NHS Blood and Transplant

Research, Innovation and Novel Technologies Advisory Group (RINTAG)

Increasing the **N**umber of **O**rgans **A**vailable for **R**esearch **(INOAR)**

1. Status – Public

2. Executive Summary

2.1 In 2017 NHSBT's Research Innovation and Novel Technologies Advisory Group (RINTAG), formed a sub-group to increase the number of organs available for research. This sub group was named INOAR.

2.2 The main proposal of INOAR was to extend the existing NHSBT Research HTA Licence (12068) to permit the removal of whole organs for research purposes. This licence (currently used for QUOD), covers 41 hospitals in England, Wales and Northern Ireland.

2.3 INOAR's proposals to increase the number of organs available for research were agreed in principle by RINTAG, Organ Donation and Transplantation SMT and Quality Assurance SMT in 2017.

2.4 From 23rd October 2019, SNODs in QUOD-licensed hospitals in England, Northern Ireland and Wales, and all hospitals in Scotland will discuss the opportunity with donor families to consent or provide authorisation to the removal and storage of the Heart, Lungs and Diabetic Pancreas for research.

2.5 Without exception, organs will be prioritised for clinical use before research.

3. Action Requested

Note the progress of the INOAR project and proposed 'go live date' of the 23rd October 2019.

4. Background

4.1 Utilising the Liverpool Research HTA Licence to remove organs for research will - in addition to increasing the number of organs available for research - deliver the following benefits:

- Reduce the complexities of the consent process for families
- Reduce the complexities of the consent process for SNODS
- Enable a more consistent and transparent research allocation system
- Lessen the complexities for researchers by reducing the requirement for specific HTA licences

4.2 INOAR is a change in practice across the entire donation, offering, allocation and retrieval pathway, resulting in changes for Organ Donation Services Teams, Hub Operations, the National Organ Retrieval Service, Information Services, and the Donor Records Department.

4.3 The INOAR project has encountered software/ electronic and operational challenges and the initial go live date of November 2018 was not achievable. Project management support has been in place since March 2019 to progress INOAR

4.4 A 'Dragon's Den, Process Sense Check' workshop was held in July 2019 to walk through the end to end process.

5. Update

5.1 The following provides key information relevant to the RINTAG, regarding changes to practice along the donation, offering, allocation and retrieval pathway. Further information can be reviewed in Appendix 1. (NORS FAQ INOAR).

Donation

5.2 Families will be given the option to consent/authorise for the removal of organs for research. This discussion will take place only after consent/authorisation for organ donation has been given**.**

5.3 Training devised by the ODT Research Team and Professional Development Team was delivered to the ODST Quality Leads on the 31st July. SNODs are currently being trained via the ODST Quality Leads prior to 'go live'.

5.4 If the patient is being referred to the Coroner/Procurator Fiscal, the removal of organs for research must be included in the request. The Chief Coroner/ Procurator Fiscal have been briefed regarding the removal of organs for research.

Offering

5.5 If there is consent/authorisation for the removal of organs for research, Hub Operations will send a pager to the relevant research studies with the offer of an un-transplantable organ (contraindicated/ offered for transplant and declined by all centres). Researchers have 45 minutes to respond to the offer if they wish to accept the organ (Appendix 2. Researchers flow chart).

5.6 There are 2 time points when Hub Operations may offer organs to researchers:

- Prior to theatre, when the organs are contraindicated for transplant, or have been offered for transplant and declined by all centres.
- When organs have been retrieved for transplantation but have been found to be unsuitable on further examination on the back bench in theatre, or at the transplanting centre.

Allocation

5.7 The organ will be allocated according to the ODT research organ allocation sharing scheme. Studies are ranked when they apply to RINTAG and re-ranked approximately every six months.

Retrieval

5.8 NORS teams will not be mobilised purely for the removal of organs for research.

5.9 NORS teams will be only asked to remove organs within their scope of practice

5.10 NORS teams will perfuse and package organs as per organs for transplant.

5.11 Removal should be documented on the HTA-A Research Forms (Appendices 3 & 4)

Post donation

5.12 Information Services will manage the return of HTA A Research and HTA B Research forms, ensuring the traceability of organs removed for research.

6. Stakeholder Communications

6.1 There are a number of internal and external stakeholders. Communications regarding the project have included:

- Development of an INOAR video https://app.vyond.com/videos/da64a444-63ec-491e-aa1d-bc642cedac2
- FAQ's to accompany SNOD training materials and controlled documents
- Letter from RINTAG Chair and National Clinical Lead Organ Retrieval to NORS Leads and NORS FAQ's
- INOAR article in HTA newsletter https://us9.campaign-archive.com/?u=8a7f5f861d1a022a25974b965&id=3da7efe5d4&e=b5ffbf0a3f#INOAR
- Monthly communications to researchers via the ODT research team: https://sway.office.com/IRysXEJWrkWuR8Ei?ref=Link
- Communication to perioperative practitioners via the NHSBT Retrieval and Transplant Project Lead Specialist.
- Training delivered via the National QA Manager to ODT Regional Managers, who named Persons Designated under the NHSBT HTA research licence.
- INOAR Project progress is reported via ODT Change Programme Board (monthly).

7. Next Steps

7.1 A workshop is scheduled for 3rd October 2019 whereby Ian Bateman – Director of Quality at NHSBT and DI for NHSBT's HTA licence – will be in attendance to gain assurance that the end to end process is robust and compliant with legislation.

7.2 After 'go live' a period of monitoring and evaluation to ensure continuous improvement will include:

- A review of approach, consent rates and acceptance rates for the removal of organs for research.
- The impact of the removal of organs for research on the length of the donation process

- The impact of the removal of organs for research on other research studies including QUOD and specific studies.
- Complaints and compliments
- Service evaluation feedback forms
- Incident reporting
- INOAR lessons learnt

7.3 Further iterations of the project will require the following to be undertaken:

- Business Case
- Mandate
- Budget
- Resources
- Formal CPB approval

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