

INOAR Conclusions and Recommendations
RINTAG 9th October 2017

Summary

1. A RINTAG Sub-Group (Increasing the Number of Organs Available for Research – 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.
2. This paper provides a summary of the conclusions and recommendations from the Increasing the Number of Organs Available for Research subgroup (INOAR). The aim is 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.
3. INOAR recommends 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.
5. This change to the licence will mean that the legislative responsibility of this activity, under the Human Tissue Act (2204), will be that of NHSBT's Director of Quality – Ian Bateman, who is the Designated Individual for HTA Licence 12068. A robust governance framework will be required to support this change.

Recommendation

6. INOAR puts forward the following recommendations for RINTAG's consideration for increasing the number of organs available for research:
 - i. The QUOD licence should be extended to support removal of specific organs for generic research purposes (transplantation / healthcare). This would remove the requirement for 'specific' consent for individual research projects, and families would be asked for consent for removal of specific organs for generic research projects. This would need additional governance, that should be built in to current standard practices/ documentation as far as possible (e.g. QUOD form, HTA A/ B form etc).
 - ii. There is currently a clear and transparent process for consenting for research purposes. This would not be diminished by the removal of 'specific' consent. A list of all live studies should be accessible by SN-ODs to inform discussions.
 - iii. In addition, the ODT website should include data on all live studies and families should be made aware of the site so that they can access more information.

- iv. There should be an interim period of 1 year, whereby existing studies with 'specific consent' - those centres who have their own HTA licence for removal of organs- will be supported. During this period, those studies should seek amendment to REC approval, if necessary. In addition, NHSBT will liaise with Designated Individuals (DIs) for those studies that are currently working under centre-specific HTA licences.
7. In addition, INOAR suggests the following changes to support the ODT research infrastructure:
- v. Work to establish a number of Research Ethics Committees with interest/ expertise in organ donation should continue.
 - vi. Researchers should be encouraged to write to donor families, SN-ODs and ICU to thank them for the organs. This will help to motivate and engage SN-ODs and ICU with the research process and provide reassurance of the outcomes resulting from the donation.

Background

Aims

8. INOAR was established to identify the barriers to maximising the potential for organ donation for research purposes in the UK and make recommendations on how these can be overcome. The full remit, membership and approach is provided at Annex A for reference.

Generic and Specific Consent

9. Under the current licence terms, organs can be allocated to research in two situations:
- 'Generic' consent – the family has consented for research if the organs are removed for the purposes of transplantation and then not suitable.
 - 'Specific' consent – there is a licence in place in the donating hospital to permit removal of organ/s for a known study for which families give their specific consent. If the study is unable to accept the organ(s), then they are not able to be used for any other research purposes because of the restrictions of specific consent. Specific Consent allows removal of organs even when the primary intention is not transplantation

Stakeholder engagement

10. The proposal to amend the QUOD licence [HTA Licence number 12608] has been shared with Ian Bateman (Director for Quality), who agreed in principle, but requested further details regarding the governance structure/ processes and reassurance that the tissue service would not be adversely affected.

Differences in UK legislation

11. It should be noted that the legislation in Scotland is different to that in the rest of the UK and there is no requirement for additional specific authorisation for organs that were not removed for the purposes of transplantation

Conclusions

Barriers/ Issues

12. The current HTA licensing situation means that NHSBT do not support removal of whole organs for research purposes. This has led to different consent processes – referred to as ‘generic and specific’ depending on whether organs are removed for transplantation purposes (then not suitable) or removed for a known research study under the donor hospitals own licence. Having two consent processes creates the following difficulties;
- Additional consent procedures for donor families in those hospitals that hold an HTA licence.
 - Concern for SN-ODs that they are potentially misleading families, who may give consent for removal of organs for a ‘specific’ research study but organs may be placed in a ‘generic’ study (dependant on the stage in the process they were considered not suitable for transplant).
 - Additional work and significant delays for researchers in obtaining additional licences, REC approval and governance procedures in the donating hospital.
 - Confusion for researchers regarding which organs they may be eligible to receive.
 - Limits the numbers of organs that could be retrieved for research, even though families may have given consent for use for research purposes.

Potential benefits/ disbenefits

13. INOAR believes that a change to use the QUOD licence¹ to remove organs for research will make specific and generic consent obsolete and deliver the following benefits:
- Reduced burden on families through stream-lining the consent process.
 - Reduced burden on SN-ODs for the consent process.
 - A more consistent and transparent process regarding where organs may be placed.
 - Reduced burden on research teams, by no longer needing to obtain specific HTA licences for removal of organs .
 - Reduced burden on local hospital DIs
14. INOAR estimates that this approach will provide and 694 organs per year for research purposes, including:

Kidney	143
Liver	115
Pancreas	108
Bowel	51
Heart	105
Lungs	172

15. See Annex B for statistical analysis.

16. The change in licence provides the following issues for NHSBT:

¹ NHSBTs Research licence (HTA licence number 12608)

- The legislative responsibility of this activity, under the Human Tissue Act (2204), will be that of NHSBT's Director of Quality – Ian Bateman, who is the Designated Individual for HTA Licence 12068.
- As a result, any risk will move from the local hospital to NHSBT.
- A robust governance framework will be required to support this change.

17. The following issues should also be considered:

- Any studies requiring organs and tissues not normally retrieved by NORS teams will still need to be removed under an establishment's own licence. NHSBT will only support removal of organs for which NORS teams are trained and competent to remove for transplant
- The QUOD licence only covers 41 hospitals, so it will not address all donating hospitals. However, the QUOD licence does cover all hospitals that currently remove organs for research using their own HTA licence (those for which specific consent is provided).
- No amendments would be needed to the consent form, but there would be a need to re-train SN-ODs in the consent for research purposes.

Resource Impact

18. The change in policy will carry the following resource impact for NHSBT:

- Re-train SN-ODs in the consent process for research processes. This could be built in to standard on-going training offered to teams.
- NORS teams may be asked to retrieve additional organs from donors they are attending. This is not expected to add significant additional time to the retrieval process, but this would need to be kept under review.
- The Hub Operational Office will be offering more organs for research purposes, which will take additional time. However, the allocation pilot has demonstrated that the new text offering system has reduced the time required for offering research organs.
- Quality Assurance team would need to revise the licence and governance procedures.

Next Steps

19. Subject to RINTAG and ODT Senior Management Team agreement, the following steps are suggested:

- October: Further liaison with NHSBT Tissue Services team to ensure no adverse impact on heart valve retrieval. Feedback to Quality Assurance Team to provide reassurances regarding impact on tissue services and proposals for governance structure. Liaison with the Human Tissue Authority
- November: Recommendations to ODT Senior Management Team. Final recommendations to Quality Assurance SMT.
- December: Commence work to implement new structure.

Request for Action

20. RINTAG is asked to comment on the above INOAR conclusions and advise on recommendations to be put to the ODT Senior Management Team.

Annex A

INOAR Remit, Membership and Approach

Remit

INOAR was established to review the various UK legislation and ethical frameworks, together with UK policies, guidance and clinical practice relating to obtaining organs for research to:

- Identify current barriers to the availability of organs for research purposes and to;
- Suggest which steps are appropriate to overcome these barriers in order to:
- Make recommendations for a new approach that will increase the consent rates and the number of organs available for research in the UK. This could include recommendations regarding:
 - Changes to UK legislation and national guidance
 - Changes to UK clinical practice

Membership

Co- Chairs: Elizabeth Murphy (Lay member RINTAG); John Dark (National Clinical Lead Governance, ODT)

Members:

- Paul Murphy (NODC Chair, National Clinical Lead – Organ Donation)
- Mr Anthony Clarkson (Assistant Director – Organ Donation & Nursing ODT)
- Vicky Gauden (NHSBT National Quality Manager)
- Rutger Ploeg (NRG Chair, Director of QUOD)
- Lesley Logan (NHSBT Regional Manager)

In attendance:

- Maria McGee (NHSBT Research Project Manager)
- Claire Williment (Head of Transplant Development)
- Heather Crocombe (Clinical Support Services)
- Paul Rooney (Tissue Services)

Approach

- 3 meetings
- Legislation review
- Literature review
- Stakeholder engagement (particularly Tissue Services, ODT Quality Assurance)

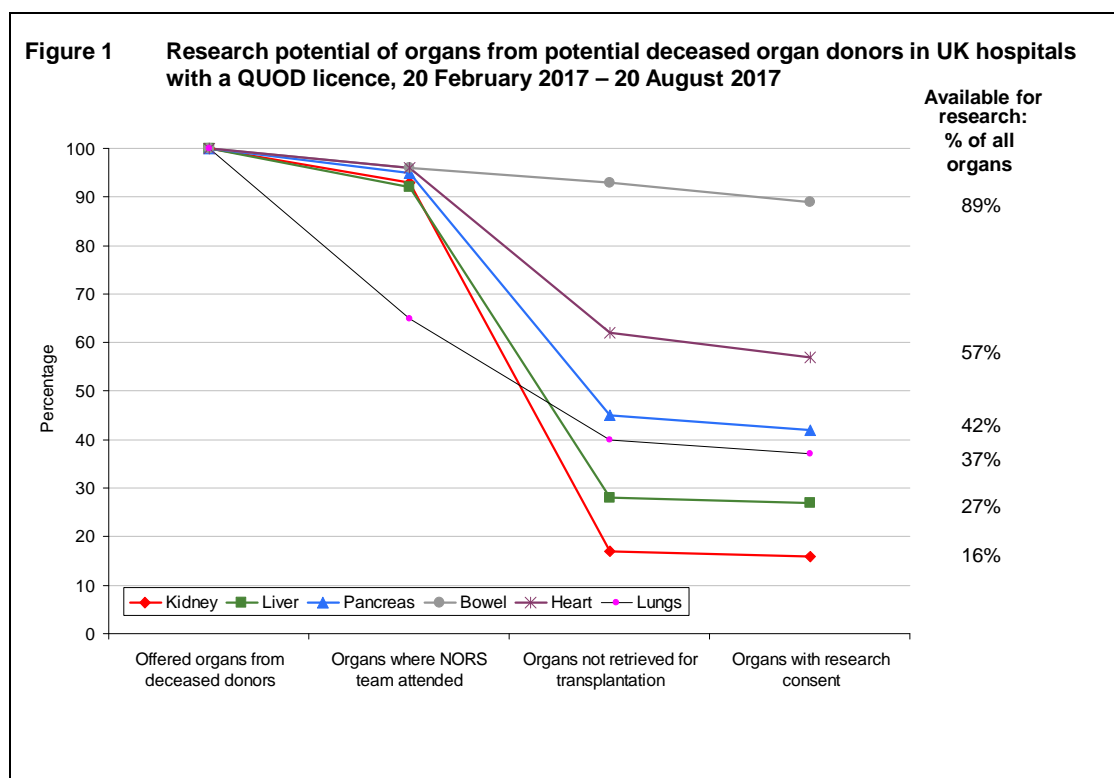
Annex B

**RESEARCH POTENTIAL OF ORGANS IN QUOD LICENSED HOSPITALS
20 FEBRUARY 2017 TO 20 AUGUST 2017**

DATA

UK Transplant Registry data was used to identify organs available for research. The cohort of data used was all offered organs from potential deceased donors in UK hospitals with a QUOD licence. The time period covered, 20 February 2017 to 20 August 2017, was the 6 month period following the change in the allocation of research organs. This is also comparative with time periods reported on in RINTAG papers for the October 2017 meeting.

Figure 1 shows the percentage of organs available for research out of all offered organs from potential deceased donors in QUOD licensed hospitals. This shows that many offered bowels are not retrieved for transplantation, resulting in 89% being available for research. However offered kidneys are likely to be retrieved for transplantation, which means 16% of offered kidneys are available for research. The numbers and percentages behind this figure are provided in **Table 1**.



Organ	Offered organs from deceased donors		Organs where NORS team attended		Organs not retrieved for transplantation		Organs with research consent	
	N	%	N	%	N	%	N	%
Kidney	882	100	818	93	153	17	143	16
Liver	432	100	399	92	121	28	115	27
Pancreas	258	100	245	95	116	45	108	42
Bowel	57	100	55	96	53	93	51	89
Heart	183	100	175	96	113	62	105	57
Lungs	459	100	300	65	184	40	172	37

Figure 2 shows the percentage of organs available for research out of all offered organs from potential deceased donors in QUOD licensed hospitals. This shows that for hearts, lungs and bowels almost all retrieved organs are transplanted, resulting in a small number being available for research. However only around half of retrieved pancreases are transplanted, which means 24% of offered pancreases are available for research. The numbers and percentages behind this figure are provided in **Table 2**.

Figure 2 Research potential of organs from potential deceased organ donors when organs are initially removed for transplantation purposes in UK hospitals with a QUOD licence, 20 February – 20 August 2017

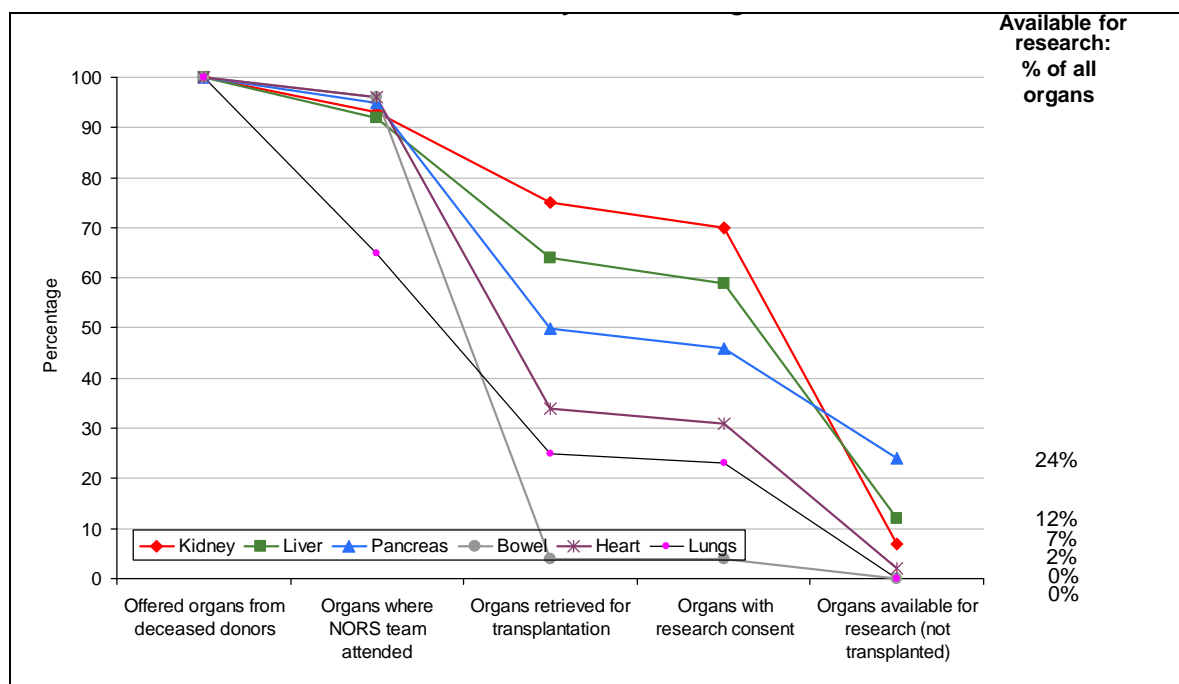


Table 2 Research potential of organs from potential deceased organ donors in UK hospitals with a QUOD licence, 20 February 2017 – 20 August 2017

Organ	Offered organs from deceased donors		Organs where NORS team attended		Organs retrieved for transplantation		Organs with research consent		Organs available for research (not transplanted)	
	N	%	N	%	N	%	N	%	N	%
Kidney	882	100	818	93	665	75	613	70	58	7
Liver	432	100	399	92	278	64	256	59	52	12
Pancreas	258	100	245	95	129	50	118	46	62	24
Bowel	57	100	55	96	2	4	2	4	0	0
Heart	183	100	175	96	62	34	57	31	4	2
Lungs	459	100	300	65	116	25	106	23	2	0

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Statistics and Clinical Studies

September 2017