Dear Lorna

As requested, please find below responses to the Committee’s questions following the second oral evidence session on the Human Tissue (Authorisation) (Scotland) Bill (the Committee’s questions are in bold):

1. Once the families have authorised donation, there appears to be 24 hours or in some cases 36 hours delay between the decision taken and the actual transplant taking place. Please can you advise on the reason for this delay?

NHS Blood and Transplant (NHSBT) has outlined the steps which form the process, below, and provided a detailed breakdown of the process, attached at annex A.

1. Donor referral
2. Donor Characterisation (a comprehensive review of the clinical and lifestyle history of the donor that can be accessed in this time critical setting – needed for recipient safety)
3. Organ Matching, Offering and Allocation (an important aspect for fairness across the UK)
4. Retrieval team mobilisation and travel to donor hospital
5. Retrieval operation (this is a difficult operation, the organs need to be removed safely, it takes 4 hours minimum, often more than 6)
6. Transport of organs to centre where the designated recipient has been prepared
7. Final Checks on the organ and the recipient
8. Transplant

2. Members also had the following questions regarding infrastructure and resources allocated to organ donation in Scotland:

For bullets 2 to 4 below, as requested we have provided a response regarding transplantation within Scotland, and not retrieval operations. Given the UK-wide nature of
transplantation, most specialist forms of transplant for patients resident in Scotland are carried out in Transplant Units in other parts of the UK.

The three transplant units in Scotland have provided the following information:

- **How many transplant surgeons are currently working in Scotland?**

  **Edinburgh Transplant Unit** - currently has 11 permanent consultant staff undertaking transplants, although all of those surgeons also undertake other work apart from transplantation so are not full time (3 are also University of Edinburgh staff and therefore spend part of their time engaged in work for the University).

  **Glasgow (West of Scotland) Transplant Unit** - 7 surgeons make sessional contributions to the transplant service, but all have extensive non-transplant commitments so none of these surgeons works full-time on transplantation.

  **Golden Jubilee Transplant Unit (GJNH)** – has 3 transplant surgeons and 1 locum.

- **What type of transplant operations will they undertake e.g. heart and lung or pancreas and kidney?**

  **Edinburgh Transplant Unit** – adult kidney (living and deceased donors), adult liver (primarily deceased donors, but occasionally living donors), adult simultaneous kidney and pancreas, pancreas and pancreatic islet transplants.

  **Glasgow Transplant Unit** – adult and paediatric kidney transplants (deceased and living donors).

  **Golden Jubilee Transplant Unit** – adult heart transplants.

- **Are you able to offer any insights into the time of day that these operations take place?**

  **Edinburgh Transplant Unit** – The Unit has indicated that the following proportions of their total transplants in 2017/18 (note – this includes living donor kidney transplants as well as deceased donor transplants) were carried out partly or fully out of hours (out of hours is anything outside 08.00 to 18.00 Monday to Friday):
  - 61 to 65% of transplants started out of hours (variations are dependent on the type of transplant)
  - 67 to 75% of transplants finished out of hours
  - 45 to 56% of transplants were entirely out of hours
  - 76 to 92% of transplants were at least partly undertaken out of hours

  **Glasgow Transplant Unit** – The Unit has indicated that approximately 70% of their transplants are from deceased donors and 30% from living donors. Over 80% of the deceased donor transplants are done at least in part at night. A significant proportion of the living donors now also extend into the night as the kidneys are transported from all over the UK as part of the UK national kidney sharing scheme. Overall approximately 60% of all kidney transplants cross into night hours in the Unit.
Golden Jubilee Transplant Unit – The Unit has indicated that regardless of when the transplantation happens, the offer precedes the operation by several hours (the heart is the first organ in offering sequence). They mobilise the heart recipient to theatre at the same time the deceased donor moves from the Intensive Care Unit to theatre in the donor’s hospital to ensure minimal delay to the retrieval process and minimise ischaemic times (i.e. when the heart is out of the body and not receiving a blood supply or oxygen and so it will deteriorate too much if the transplant does not begin within a few hours). This invariably means spending 24 hours on the case – in others words at least part of the process occurs out of hours, even if it is not the transplant itself.

The proportion of actual heart transplants carried out at night varies, but the Unit has indicated that the proportion of transplants carried out during the night over recent years is as follows:
- 2018 (so far) – 20% at night
- 2017 - 73% at night
- 2016 - 67% at night
- 2015 - 57% at night

- **Is a surgeon required to complete a certain number of transplants per year to maintain competency level?**

The British Transplantation Society has provided the following information:

A surgeon is not required to complete a certain number of transplants per year. As with all medical professionals, we undergo annual appraisal and our operative numbers are reviewed at this. In addition, as a unit, we undertake regular discussions of morbidity and mortality of transplant patients, and surgical issues are discussed in full. This is also included in the information at our annual appraisal.

Transplantation is unique as a surgical specialty; it commonly involves several consultants working together, and a different team of surgeons retrieve and transplant the organs. The outcomes of each unit are scrutinised closely through national data collection by Organ Donation and Transplantation, and, if rates of complications increase within a unit, this is flagged to the unit and triggers a review of those cases.

I hope you find the responses provided helpful.

Yours sincerely,

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Organ Donation, Organ Retrieval and Organ Transplant Pathway

Executive Summary

Organ Donation and Transplantation from deceased donors is a challenging area of clinical practice and the inherent risks associated with rapidly characterising donor organs, recovering and transplanting them are well known. Very few pathways in the NHS are so complex and involve so many stakeholders.

Donor and transplant numbers have risen greatly in the last 10 years which is a great source of pride for everyone involved and most importantly represents many more lives saved by the gift of donation.

NHSBT’s Organ Donation and Transplantation Directorate (ODT), is responsible for directly managing some elements of the overall clinical pathway: it commissions but does not manage the National Organ Retrieval services and influences but is not responsible for the transplant service, other than monitoring outcomes. The pathway is a complex system involving many organisations throughout the UK and is reliant on the commitment of many to ensure we continue to increase transplant numbers in the United Kingdom (UK).

The length of time taken from patient referral by the ICU Clinician to the commencement of the organ retrieval operation has increased in the last few years. The reason for the increased time frame is multifactorial: increasing age of organ donors, with an increased referral of more marginal donors requiring a detailed and thorough patient assessment which can take longer.

The donation pathway is reflected in Figure 1 below:
There are 3 key elements to the pathway:

**Donation Referral and Characterisation**

Early referral by the Intensive Care Unit (ICU) team to the Specialist Nurse Organ Donation (SNOD) is always advocated as the pathway can commence and the donor be facilitated within a timely manner. Once the SNOD is informed of the potential donor they can mobilise to the ICU if they are not present and begin the process of donation. Of course early referral makes it appear that the pathway to transplant takes longer while it simply reflects planning of a complex procedure.

The SNOD will review the medical and nursing notes in detail prior to meeting with the family to discuss consent/authorisation. They will also talk with key medical staff and ensure that there is a clear medical plan in place prior to talking with the family. The planning conversation is vitally important with all those involved so that the concept of organ donation is only broached after a family understand Brain Stem Death (BSD) or understand and accept that treatment withdrawal is planned.

The formal process of approaching the family and formal consent/authorisation only takes places when a family have a clear understanding that death has occurred or is imminent. Once the family have been approached and consent/authorisation has taken place then the donation pathway begins. This can take varying levels of time: every family is different. Ultimately, some SNODs may be required to spend a lengthy period of times with families to aid understanding. Each family and each situation are unique.

Donor characterisation is the most crucial element of the pathway that takes place once consent/authorisation is confirmed. It must be carried out meticulously to ensure that all information in relation to the patient has been assessed and documented and expert advice sought when needed. This attention to every detail ensures we continue to keep transplants safe.
The SNOD will review thoroughly:

- The patients’ medical and nursing notes and document the patient’s full medical history. This is often made more cumbersome if the nurse does not have direct access to the Hospitals electronic systems e.g. they will be reliant on the assistance of the resident staff to navigate the hospital records or may have to spend time getting a locum password to access the patients’ medical records.

- Locate any medical records in other hospitals where the patient may have had previous medical treatment and ensure these are also reviewed.

- Contact the patients GP to ensure that there are no known contraindications to donation.

- Conduct a full and detailed interview with the next of kin to ensure that the Medical and Social History paperwork is completed. This is a very detailed questionnaire that asks details on the patients medical, social, behavioural a travel history. Many of the questions are of a sensitive nature and often take time.

- Contact any other Allied Health Care Professionals that may have known the patient e.g. Community Psychiatric nurses, District nurses etc.

- Conduct a detailed top to toe patient assessment checking for any scars, abrasions, lumps or anything that may be of relevance to the safety of the potential transplant patients.

- Bloods are taken and despatched to support donation (bloods for microbiology and bloods for tissue typing). These bloods are the transported to the laboratory that complete HLA typing and microbiology. Often the travel times for the bloods can take up to 3 hours for them to reach the laboratory before testing can commence. HLA typing takes approximately 3-4 hours per patient whilst microbiology screening takes up to 60 minutes per patient. Organ offering in most cases (lung, kidney and pancreas) cannot occur until the HLA type has been reported.

- Ensure that routine bloods from the day of donation have been taken the results fully documented.

- Ensure that the historic bloods are available and documented to inform clinical decision making at transplant centres.

- Assess the patients travel history and ensure any supplementary bloods required are taken and sent to the laboratory e.g. bloods for malaria and T Cruz if the patient has travelled to areas that mandate testing.

- For donors who are suitable for cardiothoracic organ donation- arrange for an ECHO and an ECG to be performed.

- All cardiothoracic donors must have regular blood gases taken on varying levels of oxygen which must be available once the organs are offered to transplant units.

- A chest x ray must also be available to transplant centres.

- Any tests or investigations that the patient have had during their admission to hospital as part of their care must also be documented and communicated to transplant centres.

- There is a commitment to provide the highest number of donor organs in the best possible condition through optimisation of the physiology (blood pressure, urine output, oxygen saturation etc. To do otherwise might be regarded as a betrayal of the trust that a donor and
their family place in the healthcare professionals who propose donation as a component of end of life care.

- Document all clinical findings on NHSBTs electronic offering system (EOS) so that the transplant centres have the full information available to them to enable informed clinical decision making.

Some patients will have detailed complex medical, social, behavioural history and this assessment can often take several hours to complete thoroughly. The SNODs will also seek expert medical advice should they be concerned about any patient findings.

It is only when the full information as listed above is documented on EOS and the HLA and microbiology results are available that the patient can be registered with ODT HUB Operations and organ offering can commence. The pathway described above is similar irrespective of donor type: Donation after Brain Stem Death (BSD) OR Donation after Circulatory Death (DCD)

Organ Allocation and Offering

The next part of the pathway is organ allocation and organ offering which is performed by ODT Hub Operations (formally called the Duty Office) which operates a 24-hours-a-day, 365-days-a-year service. The role of ODT Hub Operations is varied and includes a range of responsibilities

- Receiving and recording information on potential and actual donors
- Matching and allocating organs in accordance with the national sharing schemes. Each organ group has its own specific allocation scheme. In the main, super urgent patients get organ offers first, followed by urgent patients in the UK. If the organ has not been accepted, then it will be offered via the elective transplant waiting list
- The allocation schemes are complex and must be adhered to ensure fairness and equity for all patients in the UK.
- Organ offering can take several hours particularly when the patient is a multi-organ donor or during periods of high activity nationally
- Strict adherence to the 45-minute organ offering time is maintained
- Once organs have been accepted mobilisation of the National Organ Retrieval Service commences. This takes time to coordinate transport/book and arrange flights if needed

Organ Retrieval and NORS Mobilisation

Organ retrieval is a challenging surgical procedure, and throughout the UK 7 Abdominal Retrieval NORS Teams and 3 Cardio-thoracic NORS Retrieval Teams are available 24-hours-a-day, 365-days-a-year.

- Once a donor has been registered by the ODT HUB staff and organs accepted then NORS mobilisation begins. If the patient is a multi-organ donor then both the CT NORS team and the Abdominal NORS team will be mobilised.
- A suitable, convenient time is arranged by the SNOD at the donor hospital. This will often be determined by the availability of theatres, availability of an anesthetist at the donor hospital. Moreover, it will often be determined by the activity of the acute team at the donor hospital.
• Once a time to commence the organ retrieval or a time to withdraw life-sustaining treatment has been agreed then the closest, available NORS teams will be mobilised when possible.

• NORS teams usually travel up to 3 hours from their own hospital base. Once the team arrive it can take up to 45 minutes for the team to set-up in the theatre suite and not least review the patients notes and conduct the surgical safety checklist with all involved.

• It is only when it is safe to do so, determined by the Lead Surgeon that the operation begins

• For DCD cases, once death is certified and the stand-off time has passed the operation will begin.

• The procedure consists firstly in assessing the suitability of the organs and excluding the presence of major contraindications to donation that could pose a risk to the potential recipients.

• The retrieval operation is very challenging because of the physiological anatomical variations and/or pre-existing conditions of the donor. Both the cardiothoracic and abdominal NORS teams cooperate, alternate or work simultaneously at the operating table.

• Retrieving the organs requires a highly skilled lead surgeon who is competent, accredited and capable of identifying and respecting the complexity of the donor’s anatomy.

• Once removed, the organs are again assessed individually, and the quality of the organ is relayed to the transplanting team.

• They are then packed as per protocol and transported to the accepting transplant units.

**Transplant Centre**

The donated organ then must travel to the transplant centre where the new recipient has been prepared. Since the matching systems are run across the UK, the designated centre may be close to the donor hospital or at the other end of the country.

Final checks must be made for safety of the recipient and then the transplant procedure can be begun.

Once the surgeon has done the preparatory work that may involve removing the diseased organ (in some types of transplant eg heart, liver), the donated organ is removed from storage and can be connected to the circulation of the recipient.