**INOAR Report for RINTAG October 2018**

**Previously…..**

1. A RINTAG Sub-Group (**I**ncreasing the **N**umber of **O**rgans **A**vailable for **R**esearch – INOAR) was established to make recommendations on what more could be done to address the gap between the availability of and demand for organs for research purposes. The aim is two-fold:

1.To ensure that as many organs as possible are used for research.

2. To ensure that a donor's/ family's wish to donate for research purposes where transplant is not an option is honoured wherever possible.

3. INOAR recommended an extension to the Liverpool Research HTA Licence (12068) to permit the removal of whole organs for research purposes. This is the licence currently used for QUOD and will mean that all 41 hospitals currently covered by QUOD will no longer need additional local licencing arrangements for the removal of whole organs for research purposes.

4. Activity will be limited under the new licence procedure to only remove organs/ tissue that NORS teams are trained and competent to remove. Any other tissues and organs would need to be considered on a case by case basis through RINTAG/ ODT Senior Management Team in line with existing processes and may still need to be removed under local licence arrangements.

**Update**

1. The proposal was supported at RINTAG in 2017 and spring 2018
2. The proposal was fully supported at the Change Portfolio Board (CPB) in late October 2017
3. The proposal was supported in Principle at SMT (Senior Management Team) in November 2017
4. It became apparent after the last RINTAG meeting that the biggest shortfall in organs for research was for hearts and lungs.
5. In parallel with the work in INOAR, the QUOD-EXPAND application to the MRC was successful. This project involves collecting the diabetic pancreas, hearts and lungs for a cell atlas, based in Newcastle, but available, like all QUOD samples, to a broad range of investigators

The next steps involved:

**Traceability:**

1. a paper research HTA A from has been developed, which supplies all the information required by NHSBT for NTxD, and for the HTA. It provides some key donor details, but many of these will need the researcher to access EOS Mobile – a system already in place
2. Information Services are happy to handle the paper Research HTA A form, but not in large numbers

3. The forthcoming (2019) Electronic HTA A form will have a research section, and automated data collection, removing any restrictions on what Information Services can handle
4. Retrieval will always be undertaken by a certified NORS team, who are full cognisant of the various regulatory frameworks and trained and competent to remove organs for research.

**Hub offering of organs for research:**

1. There is a robust process in place at present, but given the pressures on the Hub from recent changes in allocation, there was concern that a large increase in research, rather than transplant, activity might lead to difficulties

**Consent for Research:**

1. This development will markedly simplify the consent process for the SNOD on the ground. Families will be able to consent to the removal of organs for the purpose of research, which is clearly of benefit if transplantation is not going ahead. This will reduce the number of studies through which specific consent for research is required.
2. In parallel with changes to the consent process for Tissues, a series of meetings were held to modify the donation consent paperwork. The new arrangements for gaining consent for removal of organs for research, if not suitable for transplant, have been incorporated in this process
3. SNOD training with the new form has not yet been rolled out

**Retrieval Pathway**:

1. Removal of an Organ for research has to be performed by a fully trained and accredited NORS surgeon.
    a. We do not anticipate a significant increase in workload for retrieval teams (See Predictions of Activity, below) Removal of a pancreas for research or banking, in addition to the retrieval of other abdominal organs, is a small amount of work. Similarly, there is some additional time for retrieval of a heart or lung by a CT NORS retrieval team who were already present. There are special circumstances - the need for the team to be doing back to back retrievals, or to take a removed heart straight back to the centre - when clinical priorities will always take precedence.
    b. Guidance for NORS on expectations of removal of organs for research will be agreed in conjunction with NHSBT commissioning and the National Retrieval Group.

**Continuation of Specific Consent**

1. A major advantage of the INOAR process was that Specific Consent for organs for research might not be needed any more. This was seen as a real bonus for SNOD teams.
2. However, INOAR only extends to “QUOD Donor Hospitals”. For studies, particularly in perfusion, where the research team needs to be involved in the retrieval, this might have significant impact on research activity
3. Some small-scale studies, such as the olfactory bulb retrievals, would not be covered by INOAR, and would continue to need specific consent

4. After a series of meetings, it was agreed that small-scale, local use of the specific consent route for research studies would be vetted by a subgroup including the Chair of RINTAG, the ODT Medical Director and key members of the NHSBT Research team, but with this arrangement in place, they would be allowed to continue

**SMT May 2018**

Because of concerns about overloading various systems, a detailed proposal for INOAR was put to the SMT in May 2018, suggesting that initially the INOAR process extend to Hearts, Lungs and the Pancreas in the Diabetic Donor. An additional advantage is that utilisation is worse for the thoracic organs, compared with abdominal, but the perfusion technologies have a considerable potential. These can only be developed in the UK if there is access to donor organs turned down for transplant

This proposal was accepted by SMT

**Current Situation**

After a lot of hard work by members of the NHSBT Research Team, with input from a range of individuals, most of the steps described above have been completed.

It had been planned to have everything arranged for roll-out at the beginning of December

The final process is in training of the SNOD teams, and this is yet to begin. As a result, the planned roll-out date is December 5. Whilst this is an aspiration, in reality, this may drift to the early New Year

John Dark
Co-Chair, INOAR, September 2018