NHS Blood and Transplant

RINTAG
11th May 2018

INOAR Report

1. Status – Public

2. Background

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 was two-fold:

- To ensure that as many organs as possible are used for research
- To ensure that a donor's/ family's wish to donate for research purposes where transplant is not an option is honoured wherever possible

At an early stage, it was appreciated that in order to fulfil these aims, we would need to navigate the regulatory framework.

It was noted that where organs were removed for the purposes of transplant and subsequently declined, and were offered for research through the Generic Consent route, directing these organs to recognised research studies was relatively straightforward.

The key difficulty is where the organ is turned down for transplant either unseen or before removal. This category includes most heart and lungs and also abdominal organs with contra indications to transplant. A prime example here is the diabetic pancreas.

In order for these organs to be removed from deceased organ donors, the premises need to be HTA licensed in England, Wales and Northern Ireland and Specialist Nurses Organ Donation need to obtain specific consent.

An early solution from INOAR was to recommend 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 listed as satellite premises on this licence, will no longer need additional local licencing arrangements for the removal of whole organs for research purposes.

As a logical extension to those licensing arrangements which had permitted QUOD in the first place, Ian Bateman, the relevant DI for the Liverpool Research HTA Licence, agreed to this change in principle, as long as there were appropriate Governance

and traceability structures in place.

Activity will be limited under the new licence procedure to only remove organs/ tissue that NORS teams are currently 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.

Practical Implications:

1. This development will markedly simplify the consent process. Families will be able to consent to the removal of organs for the purpose of research, this will reduce the number of studies through which specific consent for research is required.

2. Abdominal organs intended for transplantation are removed for examination in accordance with the always explant policy. As a consequence, a greater proportion of abdominal organs are available for research compared to cardiothoracic, and can be used for research if generic consent is in place.

3. Some organs will not be removed for transplantation as they are either contra -indicated, offered and declined by all centres prior to retrieval, or declined on inspection, for example the diabetic pancreas, heart and lungs.

4. This proposal will simplify the process of retrieval of organs for research or tissue banking.

5. Removal of organs for research will only occur when there is the relevant NORS team attending, additional time may be required for the removal of organs for research. This should not impact on the retrieval of organs for transplant or the responsiveness of NORS to attend organ retrievals.

6. Guidance for NORS on expectations of removal of organs for research will be agreed in conjunction with NHSBT commissioning and the National Retrieval Group.

3. Progress

The recommendations of the INOAR working group was supported by RINTAG and the Change Portfolio Board (CPB) in October 2017. It was supported in principle by SMT in November 2017, subject to development of a robust governance and operational process.

An additional change since the INOAR recommendations is the award of a grant from the Medical Research Council (MRC) to QUOD to support tissue banking and archiving in an Atlas of whole hearts and lungs and pancreas from diabetic donors. The preparation and archiving of these organs will be carried out in the MRC Molecular Pathology Node in Newcastle.

The preparation, tissue banking and subsequent distribution of material from whole organs associated with QUOD is covered by the recently renewed QUOD REC approval (18/NW/0187). The regulation of removal of these organs will fall under the INOAR proposals.

Following the addition of the QUOD/MRC expansion, and the need to develop practical and pragmatic recommendations to RINTAG, a great deal of background work has been undertaken.

As a result, the further and detailed Recommendations which have been developed are:

1. **Donation Pathway**. The steps involving the SNODHUB and NORS are set out in Appendix 1. Changes to Consent/ Authorisation forms will be required. This work will be incorporated into an existing review of these forms.

2. **Retrieval Pathway**. Removal of an Organ for research has to be performed by a fully trained and accredited NORS surgeon (Appendix 2).

We do not anticipate a significant increase in workload for retrieval teams. 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.

3. **Offering**. The current route of the HUB offering of organs for research (via group text/ email) is consistent with the pathways above. The researchers on receipt of the group text/ email will, as at present, have access to EOS Mobile, to check on relevant contraindications. Organs will be allocated in accordance with the agreed RINTAG allocation scheme. It is appreciated that there will need to be some communication between the researcher and the SNOD, in order to check on some details and to set up timings, for instance for couriers from the donor hospital to laboratory

4. **Governance and Traceability.** This will be ensured by:

a) Retrieval will always be undertaken by a certified NORS team, who are full cognisant of the various regulatory frameworks, the need for responsible behaviour and the knowledge of the relevant paperwork

b) There will be a requirement to introduce new forms to ensure traceability i.e. a research equivalent of the HTA A and B form. It is envisaged that the HTA A and B forms (Research) will be initially be in paper form and the return of forms managed by the information services team, to ensure traceability. There may an opportunity to move to electronic forms in the future in line with the ongoing work in relation to HTA A and B forms, although this is resource dependent.

c) The number of organs removed for research purposes under NHSBT licence will need to be collated and provided to the HTA on an annual basis.

Finally, we have established a hierarchy, taking into account transplant and clinical tissue banking requirements and the existing RINTAG research allocation framework.

PANCREAS
1. Organ for transplant

2. Organ for research, as dictated by RINTAG priority
3. Organ for Banking, as dictated by RINTAG priority

LUNG
1. Organ for transplant
2. Organ for whole-organ research, as dictated by RINTAG priority
3. Whole Organ for tissue banking - must have CT NORS team
4. Part Organ for tissue banking - could be removed by Abdo NORS team

HEART
1. Organ for transplant
2. Organ for clinical tissue banking - heart valves
3. Organ for whole organ research, as dictated by RINTAG priority
4. Whole organ for tissue banking –
5. Part organ for tissue banking - could be done by abdominal team, and may be compatible with clinical heart valve banking

Predictions of Activity

There are clearly a lot of instances when the abdominal NORS team attends but the pancreas is not taken. With regard to other organs, we know there is demand for research, but this will not change with the new arrangements -quite a lot of kidneys, for instance, are offered for research and turned down on logistic grounds. We do not anticipate the changes to significantly alter workload, other than for some pancreata for QUOD (Appendix 3).

With regard to the CT organs, and CT NORS retrievals, the picture is just now emerging. In a 12 month period, CT NORS teams attended 281 retrievals. 180 hearts were not retrieved for transplantation, 93 were used for heart value donation and therefore 87 hearts were potentially available for research.

With regards to lungs, in a 12 month period, CT NORS teams attended 281 retrievals. On 184 occasions no lungs were retrieved for transplantation and therefore potentially available for research.

The number of lungs that QUOD have indicated that they require over 2 years is 20. Even if there is a big increase in lung research activity outside the three studies currently registered, the activity burden on SNODS and the Hub is going to be very modest.

4.Conclusions

The proposed detailed changes from INOAR have the potential to facilitate significant research, to the benefit of transplant patients, in hearts and lungs. They also have the potential to have a major beneficial effect on diseases leading to transplant, initially diabetes, but subsequently a range of end-stage heart and lung diseases.

In the first instance, the new process is restricted to Hearts, lungs and diabetic pancreata, and NORS teams have to be in attendance. There will be a significant reduction in work for SNODS, a small but closely controlled increase in work for the hub and the potential for major benefits.

We ask RINTAG to support this initiative, in particular while we navigate the other potential hurdles in other parts of the organisation

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