3-MONTH REVIEW OF THE INCREASING THE NUMBER OF ORGANS AVAILABLE FOR RESEARCH (INOAR) PROJECT
RINTAG MEETING
25TH MAY 2021

This is an edited version: the full researcher feedback has been removed.

Background

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 subgroup was named INOAR.

Owing to a number of software/electronic and operational challenges and the COVID pandemic the initial go live date of November 2018 was unfortunately not achieved, nonetheless the INOAR project was able to go live on the 13th January 2021. Consequently all Specialist Nurses (SNs) in QUOD-licensed hospitals in England, Northern Ireland and Wales and all hospitals in Scotland are now in a position to approach donor families to consent or provide authorisation for the removal and storage of the heart, lungs and diabetic pancreas for research.

Utilising the Liverpool Research HTA Licence to remove organs for research has increased the number of organs available for research.

In addition, the following benefits are achieved:

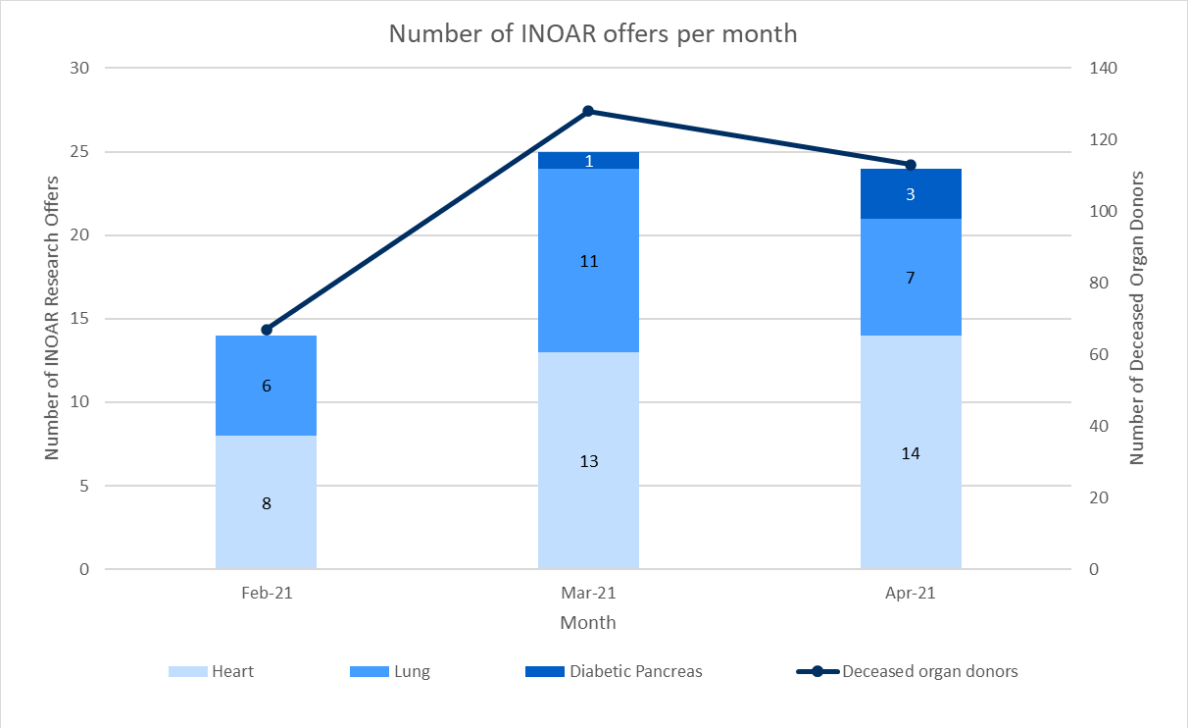
- Reduction in the complexities of the consent process for families
- Reduction in the complexities of the consent process for SNODs
- A more consistent and transparent research allocation system
- Reduction in the complexities for researchers by reducing the requirement for specific HTA licences

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.

Data Overview

Please note that the data presented in this report are from the 1st February – 30th April 2021 following an audit of all potential donors.

Organ-specific flowcharts looking at the fates of the potential INOAR donors (adult deceased organ donors in any hospital in Scotland, or a hospital in England, Northern Ireland and Wales covered by NHSBT's satellite HTA licence) are available in Appendix A.



Consented Solid Organ Donors in QUOD Hospitals (England, Wales, Northern Ireland) & Scotland)	220
Consent for the removal of at least one organ - Hearts, Lungs and Diabetic Pancreas for Research	162
No Consent for the removal of Hearts, Lungs and Diabetic Pancreas for Research	44
Non approach for the removal of any of these organs: heart, Lungs and Diabetic Pancreas for Research.	14*

**Documented reason why families not approached for INOAR based on information extrapolated from Donor Path. 7 abdo only and Heart accepted for Heart for Valves, 2 coroner's restrictions, 2 families requested abdo only, 2 document n/a but likely family decline, 1 misunderstanding of process.*

Hearts

35 hearts were offered through INOAR in this time period, but unfortunately none of these offers resulted in a removal of a heart for research. A small number of these were initially accepted by studies but later declined. However, at the time of writing this report, we have had 2 hearts accepted and retrieved for research, but these do not appear in the data as both were retrieved after the 1st May.

On initial discussion with researchers the main reason for non-acceptance has been due to the fact that it was an abdominal team retrieving the heart, who would therefore be retrieving within their scope of practice i.e. retrieving heart for valves which are subsequently perfused and transported on

saline, while the researchers required hearts that had been perfused with perfusion fluid such as cardioplegia. 29 out of the 35 offered hearts were being attended by an abdominal NORS team only.

Lungs

There were 24 offers for lungs. 17 of these offers were accepted, leading to 9 removals. In the 8 cases where lungs weren't removed, 6 were due to all centres declining hearts for transplant after initially accepting meaning that the CT NORS team stood down. Of the remaining two cases:

- A single lung was found to be transplantable so INOAR was stood down
- The CT team did not bring lung retrieval kit with them (incident submitted).

Pancreases from donors with diabetes.

There have been 7 donors with diabetes in an INOAR-suitable hospital during the data collection period. 6 of the donor families consented for the removal of their relative's pancreas for research. In 2 cases, all centres declined organs for transplantation on initial offering, therefore the donor did not proceed to theatre. Of the 4 pancreases that were offered, all 4 were accepted and removed for research.

**Please see appendices for Organ Specific breakdown, please note at the time of writing this report this data has not been validated, this data has been extracted from EOS and DP following an audit by the Research Team of all donor files from 1st Feb – 30th April 2021.*

Feedback.

Specialist Nurses (SNs)	Anecdotal feedback from the Specialist Nurses has been variable. There were some initial concerns in terms of the possible extension of the consent/authorisation conversation and the perceived impact on donor families. Some SNs have found success by mixing up the order of the consent/authorisation conversation. Instead of separating the conversation and approaching for organs, tissues and research separately, they have found it advantageous to blend them altogether; for example, talking about donation of their relative's heart for transplantation, heart for valves and then for research. This feedback has been communicated to the rest of the Specialist Nurses during practice sharing sessions and subsequently some SNs have cited a reduction in their concerns and perceived anxieties around approaching families. A recurring comment is that this is of particular concern where there are additional specific research consent/authorisation requirements too. Some questions have been raised around the possibility of adding a 2nd offering point post mobilisation of team/in theatre. Another common theme has been around CT teams standing down on lung removal for INOAR when the heart is declined for transplant in theatre and subsequent loss of the lungs for research.

	The SNs have also queried why more organs have not been accepted for research studies; particularly hearts. Concerns were also raised about a research study contacting them requesting hearts to be perfused with cardioplegia when only abdominal teams have been attending. They have been advised that NHSBT has agreed to this but this was incorrect and a research team misunderstanding. This has resulted in the SNs contacting regional managers and having multiple calls to deal with. Additional comments from the SNODs/SR were regarding a small number of families who had felt uncomfortable donating organs purely for research, while this is balanced with other families who have stated that they find comfort in the knowledge that in the event that their loved one organ has not been suitable for transplant but has gone to research and will still be helping others in the future.
Researchers	The ODT Research team has conducted feedback sessions via Teams with some of the main research groups affected by INOAR. Unfortunately due to time constraints we have not been able to complete feedback sessions with all studies affected (there are 3 studies outstanding). As each study has different requirements, and so as not to lose any nuance in their feedback, we have included all of the responses for the sessions we conducted in Appendix B. In addition, we have noted concerns from some researchers about the loss of organs from specific consent research studies (which were stopped following the implementation of INOAR). Data from the Northern team suggests that 5 non-diabetic and 1 diabetic pancreases (between 13th January - 16th April 2021) that families would have traditionally been approached for, weren't due to the INOAR changes. Therefore all 6 could be considered missed opportunities.
Hub Operations	Feedback included that during the implementation phase there were some confusion/misunderstandings on the new INOAR processes, nevertheless these were addressed and subtle amendments have been made to their SOP which has resolved these. The use of offering prompts on the NORS mobilisation pager has proven successful. The subject of a 2nd offering point was discussed following feedback from Researchers and SNs. It is felt by Hub Ops that the rationale for not adding in a 2nd offering point in the initial INOAR work up still remains the same, i.e. workload, the risk of research organ offering being missed at this later stage. Having a standard mobilisation cut off point for INOAR organ offering is felt to work well and is easily followed.

Governance and Quality

Following INOAR implementation in January 2021, several incidences have been reported via OTDT Clinical Governance. In the main they were communication-related, between Hub Ops, SNs, and NORS teams resulting in INOAR organs not being offered or accepted as per agreed policy. Whilst these were small in numbers, amendments have been made to existing SOPs to prevent future loss of research organs.

There were also a number of incidents submitted concerning the additional requests from Researchers for additional blood and tissue samples to accompany the whole organ which is currently outside of the current protocol. This has been discussed with the researchers who had requested additional samples to ascertain the rationale behind their request. The feasibility for future inclusion of blood and additional samples to accompany INOAR organs for research will be explored.

Recommendations to RINTAG.

Following this review of the data and listening to feedback from both internal and external stakeholders, we would like to propose the following recommendations to further increase utilisation of organs for research.

- Scope the feasibility of including blood samples for INOAR organs to mirror those that are currently sent with transplantable organs which are subsequently declined and used for research.
- Open dialogue between Researchers and NORS leads to assess how to improve acceptance of hearts when being retrieved by abdominal NORS teams, while ensuring the NORS teams are not asked to work outside of their scope of practice and with no additional clinical risk to abdominal organs.

Authors

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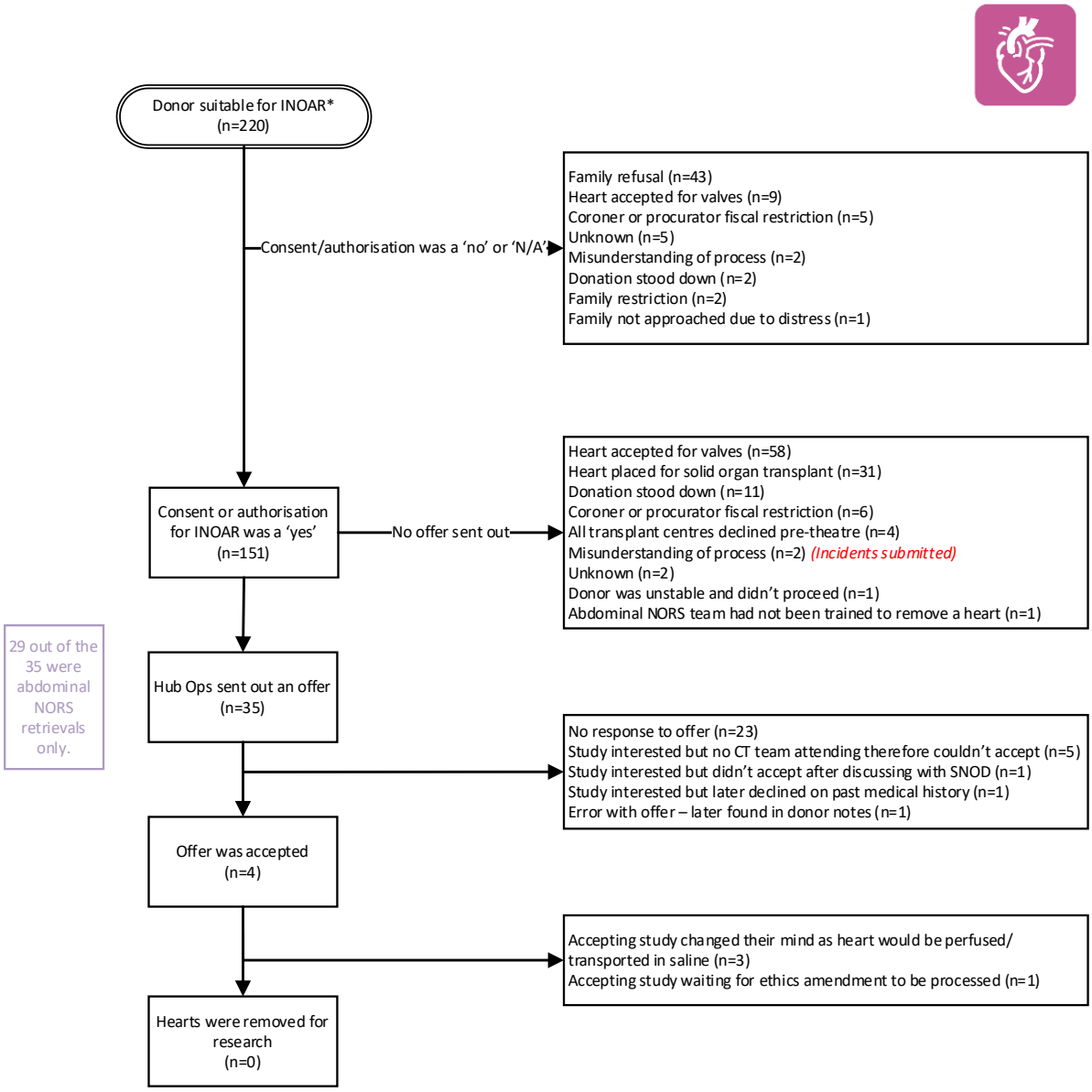
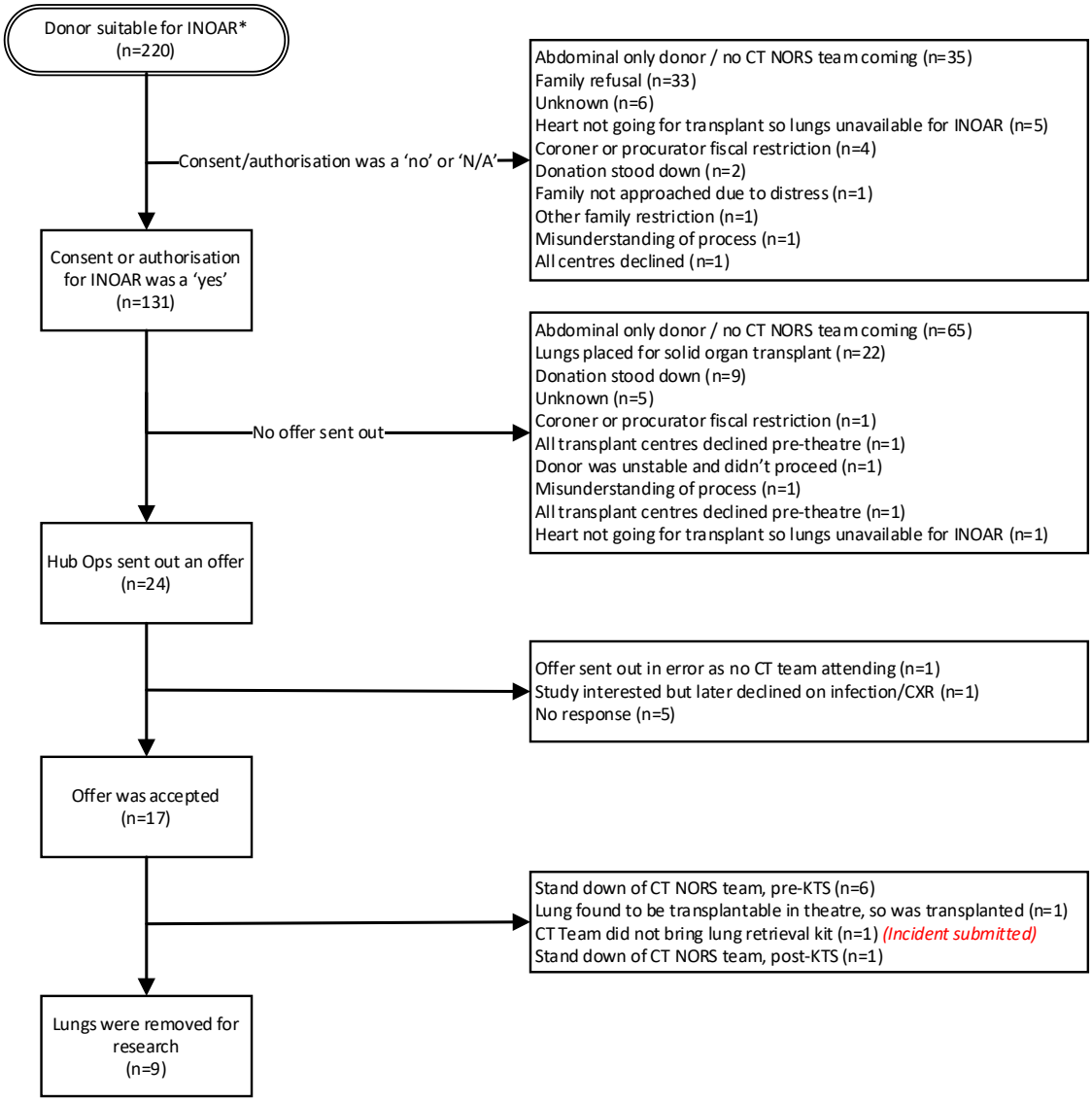
Appendix A: INOAR Flowcharts



*Adult donors in Scotland or a QUOD-licenced hospital in England, Northern Ireland or Wales. Time period: 1st February – 30th April 2021. Please note that these data are rough and have not been validated – they have been primarily pulled from the homepage of EOS/DonorPath and combined with research offer data (from the ODT Research team) and other data (from the NHSBT Statistics team).



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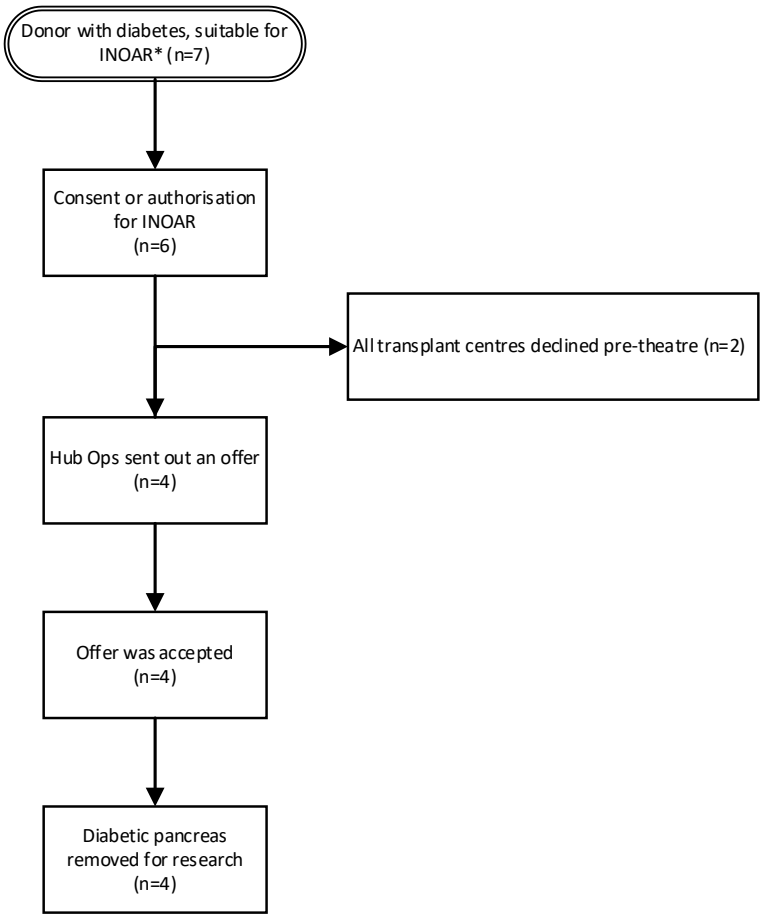

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