

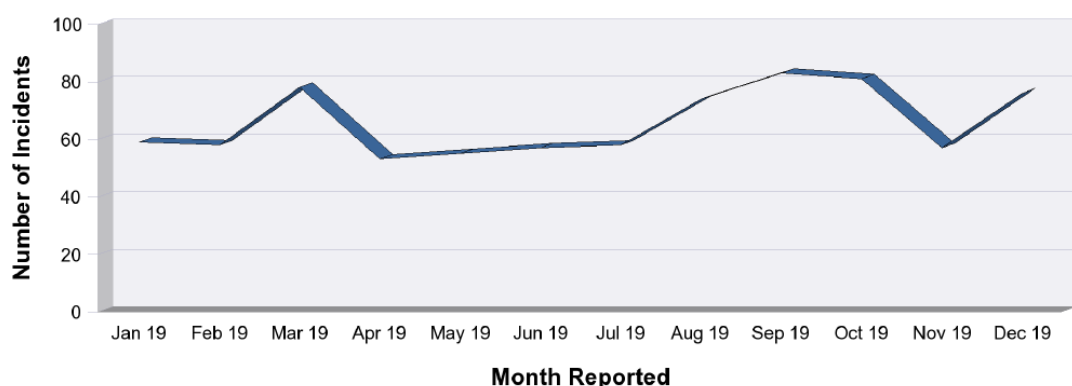
Retrieval Advisory Group ODT Clinical Governance Report March 2020

1. Status – Confidential

2. Action Requested

RAG are requested to note the findings within this report and respond to the questions raised below.

3. Data



4. Learning from reports

Below is a summary of the findings and learning from key clinical governance reports submitted to ODT:

Date reported: 21st February 2020

Reference: INC 4634

<p>What was reported</p> <p>Liver declined when assessed at accepting centre on function; liver on OrganOx. Re-offered and a different centre expressed an interest to accept for transplantation. Request made for liver to be transported to second accepting centre on OrganOx (with the aim to return OrganOx machine back to original centre). Initial accepting centre did not wish to transport OrganOx machine and offered to place liver on ice and transport. Liver declined.</p>
<p>Investigation findings</p> <p>The use of the OrganOx machine is not a commissioned service and therefore is facilitated by individual centres.</p> <p>There is no national agreement regarding the transportation of livers accepted and subsequently declined whilst on the OrganOx.</p>

Learning

As the use of machine perfusion is increasing, it is suggested that a national agreement around the sharing of organs whilst on machine perfusion, such as OrganOx, is considered. A small group chaired by Derek Manas will review this option. This will also be raised at LAG for awareness.

Date reported: 3rd December 2019

Reference: INC 4460

What was reported

Liver retrieved by NORS team and placed onto the OrganOx by the accepting team at the donor hospital and transported back to base. The travel time was estimated at 1hour 40minutes. The battery on the OrganOx was checked while plugged in at the donor hospital and was recorded at 95% and was 89% when transported to the vehicle.

The OrganOx was plugged into the power supply (believed to be the correct power source) in the back of the ambulance. Both when transferring the OrganOx to the vehicle, and during transportation the alarm activated; however, it was a code that OrganOx support had advised can activate when going over bumps and should settle down on smooth roads. The vehicle was stopped at approximately 03:20am to check the alarms, no issues with the machine were identified and the team continued.

When the team arrived back at base at approximately 04:25am, 1hour and 38 minutes after leaving the donor hospital the OrganOx was found to be fully shut down, with no visual display or obvious power. The OrganOx was immediately mobilised to the transplant theatre, an emergency cold flush was given with liver preservation solution (UW). The liver was subsequently deemed untransplantable.

Investigation findings

Following OrganOx internal investigation it was shown that whilst the OrganOx was plugged into the back of the ambulance, it was in fact running on battery. Following discussion with Amvale it was confirmed that the vehicle used to transport the OrganOx did not have a direct power inverter fitted. The device was plugged into a cable that was fed from a 12v power supply which will only supply a fraction of the power required to run the OrganOx. Engineers found the device would continue to try and draw the required wattage. It is believed that the action of plugging the machine into an inferior power supply may have resulted in damage to the power circuits. This damage caused the second battery (of two) to fully discharge in 11minutes.

Learning

Amvale have confirmed that not all of their vehicles have inverters fitted that can provide a stable and satisfactory 240v power supply and so cannot provide assurances that the organ transport machine can be adequately charged whilst in transit. Therefore, the guidance is:

1. Machines should have adequate battery supply to support transportation of an organ from the donor hospital to the accepting centre without the reliance of a power source in the vehicle (as there is no guarantee this will be available).
2. All individuals transporting any organ on machine perfusion should be made aware of the above risk.
3. If teams have the use of one transport vehicle, a 'dry test' should be

undertaken to ensure the power supply is adequate.
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Date reported: 19th November 2019

Reference: INC 4427

What was reported

The NORS team were mobilised to a known Hepatitis C (HCV) positive donor; both kidneys had been accepted. Upon arrival the NORS surgeon raised concerns around the coagulopathy (abnormal clotting) in light of the positive virology result and requested further bloods were sent.

The repeated clotting results showed the donor had worsening coagulopathy; the NORS surgeon was uncomfortable proceeding in the presence of uncorrected coagulopathy and the associated bleeding risk in a Hepatitis C positive donor. Following conversation with the Clinical Team a decision was made to transfuse FFP and platelets. The process of awaiting results and locating platelets led to a 6-hour delay to retrieval.

Investigation findings

Whilst on reflection the NORS team felt they would not change their management if the situation arose again, they also raised that as the utilisation of organs from Hepatitis C positive patients is likely to increase, more guidance would be welcomed.

Due to the uniqueness of this case a second review was completed by the Chair of the Retrieval Advisory Group and the below guidance has been provided.

Learning

1. The closest parallel to this situation is hepatectomy in HCV+ viraemic patients with liver failure. Such may receive platelets and factors in the immediate pre-operative phase, but this may not be required until after the operation has commenced. Bleeding in such patients generally relates to 'raw areas' created during mobilisation rather than coagulopathy per se.
2. There is no absolute need for pre-op platelets or factors, but it is likely that an anaesthetist would have factors/platelets available (as with any surgical procedure in a coagulopathic patient). A decision should be made collaboratively with the anaesthetist before surgery. If it is felt products are required, this should not delay retrieval, nor should there be any need to check laboratory investigations of coagulation once factors have been given. In fact, the time delay involved in such testing allows the effect of factors to wear off.
3. It is essential to minimise transmission risk in HCV+ donors. Full PPE including eye protection is required for any retrieval process. If desired, the use of sharps can be minimised (open with diathermy). Transmission risk logically relates to penetrating injury rather than the volume of blood loss. Therefore, bone fragments generated during sternotomy are likely to be the major risk to staff. Correction of coagulopathy would not change transmission risk in the event of a sharp injury in this case.

Date reported: 31st August 2019

Reference: INC 4228

What was reported

Centre accepted a multi-visceral offer and planned to mobilise for multi-visceral

retrieval. As they were not on call the centre stated they were unable to retrieve full abdominal organs and that the on-call NORS team should be mobilised. Following discussions with the Regional Manager the on-call NORS team mobilised alongside the multi-visceral team.

Investigation findings

Whilst the NORS Standards (MPD1403) stipulate that the accepting intestinal centre must also retrieve all abdominal organs, following full review with the centre and the Commissioning team it was acknowledged that it was not reasonable to expect an 'off-duty' team to provide a full NORS team.

Learning

An interim measure has been agreed that in 'off-duty' weeks an intestinal team can mobilise the appropriate team for intestinal/multi-visceral only, and the 'on-call' NORS team will be mobilised for all other abdominal organs.

It has been agreed for the Chairs of RAG and MCTAG, who were both present at the review, to discuss and agree a resolution for the retrieval of the multi-visceral organs.

Date reported: 30th August 2019

Reference: INC 4225

What was reported

Proceeding DBD. Due to logistical and surgical complexities (heart-liver patient) a decision was made to transport the heart on the OCS. The NORS team attended the retrieval as standard, and the accepting team also attended theatres with the OCS machine.

During the final stages of the retrieval, a request was made to commence cardioplegia (as standard). Once the cardioplegia delivery was started there was good aortic root pressure and at this point it would be expected that the heart would arrest. After 4-5 minutes it was identified the heart was fibrillating and not arresting. At this point it was highlighted that the concentrated cardioplegia solution had not been added to the bag of ringer lactate that had just been delivered into the aortic root; 40 mmols of Potassium chloride was requested and directly injected into the aortic root.

The retrieval proceeded and the heart was handed over to the accepting team who placed on the OCS. The total time from cross clamp to handing over the heart was 12 minutes. After assessing the heart on the OCS for an hour it was reported that the LV contractions were severely reduced, the heart was oedematous, and the lactate levels showed an upward trend a decision was made to not transplant the heart.

Investigation findings

As is standard, an agreement was made that the NORS team would retrieve the heart and pass over to the accepting team to place on the OCS. The NORS team arrived and to ensure no delay in retrieval, commenced the retrieval whilst awaiting the accepting team to arrive.

The NORS team had a brief discussion regarding cardioplegia preparation prior to commencing and it was decided to await the accepting centres team's arrival to clarify the solution to be used as it is known that different centres request different cardioplegia.

Following the accepting team's arrival discussions were had regarding cardioplegia close to cross clamp (due to the arrival timings); initially the request was for the NORS team to use what they would normally, however there was then discussions around the size of the bags used. Due to a lack of availability of the size bags the accepting team requested, the NORS team prepared the usual cardioplegia solution 5 minutes prior to cross clamp.

When the heart did not arrest it was identified that the cardioplegia had not been added to the solution and immediate steps to rectify were taken.

Learning

There were several points to highlight for either learning or further discussions:

1. The NORS team have now implemented clear drug addition labels for fluids. This makes it visually clear drugs have been added to fluids. Consideration should be made in making this standard practice across all retrievals.
2. The differences in cardioplegia solution led to a deviation to the 'standard' practice of the NORS team. CTAG (H) have been asked to consider having a national agreement of cardioplegia to prevent last minute request of what is utilised.
3. That the error was highlighted to enable immediate corrective steps and that the review has focused on ways to strengthen the process highlights excellent practice.

5. Requirement from NRG

INC 4225 – Consider if the use of drug addition labels should be standard practice for all NORS teams.

Author

Jeanette Foley
Head of Clinical Governance
Organ Donation and Transplantation