Increasing the Number of Organs Available for Research (INOAR): Project Update & Issues for Discussion
RINTAG Meeting
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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.

The INOAR project went live on the 13th January 2021. Now all Specialist Nurses (SNs) in QUOD-suitable hospitals approach donor families for consent or authorisation for the removal and storage of the heart, lungs and diabetic pancreas for research.

Data

The data in this paper cover the period 13th January – 30th September 2021. During those 8.5 months, a total of 181 INOAR organs were offered to researchers by NHSBT's Hub Operations. The organ-specific breakdown was as follows and is displayed by month in Figure 1:

- 50% of the offers were for hearts (90)
- 33% were for lungs (59)
- The remaining 18% were diabetic pancreases (32)

An INOAR 'next steps' document written by Professor John Dark in 2018 estimated:

> *"In a 12 month period, CT NORS teams attended 281 retrievals at the QUOD hospitals to be covered by the new regulatory arrangements. 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 in those same hospitals. On 184 occasions no lungs were retrieved for transplantation and therefore potentially available for research."*

Extrapolating our figures for INOAR so far, bearing in mind the ongoing impact of the COVID-19 pandemic on donation and transplantation rates, we can estimate that the first 12 months of INOAR will result in:

- 83 lung offers
- 127 heart offers (NB. these offers include hearts retrieved by abdominal teams, which were not considered in Prof Dark's paper)
- 45 diabetic pancreas offers

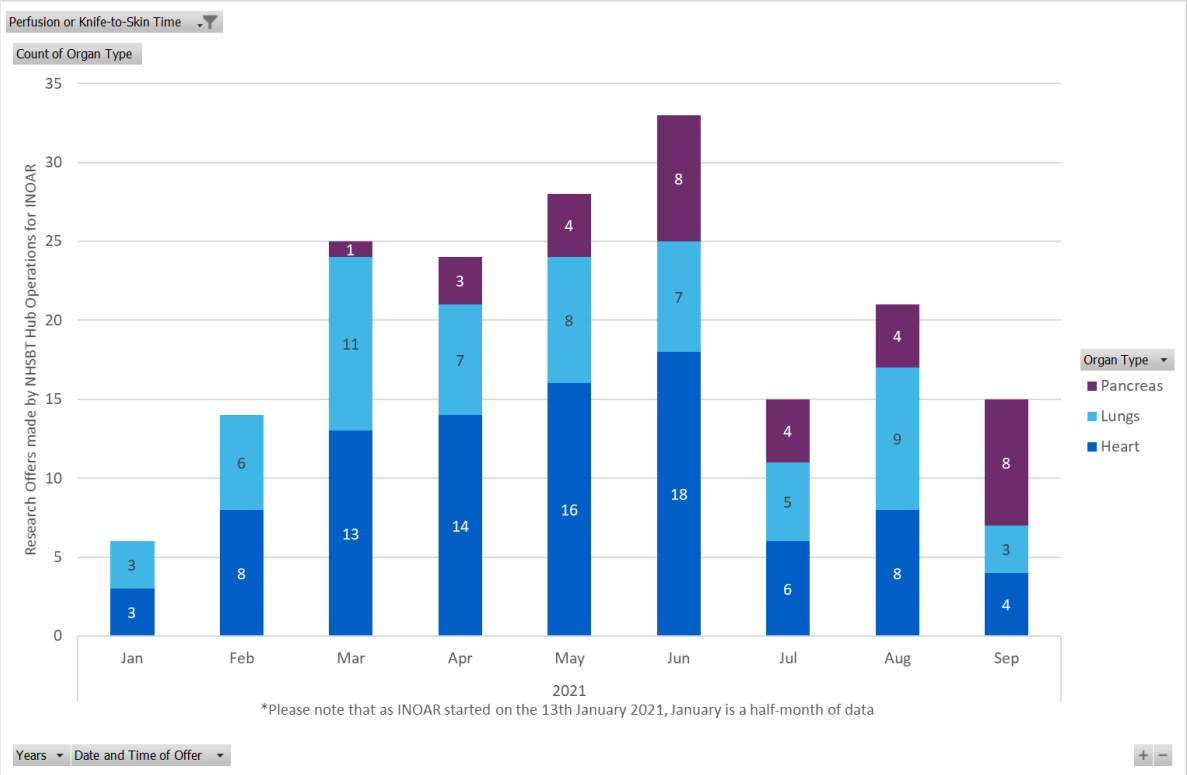

Figure 1: The monthly offers for INOAR research organs between the 13th January - 30th September 2021.

Acceptance

Diabetic Pancreases

Pancreases from organ donors with diabetes have been well-accepted by researchers, with 27 out of the 32 that were offered in this time period being accepted (84%). 22 were subsequently removed for research. Of the 5 that were accepted but not removed, this was because:

- Prolonged time to asystole so donation as a whole was stood down (n=4)
- Consent from the coroner wasn't sought, so the Regional Manager on call advised that the pancreas shouldn't be removed (n=1)

Lungs

42 out of 58 lungs that were offered for research through INOAR were accepted. 23 out of the 42 that were offered were then removed. Of the 19 that were accepted but not removed:

- The CT NORS team were stood down (n=12)
- The CT NORS team did not want to remove the lungs as they were impeding the heart retrieval / the retrieval was too technically difficult (n=2)
- The retrieved (single) lung was found to be transplantable (n=1)
- The CT team did not bring lung retrieval kit with them (n=1)
- Coroner restriction (n=1)
- Prolonged time to asystole so donation as a whole was stood down (n=1)
- Unknown – heart and lung stood down as per surgeon's advice (n=1)

Hearts

90 hearts were offered through INOAR. In one case, the offer was later withdrawn as the heart was accepted for valves. 22 offers were accepted, leading to 15 removals for research. For the 7 cases where the offer was accepted but the removal didn't take place, this was because:

- Prolonged time to asystole so donation as a whole was stood down (n=2)
- The study could no longer accept once it became apparent the heart would be transported in saline (n=2)
- The donor had positive blood cultures, so the accepting study changed their mind (n=1)
- The study's ethics amendment was still in progress (n=1)
- The NORS team did not retrieve as they didn't know which paperwork was required (n=1)

Less than 10% (8) of the offers made were for retrievals involving a Cardiothoracic (CT) NORS team. Most heart researchers have reported that they are unable to accept hearts that are retrieved by an Abdominal NORS (Abdo) teams because they are transported in saline.

Increasing INOAR Heart Acceptance

Having identified that <20% hearts offered for research were being accepted and removed for research, a stakeholder engagement meeting was held in June 2021 to explore the reasons for the lower than anticipated acceptance rate and look to see what, if anything, could be done differently to improve acceptance and utilisation rates.

Key points discussed:

- Perfusion fluids when the retrieval is being attended by an abdo team only.
- Warm ischaemic time when heart retrieved once organs for clinical use have been removed.
- Hearts that had initially been accepted for transplant and then subsequently been declined on inspection and deemed unsuitable for transplantation and tissues, were not offered for research owing to current INOAR Standard operating procedure (SOP).

Consequently, the following actions were taken away from Stakeholder engagement call:

- Explore the possibility of introducing a second offering point into our existing SOP.
- Amend the Abdo team protocol for retrieving hearts for research
- Explore allowing Researchers/other Surgeons to retrieve the heart and attend in addition to NORS teams.

Introduction of a second offering point

Many hearts are declined for transplantation on visualisation. Current INOAR SOPs state that organs cannot be offered for research at this point in the process due to the additional delays it would cause to the theatre process (waiting for researchers to respond to the offer) and due to the increase in workload for Hub Ops. However following feedback from SNs and Hub Ops in addition to the comments raised at Stakeholder engagement call there is an appetite to introduce a second offering point for CT organs that are declined post KTS. Plan to review current SOP and look to work up introduction of second offering point beginning of 2022.

Amending the Abdo Teams' protocol.

As mentioned above <10% of offers involved a CT team being present for retrieval, and currently there are differences in the way in which the CT team retrieve hearts compared to the abdo teams. When INOAR was being originally worked up it was agreed that teams would only remove organs within their scope of practice:

Team(s) Mobilised	Can this organ be offered/removed for research?		
	Heart	Lung	Diabetic Pancreas
Abdominal and Cardiothoracic NORS	Yes	Yes	Yes
Cardiothoracic NORS only	Yes	Yes	No
Abdominal NORS only	Yes	No	Yes

NORS Team	Can the Team remove this organ for research?		
	Heart	Lung	Diabetic Pancreas
ABDOMINAL	Yes (unperfused)	No	Yes
CARDIOTHORACIC	Yes (perfused)	Yes (perfused)	No

Therefore, only hearts removed by CT team would be perfused; the abdo teams would flush and transport on saline, but unfortunately this meant most hearts removed by abdo teams were deemed unsuitable. Following a series of discussions with CT and Abdo NORS leads and the Chairman of RINTAG it has been agreed that we will develop a new protocol for abdo teams retrieving hearts for research, this will involve clamping, venting and in situ perfusion. The protocol is currently in development, and we hope to pilot the protocol with 2 Abdo NORS teams at the beginning of 2022.

Allow researchers/other surgeons to retrieve the hearts to their own specification in theatre

Some researchers have been in contact with CT surgeons who could potentially join the retrieval to remove the heart for research to their own specification. This option requires careful consideration around:

- Recording which personnel were at the retrieval (i.e. development of a 'researcher' retrieval team code on NTxD)
- Ensuring that the personnel retrieving the heart for research are trained and competent, as the retrieval takes place under NHSBT's HTA licence and therefore NHSBT bears the responsibility
- Managing costs for perfusion fluid and other consumables, and who pays for these
- How the surgeons are paid for their time (as these retrievals fall outside of their NORS activity)

Other Issues with the INOAR Process

Request for Specific Consent arrangements to be restarted

A pancreas research study in Newcastle under the Blood and Transplant Research Unit (BTRU) was operating under specific consent arrangements before the introduction of INOAR. This meant that the Northern team of Specialist Nurses (and Yorkshire team, when cross-covering) were taking consent from donor families for the removal of the heart, lungs and (non-diabetic) pancreas in seven hospitals in the region, specifically for the BTRU studies. Whilst the heart study has continued, the lung and pancreas specific consent

arrangements were stopped in 4 of the 7 hospitals when INOAR was introduced to reduce the impact on the organ donation process.

As INOAR only covers the removal of diabetic pancreases for research, the study team have lost a source of non-diabetic tissue for their work. Whilst they are set up to receive untransplantable non-diabetic pancreases through the national allocation scheme, the cold ischaemic time associated with this means they accept few by this route.

One of the aims of INOAR was to make the allocation of organs more equitable and traceable by removing local specific consent arrangements. Subject to operational pressures (i.e. SN consent), does RINTAG support the request to reinstate specific consent arrangements here, and in which hospitals? If this is agreed by RINTAG, consideration should be given to other studies in the rest of the country who had their specific consent arrangements stopped or have been advised that they can't be supported.

NRP with INOAR

Following an incident where a CT team had arrived to retrieve a CT organ for transplant and abdominal NRP (aNRP) was planned to be initiated to support the abdo retrieval, owing to the increased risk of bleeding and the subsequent potential loss of organs it was considered too risky to remove CT organs purely for research. This incident was recently raised at the Governance Improvement Group (GIG) and it was requested that a consensus be agreed regarding CT organs being removed purely for research when aNRP is planned.

Following discussion with the CT NORS lead it is felt that currently while CT NORS teams are increasing their exposure and subsequently developing their expertise involving aNRP it is considered safest to stand down on removal of CT organs for research until teams have had the opportunity to become familiar to the surgical and technical differences. This will be reviewed again March 2022 as we are mindful that as aNRP becomes more frequently used in our extended criteria DCD donors we do not want to disadvantage our Research colleagues by not being able to remove CT organs for research. Immediate communication is planned for SNs/ NORS and Researchers and any controlled documents to be updated to ensure consistency in understanding and review date booked March 2022.

Summary

In summary the numbers of organs accepted and removed for research following the implementation of INOAR in January 2021 have been lower than anticipated. Nevertheless, through stakeholder engagement and being responsive to feedback from internal and external stakeholders we are hopeful that in 2022 we can look to make some changes to our existing processes that will subsequently increase the number of organs offered and accepted for research when donor families have generously consented to or given authorisation for the removal of organs for research. A big 'thank you' also goes out to the Specialist Nurses and Hub Operations.

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