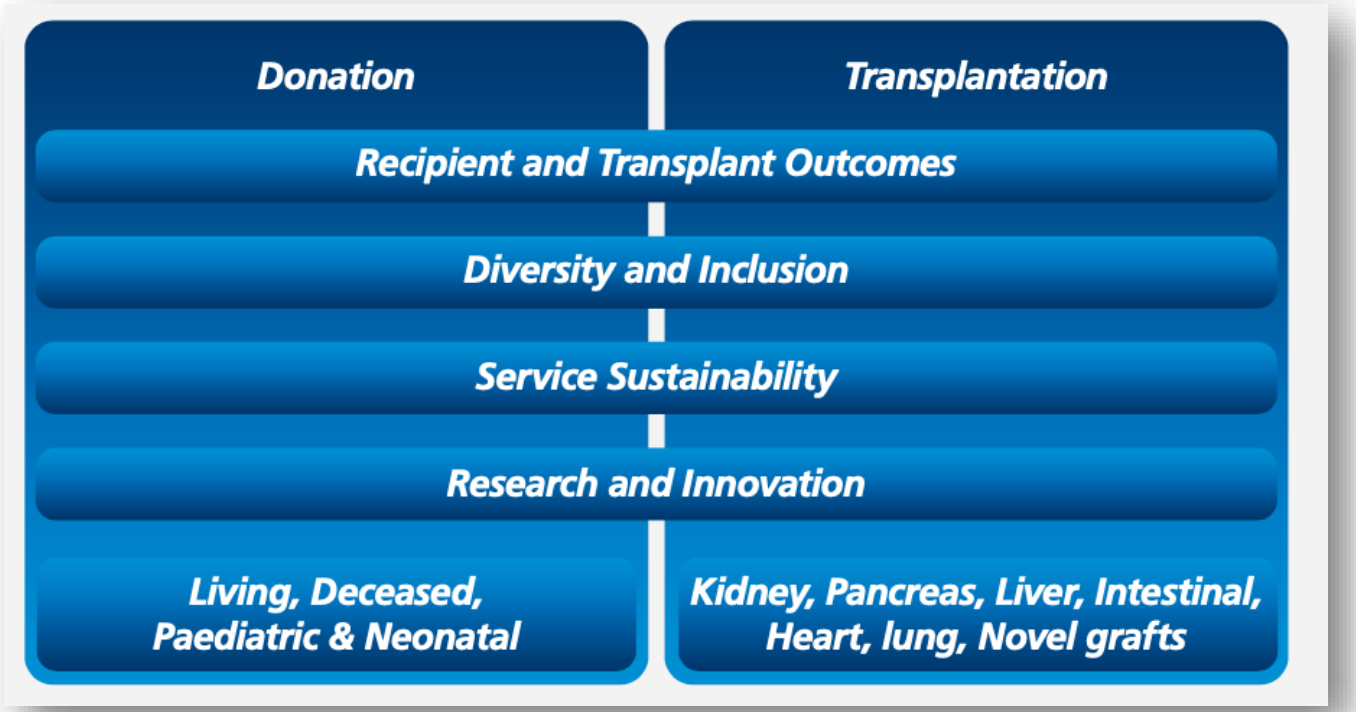
Evolution and Revolution

- **Two propositions** - across the organ donation and transplantation pathway:
  - *To increase organ donation*
  - *To increase organ transplantation*

- Previous strategies have delivered by focusing mainly **on organ donation initiatives**.
- There's great potential to increase donor numbers in both living and deceased organ donation, and an opportunity to increase organ utilisation using new technologies and techniques.
  - UK is currently ahead of ‘the pack’

Our new Strategy





A world leading organ donation and transplantation system

Focus on two – *primary objectives*

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, benefiting from new technologies and techniques.

Focus on four - *enabling objectives*

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, community and National partnerships, and NHSBT	**4**	People of all backgrounds and circumstances have timely access to the organ they need.
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.

Increasing Donation

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

- **Deceased Donation**
- **A revolution in support for organ donation and Maximise donation potential**
  - Get processes right 100% of the time
  - Use the UK Potential Donor Audit, to provide the best data to hospitals as the basis for learning and improvement
  - Improve donor selection, management and drug therapies, to expand the number of donor organs considered suitable to transplant,
  - Establish a forum for addressing ethical issues associated with innovative new practices
  - Explore the potential for donation both inside and outside the traditional hospital settings of intensive care and emergency medicine

The length of the donation process

- Frequent reason for families to withhold or withdraw their consent/authorisation for organ donation.
- To ensure that suitable recipients are sought for every organ –
  - the unintended consequence is that the donation process is 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.
- My ‘mission’ is to change that . . . .

Recognise donors and donor families

- Provide the highest level of ongoing support to donor families. This will include developing NHSBT's family after-care programme
- Public recognition of the gift of organ donation, including continuing the posthumous Order of St John Award for Organ Donation
- Increase the visibility of donor families within UK society so that organ donation becomes a societal norm.

A revolution in organ utilisation

“We will aim for optimal organ utilisation in every organ group, benefiting from new technologies and techniques.”

- Utilisation improvement plans for each organ group
- Evaluate models of organ assessment and recovery
- Support emerging technology and techniques
- Organ Utilisation Programme will drive improvements

Priorities for the next year - OUP

In scope

- Utilisation - from the point that consent for **deceased** donation until the point of organ implantation
- "Project" activity in relation to existing and planned utilisation initiatives
- Organs in scope: **heart, lung, liver, kidney, pancreas**
- Covering all of the UK

Out of scope

- Processes before donor consent and after transplantation (i.e. patient and recipient follow-up)
- Business as usual (e.g. delivery of organ offering, transportation, NORS)
- Other organs and tissues (including islets, intestinal and hepatocytes)
- Existing business cases (e.g. NRP, DCD Hearts, Joint Innovation Fund)
- Changes to the post-transplant care outside NHSBT's control/commission
- Living Donation

Organ Utilisation Programme Workstream Structure & Projects

NHSBT Organ Utilisation Programme

1 Novel Technology & Innovation

- ARCs
- Imaging
- New digital Tx mgmt. tools
- Donor optimisation

2 Education and Culture

- Utilisation Training
- Criteria & Standards
- OD & Tx Collaboratives

3 Clinical Leadership & Engagement

- OUG
- CLUs
- ☆ IOUC initiation
- ☆ '22 NOU Conference
- ☆ Excellence in OU

4 Data & Insight

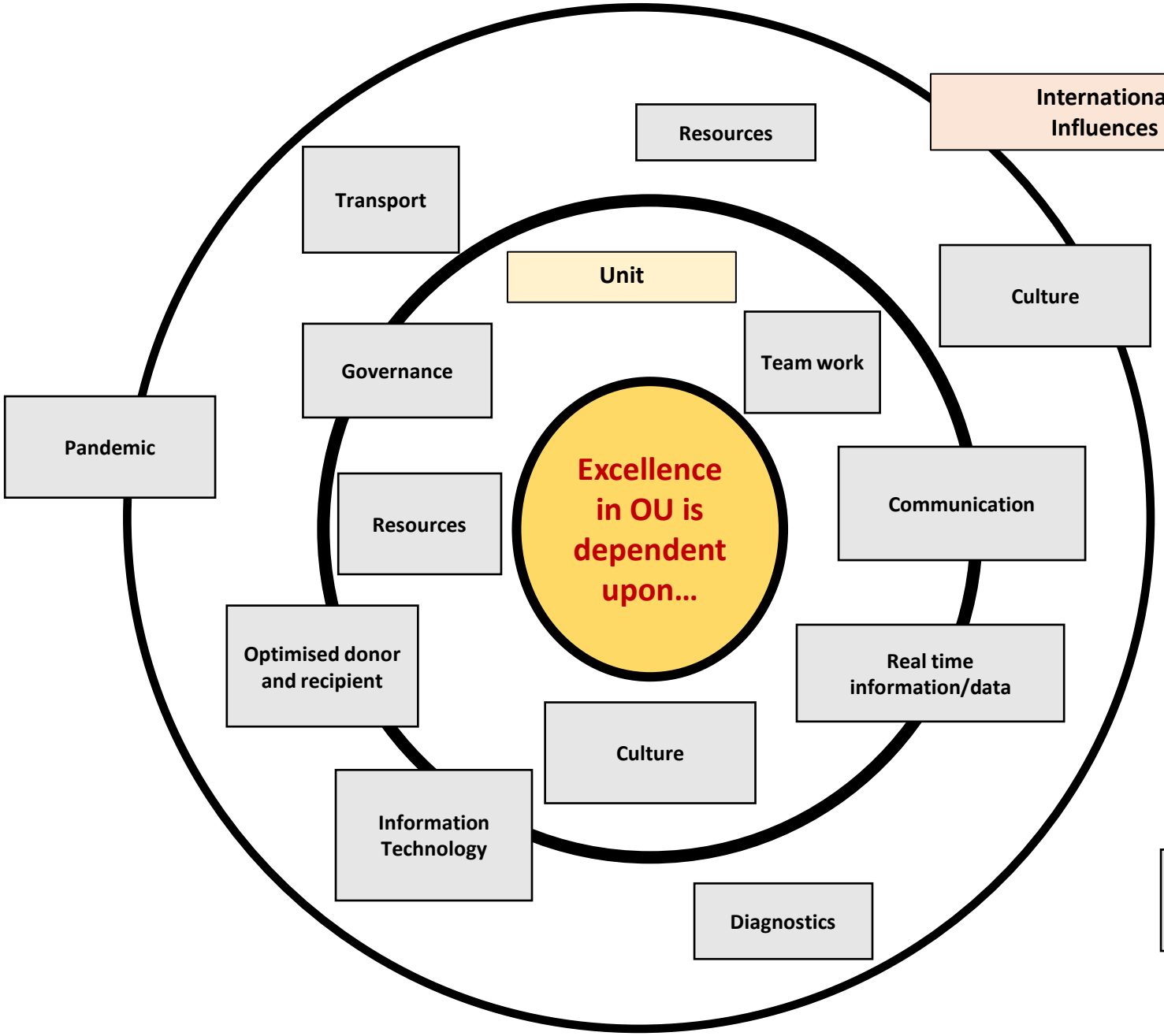
- ODTC ToR
- Higher quality donor organ definition
- Aide Memoire
- TRAC Tools
- Lack of Resources Declines Extensions
- Decline reviews

5 Digital Infrastructure for Utilisation

- Secure Image sharing
- Decommissioning and replacement of the Electronic Offering System (EOS)
- One integrated platform across pathway

Key

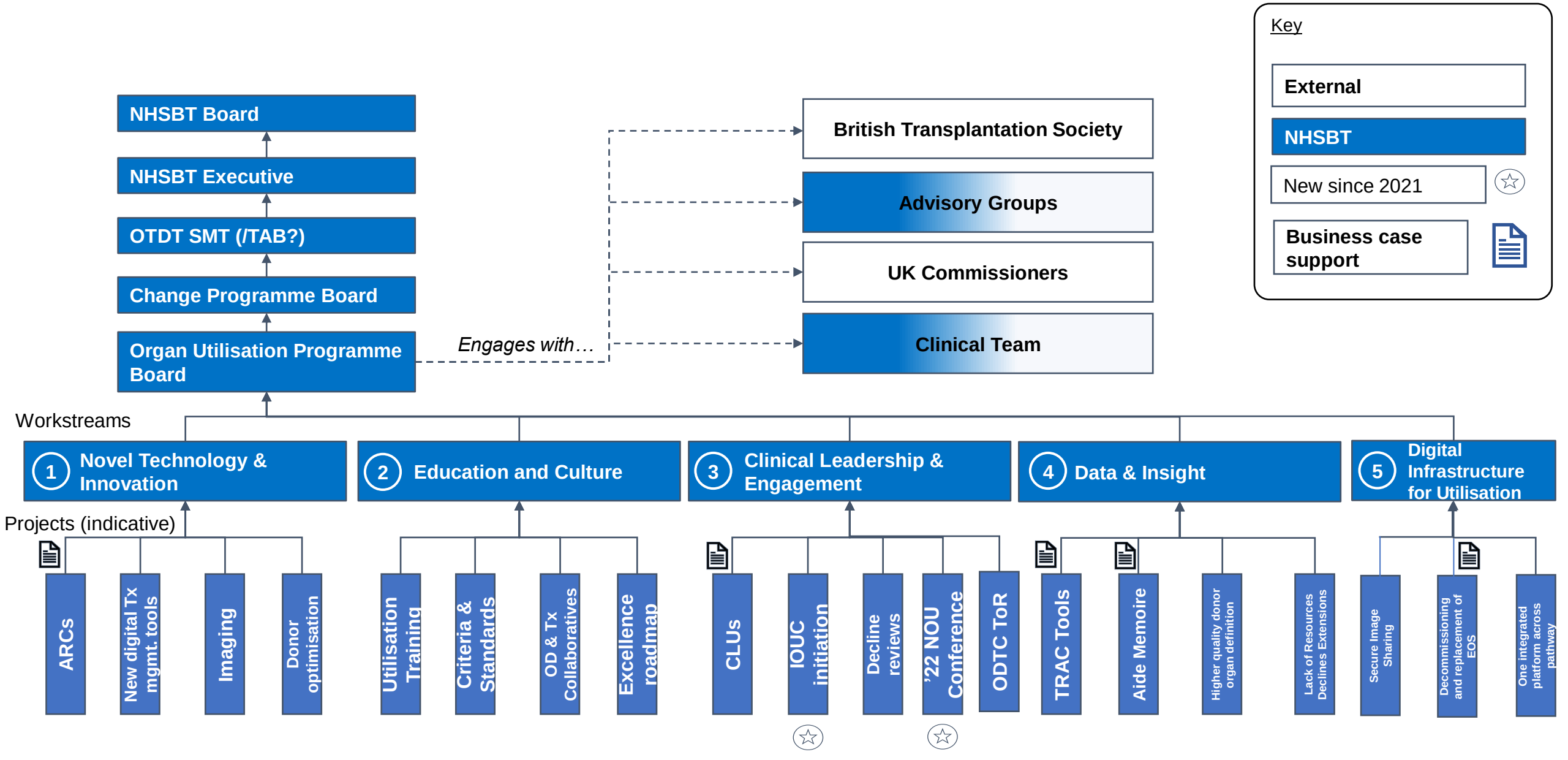
- Workstream
- Projects (indicative)
- ☆ New since 2021
- Business case development required



National / Commissioning / NHSBT culture and prioritization

Courtesy of Rhana Zakri (Kidney CLU, Guy's Hospital)

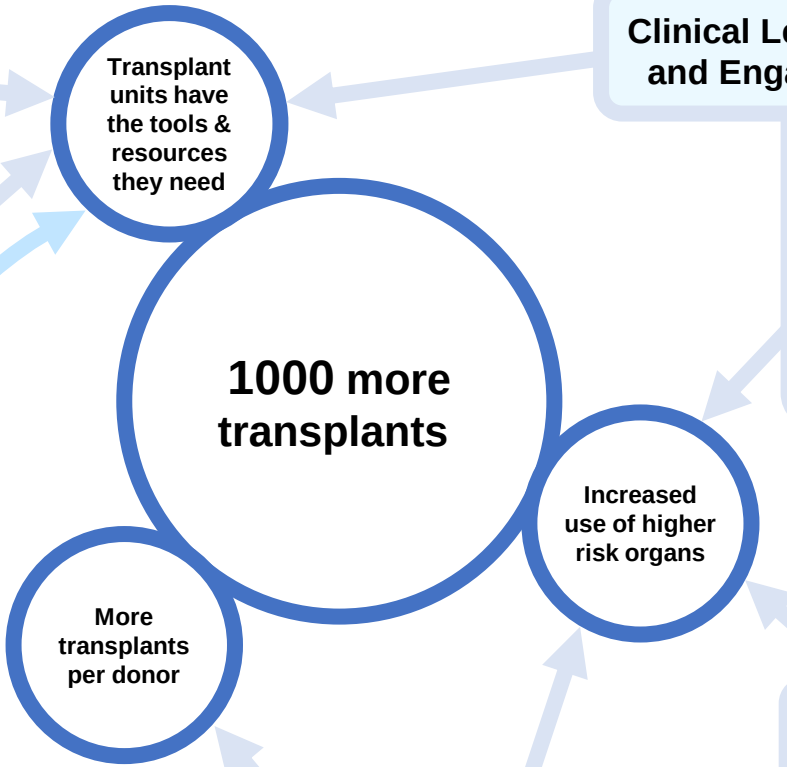
Management and Commercial Case: Arrangements



NHSBT's Vision for the Organ Utilisation Programme

Delivery of the 5-year vision will depend on collaboration across the donation and transplantation systems

Key
- NHSBT Organ Utilisation Scope
- Collaborative goal across the NHS



Data and Insight

- Review offer declines
- Provide better information to units about declined organs
- Extend the Lack of Resource (LoR) decline notifications to all organs

Clinical Leadership and Engagement

- Establish the Clinical Leads in Organ Utilisation (CLU) scheme longer-term
- Develop business case "tool-kit" to support clinicians engaging with Trusts/Boards to secure buy-in and resources
- Run an annual National Organ Utilisation Conference (NOUC)

Digital Infrastructure

Immediate
- Decommissioning and replacement of the Electronic Offering System (EOS)
- Secure Image sharing

Future
- One integrated platform for data access across the transplant pathway

Education and Culture

- Support training of donation, retrieval and transplant professionals
- Develop collaborations between organ donation and transplantation communities
- Develop roadmap to support excellence in organ utilisation within units

Novel Technology & Innovation

- Implement Assessment & Recovery Centres (ARCs): **400 additional transplants per annum in 5 years**
- Investigate options for national implementation of a transplant offer management system
- Implement NHSBT imaging solutions

NB: Programme scope limited to deceased donor organ transplantation

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 improvement plans for each organ group, working with colleagues across the UK.	Clear plans for improving utilisation for each organ group, contributing to overall increases in utilisation.	NHSBT Transplant Centres Commissioners
2.2	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

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

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.	NHSBT Transplant Centres Commissioners
2.7	Implement UK guidelines and policy on which extended criteria organs could be subject to *ex situ* perfusion.	Clarifies the role of perfusion in overcoming logistical issues that would otherwise prevent transplantation. Standards for acceptance and utilisation of organs as technology becomes more widespread.	NHSBT Commissioners
2.8	Work with regulators, to define how the introduction of new technologies to assess and improve organs 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

Maximising Living Donation

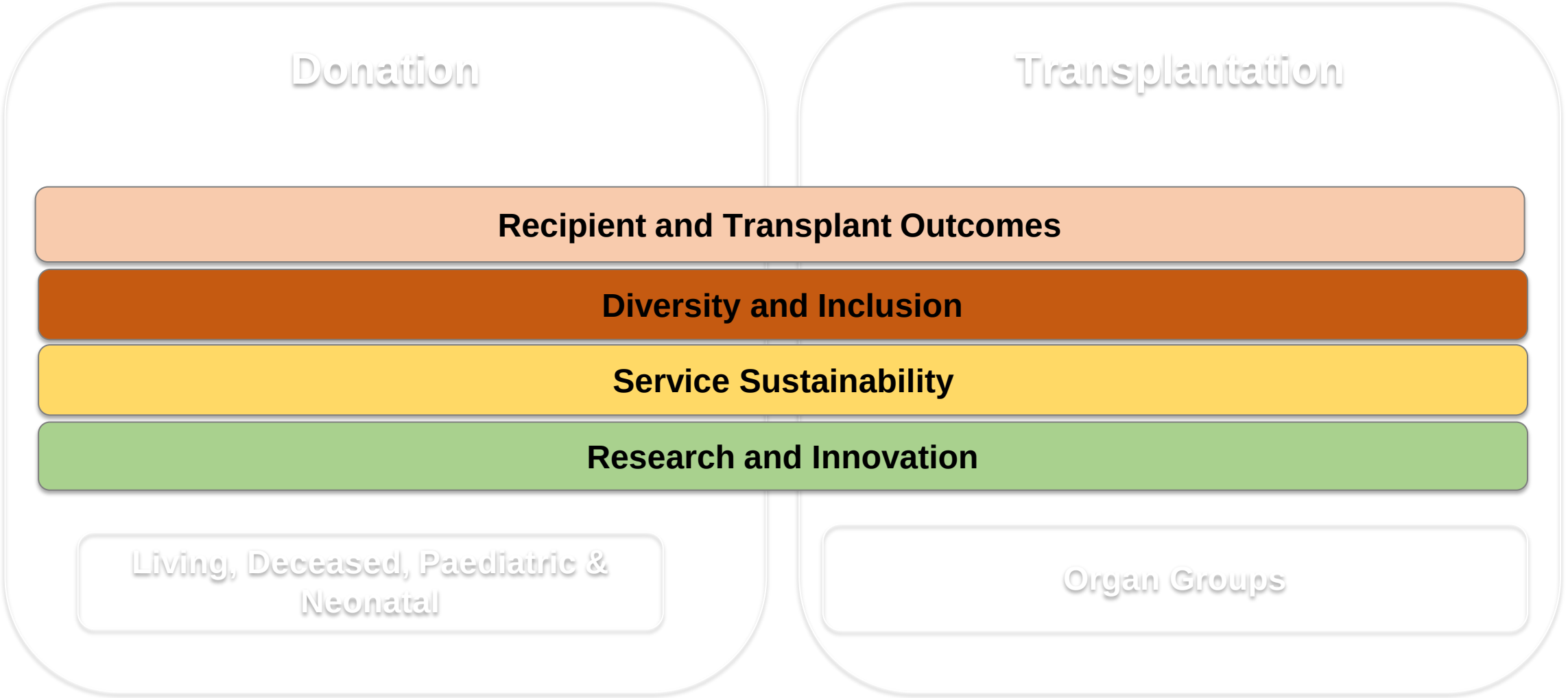
"Living Donation will become an expected part of care, where clinically appropriate, for all in society."

Silver donor pin sent to every living organ donor in recognition of the gift of donation.

Maximising Living Donation

	Action
1.	Maximise **transplant opportunities** in the UK through the **UKLKSS**
2.	Ensure that the option of **'transplant first'** is considered for **all** suitable kidney recipients, especially **pre-emptive transplantation**
3.	Make it **as easy as possible to give or receive** a living donor kidney or lobe of liver by **removing unwarranted barriers** to donation
4.	Promote **public and patient awareness and engagement** in living donation across all sectors of society and **develop the 'Living Transplant Initiative**'
5.	Address **unwarranted variation** in clinical practice by **strengthening leadership** and providing **clear policies and guidelines**
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**
7.	Use **innovative solutions** to offer more recipients the option of a living donor transplant **(e.g. antibody depletion techniques)**

Enabling objectives



Recipient outcomes will be amongst best in world

- More advanced outcome measures, focused on quality of life
- Analyse long-term post-transplant outcomes
- Equity in access to transplantation through refined offering
- Digital-first data collection model
- Enable data sharing

Priorities for the next year

Programme Objectives

Deliver the Deceased Donor Organ Utilisation components of the National Strategy

Enable culture change, knowledge-sharing and capability improvement through engagement and education

Become a more responsive organisation – engaging with transplant professionals to obtain and act on feedback

Provide structure for identification and management of issues within/across multiple organ groups

Support equity of access to deceased and living donor transplantation

Achieve the right balance of focus on donation and transplantation within NHSBT

Develop collaborative working practices between the Organ Donation and Transplantation communities

Place inclusivity and diversity at the heart of the donation and transplantation programmes

Support improvements in sustainability across the pathway

Define and promote improved utilisation of higher quality donor organs

Build a pioneering culture of research and innovation

Every donation and transplant offer a potential research opportunity.

Five initiatives planned:

- Undertake behavioural research
- Sustain essential infrastructure
- Stimulate investment in key areas
- Automate research data capture
- Support emerging clinical developments

SIGNET

Evaluating the benefits of Simvastatin given to organ donors on outcomes in organ recipients.

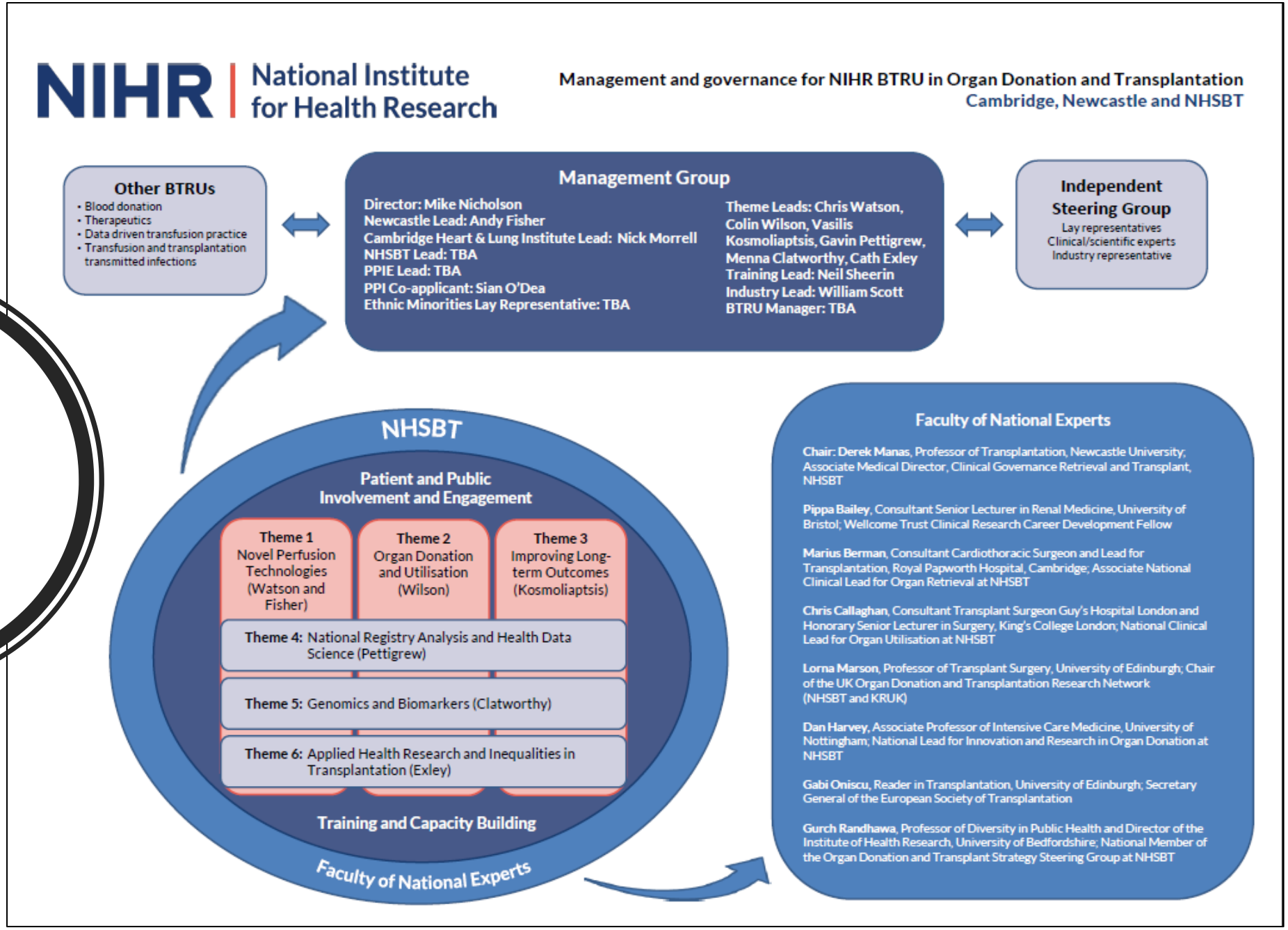
PITHIA

Pre-Implantation trial of Histopathology in renal Allografts.

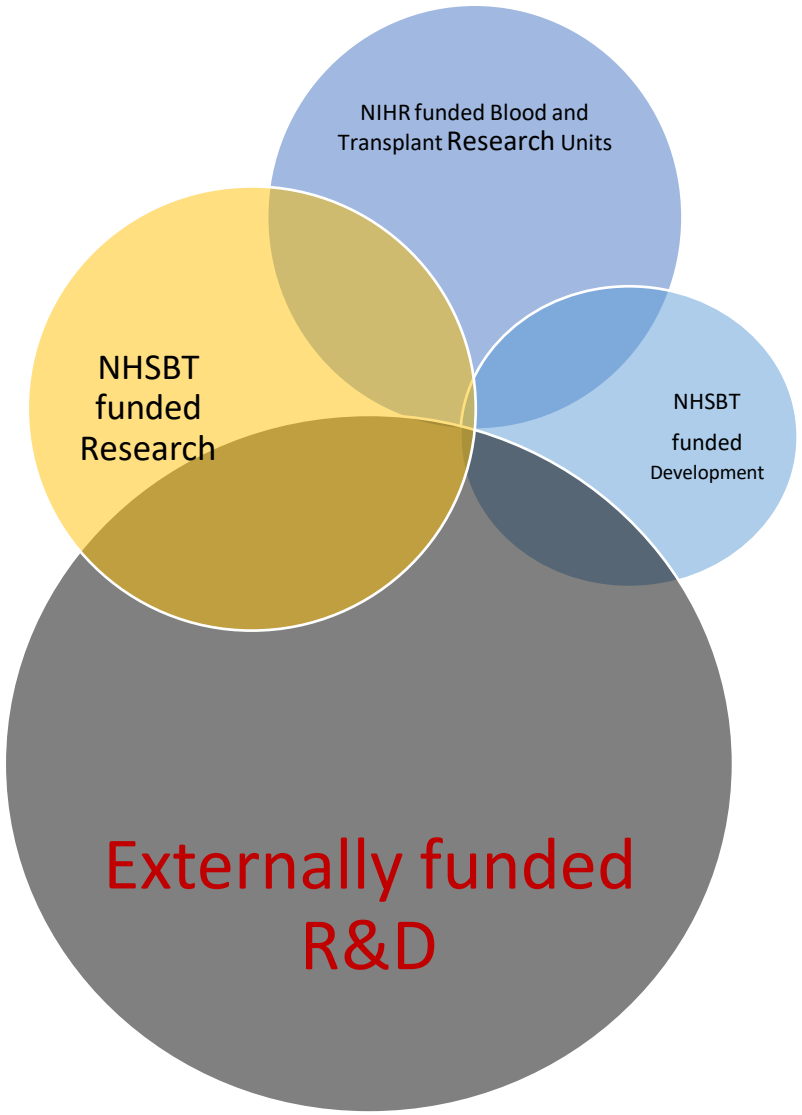
R + D

- TA- NRP
- ‘mOrgan’
- Histopathology Digital plan
- ERAS (liver and Kidney/Pancreas)
- PREMS/PROMS
- DREMS/DROMS
- Type II DCD NRP
- EX-VIVO
- Lung Allocation

OTDT BTRU


NIHR | National Institute for Health Research
Management and governance for NIHR BTRU in Organ Donation and Transplantation
Cambridge, Newcastle and NHSBT
Other BTRUs
• Blood donation
• Therapeutics
• Data driven transfusion practice
• Transfusion and transplantation transmitted infections
Management Group
Director: Mike Nicholson
Newcastle Lead: Andy Fisher
Cambridge Heart & Lung Institute Lead: Nick Morrell
NHSBT Lead: TBA
PPIE Lead: TBA
PPI Co-applicant: Sian O'Dea
Ethnic Minorities Lay Representative: TBA
Theme Leads: Chris Watson, Colin Wilson, Vasilis Kosmoliaptsis, Gavin Pettigrew, Menna Clatworthy, Cath Exley
Training Lead: Neil Sheerin
Industry Lead: William Scott
BTRU Manager: TBA
Independent Steering Group
Lay representatives
Clinical/scientific experts
Industry representative
NHSBT
Patient and Public Involvement and Engagement
Theme 1 Novel Perfusion Technologies (Watson and Fisher)
Theme 2 Organ Donation and Utilisation (Wilson)
Theme 3 Improving Long-term Outcomes (Kosmoliaptsis)
Theme 4: National Registry Analysis and Health Data Science (Pettigrew)
Theme 5: Genomics and Biomarkers (Clatworthy)
Theme 6: Applied Health Research and Inequalities in Transplantation (Exley)
Training and Capacity Building
Faculty of National Experts
Faculty of National Experts
Chair: Derek Manas, Professor of Transplantation, Newcastle University; Associate Medical Director, Clinical Governance Retrieval and Transplant, NHSBT
Pippa Bailey, Consultant Senior Lecturer in Renal Medicine, University of Bristol; Wellcome Trust Clinical Research Career Development Fellow
Marius Berman, Consultant Cardiothoracic Surgeon and Lead for Transplantation, Royal Papworth Hospital, Cambridge; Associate National Clinical Lead for Organ Retrieval at NHSBT
Chris Callaghan, Consultant Transplant Surgeon Guy's Hospital London and Honorary Senior Lecturer in Surgery, King's College London; National Clinical Lead for Organ Utilisation at NHSBT
Lorna Marson, Professor of Transplant Surgery, University of Edinburgh; Chair of the UK Organ Donation and Transplantation Research Network (NHSBT and KRUK)
Dan Harvey, Associate Professor of Intensive Care Medicine, University of Nottingham; National Lead for Innovation and Research in Organ Donation at NHSBT
Gabi Oniscu, Reader in Transplantation, University of Edinburgh; Secretary General of the European Society of Transplantation
Gurch Randhawa, Professor of Diversity in Public Health and Director of the Institute of Health Research, University of Bedfordshire; National Member of the Organ Donation and Transplant Strategy Steering Group at NHSBT

Model for R&D in NHSBT



- NIHR funded BTRUs from April 2022 for 5 years:
  - Blood Donation
  - Data Driven Transfusion Practice
  - Organ Donation and Transplantation
  - Therapeutics
  - Transfusion and Transplantation Transmitted Infections

- NHSBT funded Research –

  Research Infrastructure (eg Clinical Trials Unit), 5 Clinical Research Fellows and current Research programmes (Principal Investigators and their work-packages, mostly funded until March 2022 (some commitments beyond)

- NHSBT funded Development –

  Within operational directorates as BAU, eg Component Development Lab, Tissues Development etc, and projects such as universal platelets & plasma, post-donation testing

- Externally funded R&D –

  Grants secured by NHSBT R&D teams (mostly R rather than D), from funders such as NIHR, Wellcome, Medical Research Council, EU grants, charities etc

Priorities for the next year

Key challenges

- Changing donor characteristics, in the context of opt-out
- Complex and multi-factorial problem
    - Issues vary substantially between organ types
- Many parties have a role in organ utilisation – and NHSBT is not directly responsible for all parts of the care pathway
- Metrics have already been developed to assess utilisation
    - have limitations – and should not be used to create targets
- Many initiatives in train in various silos
    - would benefit from coordination and improved access to resources

Structure of Statistics & Clinical Research

- Part of Clinical Services Directorate
  - Statistics team, Clinical Trials Unit, Research and Development Office and Systematic Review Initiative Team
- **Statistics team** (Bristol - Stoke Gifford, 30 staff) –
  - Supporting Organ and Tissue Donation and Transplantation
  - Organ allocation, multivariate modelling, performance monitoring
  - Clinical Trials work
  - Support for studies in blood, transfusion medicine, stem cells, tissues
  - Forecasting long-term demand for blood

Organ Utilisation Group being established

- Established by the Secretary of State for Health and Social Care
- To be chaired by Professor Steve Powis

The Organ Utilisation Group will:

- Review the organ transplantation infrastructure
- Explore how resources can be best utilised
- Deliver recommendations to reduce barriers to transplantation

OUG

- Commissioning framework
- Minimum standards for each organ
- Trust board engagement
  - Owning and reviewing
- Workforce template for transplant units
- Technology
- Cardiothoracic Units
- Collaboration

Progress to Date

- 6 OUG meetings (first meeting July 2021)
- 2 OUG Forum meetings
- 2 workshops
- Online call for evidence
- Site visits
- International meetings
- Stakeholder engagement (patients, clinicians, social workers, H&I etc)
- Patient focus groups
- Patient survey
- Meetings with senior DHSC officials and UK Health Departments

Patient Engagement – Focus Groups

General feedback

- General happiness with initial care (dialysis; Cystic Fibrosis services)
- Disjointed service, with patients getting lost in the system and medical records not being shared effectively, which compromise patient care/ safety
- Lack of psychological support for patients and their families, which had a strong adverse impact on their experience, relationships and well-being
- Disparity in the level of care offered between different centres
- Poor communication, meaning some patients were concerned and confused
- Inconsistency in advice received
- Many patients explained how they had to fight to get the care they need

They were on my side. They want you to survive and will do everything in their power to help you

They never look at a patient as a whole.

The team became like an extended family.

You rely on peers to support you, as you don't want to trouble the nurses.

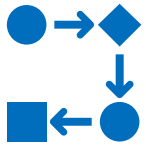
I felt lonely and saw no-one and had no support. I felt forgotten.

Summary of feedback – Challenges

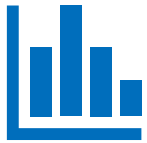
Managing and reducing staff fatigue and increasing recruitment and retention

The psychological and social support of patients

Access to theatres and beds in wards and intensive care units



Length of the donation, offering and allocation processes



Data access of digital data and imaging

Key themes for consideration

1. Equity of access (lifestyle prejudice & geography)
2. Workforce
3. Streamline commissioning process
4. Psycho-social support
5. KPIs for standardisation and monitoring against them

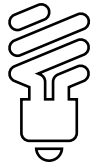
Themes

Patient centred focus, involvement, choice, information and education along the whole care pathway, PROMs, PREMs

An operational infrastructure that maximises transplant potential (a) standardised pathways; (b) Sustainability of the service

Workforce sustainability, resilience and training to meet current and future needs

Improved access to data, to inform patient and clinical decision making and resource allocation and drives improvements



Driving and supporting the use of innovation and novel technologies, such as machine perfusion

Delivering improvements through new strategic and commissioning frameworks (a) Strategic direction & oversight; (b) Commissioning

Message from Maria Caulfield

“We are approaching the second anniversary of Max and Keira’s Law, which introduced opt out as the legal basis for consent for donation. As we see consent rates increasing, it is important that we make the best use of every donated organ, with all patients on the waiting list across the country being given the same opportunities for a life-saving transplant.

We need to build on the collaboration developed across transplant communities throughout the pandemic. We also need to build on the progress we have made with innovations such as machine perfusion.

I am grateful to the Organ Utilisation Group for leading the way with this important work. I look

forward to seeing the recommendations and working with all those across the NHS to deliver improvements, which will place the UK back as a world-leader in this life-saving treatment, keeping the quality of patient care and the need for equity at the core of everything we do.”

Maria Caulfield, Parliamentary Under Secretary of State (Minister for Patient Safety and Primary Care)

Next Steps

1. Further site visits
2. Meeting with Minister and senior DHSC officials
3. Socialise recommendations with key stakeholders
4. Further meeting of OUG and Stakeholder Forum
5. Publish with Ministerial foreword

Publication date TBC – Likely to be May/ June (delay due to challenges with getting time in Minister's diary.)

How does this help LD?

- Its not all about numbers
- Its also about perhaps -
  - Exploring boundaries – change utilization
  - Having better information transfer
  - Improving recipient outcomes
  - Improving donor experiences
  - Open more Options – patients
  - Give more patient choice
  - Sustain the workforce - clinicians, teams working more collaboratively
  - Developing International collaborations