

Tissue Donation

1. Service Update

Having successfully transitioned all services to the Jack Copland Centre (JCC), SNBTS Tissue, Cells and Advanced Therapeutics (TCAT) continues to progress the work required to validate tissue processing in the new premises. While this work is ongoing, tendon and skin retrieval remain temporarily suspended; hearts for potentially life-saving heart valve retrieval continues with all hearts being temporarily sent down to NHSBT, Liverpool for processing.

TCAT continues to progress tissue processing validation with tendon retrieval expected to be re-instated in January 2019 and heart valve processing in April 2019, all things being equal.

In the meantime SNBTS Tissue Donor Co-ordinators and the Consultant for TCAT continue to provide teaching and to raise awareness about the potential of tissue donation in the various donating hospitals.

2. Deceased Tissue Donation

Current tissue donor numbers are impacted by the fact that tendon/skin retrieval is at the present time paused and are as a result not a true reflection of the potential donor numbers. In the first eight months (up to 26th November 2018) of this financial year 16 multi-organ donors and 7 tissue-only donors donated hearts for valves.

3. Pancreatic Islet Programme

The pancreatic islet programme continues to provide a potentially life-saving service to Scottish patients. In the first 8 months (up to 26th November 2018) of this financial year, 16 pancreata were processed, of which 9 (56%) yielded a successful transplantable product, leading to a transplant on 5 occasions.

Dr Sharon Zahra

Clinical Lead, TCAT, SNBTS

NHS Blood and Transplant Update

1. Change in Chief Executive

Betsy Bassis has been appointed as the new Chief Executive of NHSBT. She has been working as the Chief Operating Officer at Defra for the past four years and has managed wide-ranging and complex transformation programmes, including large scale IT programmes. Prior to joining Defra, Betsy spent twelve years at Centrica/British Gas. It is likely that she will take up her post on 4 March 2019 and Sally Johnson will continue in the role of Interim Chief Executive until then.

2. UK Paediatric and Neonatal Strategic Plan

The Board approved the UK Paediatric and Neonatal Strategic Plan. The Plan was designed to supplement the Taking Organ Transplantation to 2020 Strategy and was developed following extensive consultation with stakeholders to understand current practice and to learn how NHSBT and the NHS partners could better support donors and their families. The potential for additional transplants from the strategy was estimated at around 90 extra transplants per annum although it was noted that some paediatric organs would be offered to adults.

3. Increase in National Organ Retrieval Service (NORS) team capacity

An evaluation of NORS capacity in light of increased activity and intensity of working has been undertaken. After modelling and consultation a number of recommendations have been made which include increasing the number of abdominal teams on call to eight, improving the monitoring of intensity of retrieval activity and changing deployment of the retrieval teams to alleviate pressure on the busier teams whilst increasing activity for the quieter teams. The Board has approved these recommendations including the funding of the eighth team and further work will now take place to implement the preferred option.

4. NHS Organ Donor Register (ODR) Governance Update

The NHSBT Governance and Audit Committee (GAC) received the annual ODR Governance report. The key findings of this report are:

- For the first time since the launch of the 2015 ODR, all registration data feeds are now active and up to date.
- The significant improvements in governance have been independently supported in the outcomes of a recent internal PwC audit.
- There are a number of ongoing system and process issues which are being resolved – and there is clear progress being made to ensure the ODR strives towards being an exemplar quality management system.

5. Organ Donor Register integration with the NHS App

NHSBT and NHS Digital have been working under the direction of the Department of Health & Social Care to ensure the ODR can be accessed via the NHS App when it is launched in December. There will be a feature to allow users to register a decision on the ODR and a question asking whether a registrant's faith is a consideration in donation has been included in the App design and added to the ODR website. Additional functionality will be made available from April 2019 allowing users of the App to recall and update their details on the ODR in real time.

Due to the limited timeframe available to deliver this work, NHSBT have had to divert resource from some of the planned transformation activities for 2018/19 and reschedule it to 2019/20, which includes the digitisation of HTA A forms.

Keith Rigg
Non-Executive Director
NHSBT

Human Tissue Authority

Human Tissue Authority (HTA) Transplant Advisory Group

The HTA's Transplant Advisory Group meets twice yearly. The last meeting was on 4 October 2018.

Living donation

The HTA has been working on a project that aims to tackle the sustainability of the Independent Assessor (IA) framework and the reaccreditation process. This includes a review of the current governance framework that defines the responsibilities and accountability of IAs. Furthermore, we will be introducing some changes to make the system more robust, so that it is sustainable in the long-term and resilient to changes within the sector. We are exploring the opportunities in themes:

- **Recruitment** - To increase the visibility of the role, we have created a leaflet, which will provide information to those that are interested in the role. This leaflet will be published on the HTA website and circulated to all IAs and Living Donor Coordinators (LDCs) via email.
- **Reaccreditation** - The current IA reaccreditation system has been in place for several years. The team have developed a new continuous accreditation system, where quality checks will be carried out throughout the year. The new reaccreditation system will be launched in the next business year and the HTA will ensure that all IAs are informed of this change. We will be holding a series of webinars in Jan-Feb 2019. We will be circulating an email with all of the appropriate information, and this will be available on the portal for future reference.
- **Training** - The Living Donation Assessment Team (LDAT) is developing two mandatory training programmes (GDPR and Equality and Diversity training) to assist IAs in carrying out their roles effectively. We are also developing a non-mandatory training presentation about the IA role, case categories and new case studies; which can be undertaken by IAs if they wish to refresh their knowledge. All training material will be available on the HTA portal in 2019.
- **Governance arrangements** – The IA survey in 2017 highlighted that there is variability in practice across the UK in terms of governance arrangements for the IA role in terms of agreements/contracts with Trusts or Health Boards.

In order to standardise practice from an HTA perspective, the HTA are proposing a code of conduct; this will be signed by all IAs. This will clearly set out our respective roles and outline the HTA's expectations with respect to: IA behaviours, reaccreditation, training, communication, assessments and report writing. The code of conduct will also outline the HTA's responsibilities towards the IAs, including regular communication, training, and up-to-date guidance.

Deceased donation

Opt-out in England

- We are liaising with the Department of Health and Social Care in England and NHSBT in relation to producing a Code of Practice. The Bill is currently going through House of Lords and is in report stage.
- Amendments will need to be made to all of the HTA's Codes of Practice, including the Code of Practice on the Human Transplantation (Wales) Act 2013, to reflect the amends to the Human Tissue Act (2004) – substantive changes will be made to Code of Practice A: Guiding principles and the fundamental principle of consent, and Code of Practice F: Donation of solid organs and tissue for transplantation.
- Both the role of the family and faith considerations will be key areas to develop. HTA will be holding a multi-faith survey and roundtable meeting with representatives of faith groups to inform our guidance on the role of family and other considerations to professionals when consent is deemed.
- A consultation aimed primarily at professionals that will be using the Code will be held in Spring next year before it is finalised.

HTA licensing of tissue retrieval

- This piece of work specifically relates to the requirements that need to be fulfilled when National Organ Retrieval Services teams are retrieving organs or tissues which are subsequently applied for human application.
- The HTA continues to work closely with NHSBT on the requirements for when a licence is required under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.
- The area that remains most challenging is around donor selection criteria for islets vs solid organs. We (with NHSBT) are in the process of establishing whether it would be feasible to establish an aligned donor selection criteria that meets the requirements of both organs and tissues legislation. This was discussed with members of the Islet Steering Committee at the start of October. It was agreed that through this committee, representatives of the islet clinical community would be best placed to determine the form these criteria should take.

Ex Vivo Organ Perfusion

- Ex-vivo organ perfusion devices are increasingly being used in the UK. We have been carrying out a horizon scanning exercise to consider ways in which we can target our regulatory approach in relation to current and future perfusion devices, on the basis of risk to both public safety and to public confidence.

- To date, we have carried out a review of relevant legislation and the HTA Framework Document, held stakeholder engagement meetings, given a presentation at the June Competent Authority meeting and collated information from Regulation Managers, ODT audit reports and Serious Adverse Event and Reaction reports. We have consulted with key stakeholders working in the field and other regulatory bodies.
- We anticipate that the recommendations arising from this work will include an amendment to the Framework Document, additional stakeholder guidance, a more standardised approach to scrutiny through our audit approach, collection of data on ex-vivo perfusion via our next compliance update and strengthened information sharing with other regulatory bodies such as the Health Research Authority and the Medicines and Healthcare products Regulatory Agency.

Dr Hazel Lofty

Director of Regulatory Development
Human Tissue Authority

Living Donation Scotland Project



Network meeting outcomes:

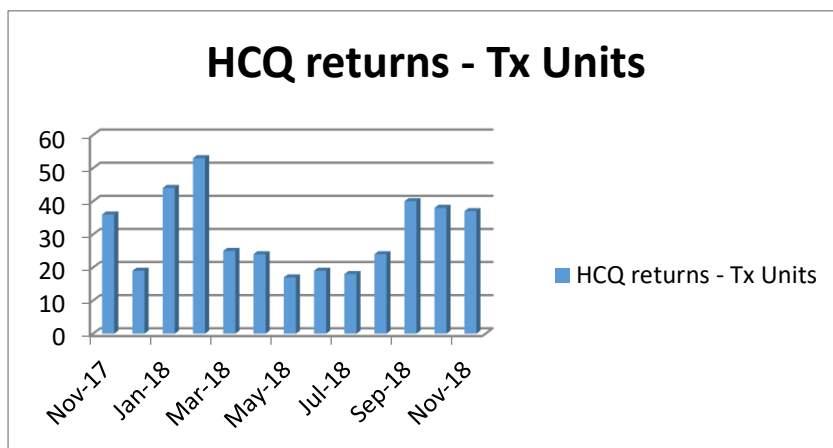
Timely Transplantation: Presentation at Scottish Renal Association meeting of data on transplant decision and living donation discussion for patients approaching end stage renal failure. Agreement to further discuss with Scottish Renal Registry on national data collection at link nephrology meeting on 7th Dec 2018.

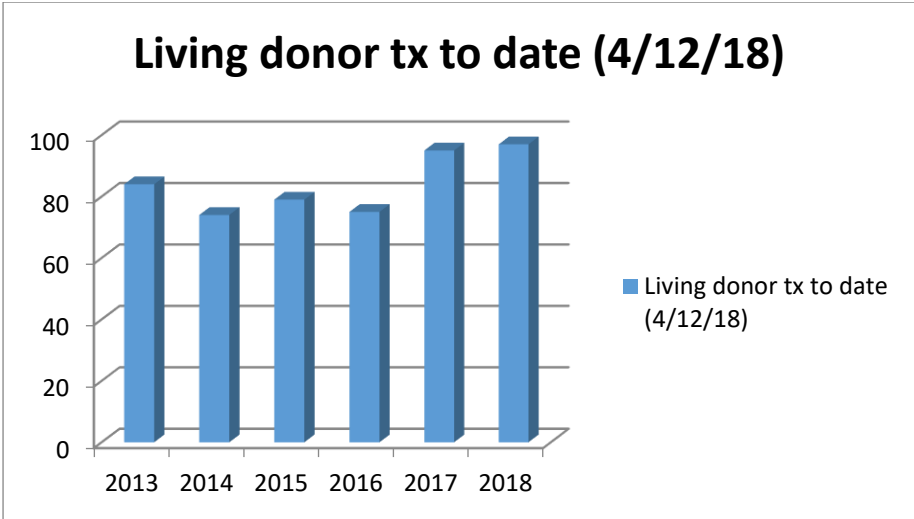
Home Education: Renal Education and Choices @ Home (REACH) pilot project underway and patient visits commenced.

Living kidney donation guide for healthcare professionals in Scotland: First draft complete for handbook for GPs, nephrologists, nurses and allied healthcare professionals in Scotland describing donor and recipient pathway; clinical information and individual unit information.

Awareness

- Social media animation released:
- <https://www.organdonationscotland.org/tell-me-about-living-donation>
- Meeting with BAME peer educators and Mosque information sessions
- Continued media and public awareness – collaboration with Torness Power Station
- Initial discussion with BBC to explore news item on kidney sharing scheme
- Meeting with Give a Kidney Scotland planning the 10th anniversary publicity drive





Living donor kidney transplants in Scotland to date 4/12/18. A further 9 transplants scheduled for Dec 18.