

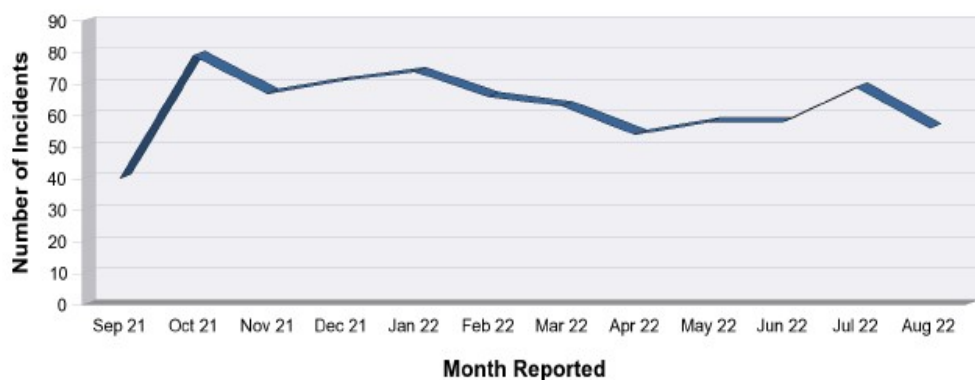
Cardiothoracic (Heart) Advisory Group ODT Clinical Governance Report November 2022

1. Status – Confidential

2. Action Requested

CTAG (Heart) are requested to note the findings within this report.

3. Data



4. Learning from reports

Date reported: 16th February 2022

Reference: INC 6122

What was reported
Donor lung histopathology 7 days' post-transplant reported "multiple granulomas with necrosis and mycobacteria on staining in donor bronchus tissue samples." Samples sent to reference laboratory for TB PCR.
Investigation findings
Five solid organs were transplanted from the donor; bilateral lungs, heart, liver and both kidneys – all recipient teams were informed by OTDT Clinical Governance (CG) of this post donation finding as were the clinical teams involved in the process.
The day following the report being submitted to OTDT CG, the lung recipient

centre informed NHSBT that they had received a “positive mycobacterium tuberculosis (MTB) DNA result obtained from the fixed bronchial tissue which had abundant acid-fast bacillus (AFB) by microscopy.” All involved parties updated by CG.

Statutory Reporting to the UK Health Security Agency (HSA) was undertaken by the lung recipient centre who then co-ordinated a national incident group to work with all parties involved to ascertain the necessary actions.

Donor characterisation

Following confirmation of neurological death, a chest X-ray was completed as part of donor characterisation.

Due to the time scales involved there was not a formal radiology report available for review prior to organ donation proceeding so the ICU clinician reviewed as per process. It was documented as “normal” on the Core Donor Data Form available to centres at the time of organ offering. As usual process, an image of the chest X-ray was taken by the SNOD and forwarded to Hub Operations to be sent to any cardiothoracic centres considering the lung offer(s). There did not appear to have been any other chest X-rays undertaken during the patient’s admission.

During donor characterisation attempts were made to contact the patient’s General Practitioner (GP) who was outside the UK; this was unsuccessful and therefore was to be followed up the next working day. The patient had been living in the UK for 5 months.

Following review of the donor Medical and Social History (MaSH) which was undertaken with the patient’s husband and brother-in-law with an interpreter. there were no responses to any of the questions which were suggestive of TB. The only thing of note was the patient’s place of birth and their recent move to the UK.

Retrieval process

Following completion of the retrieval operation, the cardiothoracic organs were packed ready for transport. At this point a donor hospital ICU clinician contacted the SNOD team to make them aware that the chest X-ray had been formally reported and it stated that there was a right upper lung nodule approximately 14mm in size. The formal chest X-ray report was emailed to Hub Operations for onward dissemination to recipient centres if requested.

The post retrieval information was immediately communicated by the SNOD to both the cardiothoracic (CT) NORS Lead Surgeon who was still present in theatres, and all accepting centres. The lead CT NORS retrieval surgeon also immediately contacted the accepting lung transplant surgeon to verbally communicate this post retrieval finding. A few hours later the interim histopathology report was communicated verbally by the lung implanting centre as a “non-malignant necrotic nodule” - formal laboratory report was pending. All centres were updated as appropriate.

During the investigation the CT NORS retrieval surgeons confirmed that they reviewed the donor chest X-ray shown by the donor hospital SNOD on the local imaging platform. They stated that it was “perceived and interpreted that there were no gross abnormalities in the donor’s chest X-ray.”

During the routine direct inspection of the lungs during the CT retrieval process the CT NORS retrieval surgeons stated that “there was no obvious gross abnormality seen or detected on manual palpation.” The cardiothoracic retrieval surgeon spoke directly with the cardiothoracic transplant recipient coordinator to discuss lung anatomy. No concerns were reported to the SNOD. There was nothing abnormal noted on the cardiothoracic HTA A form or documented in the operative record.

Post donation

Information from the GP was gained verbally (via an interpreter) a few hours post retrieval. The only new information that was not available during donor characterisation was related to a question regarding any prescribed medications. The patient had a history of antibiotics and anti-inflammatories for previous chest infections in 2014, 2015 and 2020.

When the donor family were contacted to discuss the post donation clinical finding of TB, this was new information to the them and they reported that this had not been diagnosed in the past.

Learning

Ongoing process discussions taking place in relation to the review of the chest X-ray during donor characterisation and retrieval.

Prompt communication of the post donation formal chest X-ray report by the donor hospital ICU team and the lung recipient centre incident report to CG helped to ensure appropriate management and timely of the recipients.

NHSBT final investigation report has been shared with all parties involved.

Date reported: 9th May 2022

Reference: INC 6284

What was reported

Moderate damage was identified to a donor heart on visualisation at transplanting centre.

1. Tear/hole in interatrial septum
2. Minimal right side atrial cuff supplied
3. Left atrial appendage not present (assumed has gone with donated lungs)
4. Askew pulmonary artery - One side 1/2 cm above pulmonary commissure

The heart was successfully transplanted following repair.

Investigation findings

The investigation included input from the NORS retrieval team;

1. After explantation of the heart the organ was inspected at the back table as per standard protocol. The tear/hole in the interatrial septum was identified and addressed. This finding was discussed in a timely way with the team at the implanting centre and confirmed that this would not be a contraindication to completing a successful transplant. The discussion with the lead retrieval surgeon revealed that in their view it was not possible to state if the hole was created during retrieval or was a congenital pre-existing defect.

2. The presence of minimal right side atrial cuff is a common situation when heart and lungs are retrieved from the same donor. By its anatomical nature it is always very short and attempts to provide a large atrial cuff very often causes injury to the pulmonary veins making the lung implantation very complex and sometimes impossible. Successful transplantation of the heart was achieved suggesting that there was adequate material to complete the atrial anastomosis successfully.

3. The CT centre agree that the lack of left atrial appendage in the retrieved heart may cause serious consequences including damage of circumflex artery during the implantation or making safe implantation impossible. This was discussed in detail with their lead surgeon who stated that the LA appendage was attached to the heart. The CT NORS centre noted that the LA appendage stayed attached to the lung atrial cuff. The lead retrieval surgeon understands that this is strictly against the routine retrieval technique. As per standard protocol the heart is vented through the LA appendage and they believe that the hole created to vent the heart may produce the impression of lack of LA appendage attached to heart.

4. The Team identified that the cut which is ½ cm above pulmonary commissure does not preclude safe implantation of donor heart. It appeared to the CT NORS centre that this was a correct position for the amputation of the pulmonary trunk as again it helps to ensure that the lung tissue has an appropriate length of pulmonary artery to secure successful and safe implantation while allowing the cardiac surgeons an adequate length of tissue to complete a successful and safe pulmonary trunk anastomosis. The CT NORS centre reported that discussions around length of the vessels in transplantation are quite common and very often a comment that something was 'too short' can potentially be subjective depending on who is assessing.

We asked an independent expert for their clinical opinion of the collated information.

In relation to the report of the minimal right-side cuff, the CT consultant surgeon identified that this could be a left atrial cuff as the heart is always explanted with IVC and SVC cuffs. The IVC cuff can be short because of the need to leave adequate cuff for the liver team. If the reporter did mean 'left atrial cuff' then it can happen on occasion when both the lungs and heart is

used. If the retrieval surgeon errs on the lung, then the lung surgeon gets inadequate cuff. This is part of heart/lung transplant field where the surgical teams often face inadequate cuff that needs patching work. It is normal practice to vent the lungs but cutting or sometimes amputating LA appendage. If the lungs are not used, then the retrieval team can divide the pulmonary veins. Here the lungs were used so dividing LA appendage is usual practice. If there was adequate stump of LA appendage it is usually repaired on table before implant. The CT consultant didn't think this was considered as damage as it is normal practice.

Learning

The NORS team held detailed discussions to utilise the case as a learning experience. The independent clinical expert recommended sharing via the CTAG-Heart forum for interest noting that when the heart and lungs are being used it is not uncommon to face some issue with length of cuff available. Here the pulmonary artery was cut askew but well above the valve. In the CT consultant surgeon's experience, it is usual to keep the recipient PA as short as possible to avoid any kinking and recipient's native heart is explanted to leave full length of PA left behind.

Date reported: 19th April 2022

Reference: INC 6244

What was reported

Three cases related to mismatch ABO organ allocation have been reported. One of these cases was a near miss and the other two were identified early in the pathway. The cases highlighted the importance of the safety pauses and checks embedded in the process.

Investigation findings

In all cases, the blood group of the donor was entered onto the Core Donor Data Form incorrectly. The documented blood group was then used in the automated matching and allocation process. As the blood group recorded was incorrect, the organs were offered and accepted for ABO incompatible patients. In each case the issue was identified prior to transplantation, matching runs were re-executed and organs re-offered according to the corrected blood group in all cases.

Learning

We have completed a full pathway review of the blood group process using a 'systems' thinking approach. This review started at the point of the blood group request at the donor hospital, through to the organ arriving at the hospital of the intended patient. We have identified 60 actions needed to strengthen the pathway. These are currently being addressed with all

stakeholders.

More details of the review can be found in Cautionary Tales:

<https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/27538/cautionary-tales-september-2022.pdf>

Many will be aware that a 4th case relating to a blood group error has been received. This event led to three recipients receiving unintentional ABO incompatible organs.

The factors relating to this case were significantly different to the previous cases. The donor had received a massive blood transfusion. The hospital IT system recorded the donor blood group as O although the patient's true group was B. This case is currently under investigation in conjunction with the hospital. Learning and findings will be shared.

5.Trends noted

Several cases have been reported relating to flight availability for organ transportation. Since the beginning of the year there has been an increased demand within the UK and across Europe for chartered flights. On occasions there have been difficulty in reopening or extending the opening of airports due to staff sickness and shortages amongst handling agents and security staff as activity resumes following Covid19.

Commissioning and IMT have commenced joint visits to transplant centre sites to meet staff and explore the issues fully. The teams have put together an action plan to mitigate against impact on the service. Commissioning continues to monitor all transport-related cases reported.

6.Requirement from CTAG-Heart

Note findings in this report

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