

## Clinical Governance report Heart - September 2017

In a 7 month period, January to July 2017, there were 108 reported Incidents where the Heart was mentioned as one of the Key words. This is an increase compared with previous reports, where the numbers were 47, 49 and 45 Incidents in 6 month periods.

However, only 38 of the Incidents actually involved the heart, compared with 32 in the previous period. The increase in the total is therefore a reporting phenomenon rather than a real change

Two incidents were highlighted, through a new mechanism, by the Governance Team

No less than 24 of the Incidents relate to **Retrieval**, and in 101 cases it was due to delays in the NORS teams. These delays ranged from 40 minutes to 6 hours. As an example, one was due to the team insisting on having a plane for a journey quoted at three hours. No plane was readily available, and after some discussion, the team came by road, arriving 40 minutes after the planned time. One was due to high activity, and no team available

It is anticipated that with the Duty Office assuming responsibility for mobilizing NORS teams, better communication and more oversight of the national situation will minimise these delays.

Other Retrieval issues include a complaint that there were 30 people in the operating theatres, for a TA-NRP retrieval. On one occasion, the NORS team could not place a neck-line with ultrasound control. On another, the accepting centre would insist that the NORS team perform a TOE. This is not a part of the routine of the team, and is not in the NORS standards.

One of the highlighted cases concerned loss of a heart because of overheating on the OCS machine – at one point the perfusate reached 41.5C. This was thoroughly investigated by Transmedics, and is thought to relate to the sequence in which the various components of the monitoring system were connected. Transmedics state that they have written to all users to highlight this rare and preventable problem

A surgeon filmed the retrieval, which was being done in his hospital, by an outside team using the OCS machine. There was no consent for filming, and despite the surgeon claiming it was for Education, he was instructed to delete the images. Filming is entirely reasonable if it is to aid decision making about the organ. NHSBT has a set of very clear rules for transmission and then deletion of the images. Filming for education requires donor family consent.

The final retrieval problem revolved around contaminated transport ice

### **Contaminated Ice**

A number of instances of contaminated ice in transport boxes were reported, and coalesced into a single Incident. Following initial discussion, Prof Kate Gould, from Newcastle reported her investigations. Her lab had identified positive cultures from the ice surrounding thoracic organs, and she then instituted routine culture. She then described the course of events in Newcastle, and came up with some recommendations

In Newcastle 214 samples were tested of which 76 were positive. They were mostly gram negative environmental bacteria but the numbers are significant. The ice from machines is not expected to be sterile but if the machine is maintained and used correctly the numbers of bacteria should be insignificant. When contaminated ice from the Freeman Hospital was investigated, she discovered that the ice machines were not being maintained and at the bottom there was a nasty brown sludge.

Ice machines were replaced and the cardio theatre team was given a protocol to keep it clean, but at that stage many other users collected ice from the machine. After 2 years she again noted positive samples and the machine is currently being replaced again. This time there will be one in the clean area of theatre, reserved for transplants and another kept in the dirty corridor for the adult and paediatric ITU's.

It has been argued that it does not matter that the ice is contaminated because it is not in contact with the organs. Never the less, the bags are opened in theatre and the heater cooler incident has alerted us to the possibility of low level aerosol formation causing serious infection.

Prof Gould has contacted Microbiologists in the other centres when she has had positives from them. This network has been very aware of the problem and she has supplied centres with the local SOPs because their ice machines were in a similar state to the Freeman's in 2014.

Finally, the ice from machines frequently grow *Mycobacterium chelonae*. This is not surprising because it is in the Northumbria water supply. Other supplies may have other *Mycobacteria* and this was the original source of *M.chimeriae*. The sequelae of the *M Chimeriae* infections are well known to the whole cardiothoracic community

It is recommended that transplant retrieval teams use ice only from machines maintained to a high standard and follow the device manufacturer's instructions for care/maintenance, and test approximately monthly. All centres should have their local ice machine maintenance/cleaning protocol. Although there have been no direct links between positive ice cultures and post-operative infections in transplant recipients, Prof Gould's view is that it is only a matter of time before such infections occur. The issue of atypical mycobacterial contamination is a particular concern, and the *M Chimeriae* experience should serve as a warning. The only way to prevent any risk from ice from ice machines is to use sterile ice which is more expensive

**Transplant Centres/Duty Office**

There were some minor errors in allocation in the Duty Office, but this did not disadvantage any recipient

There were several instances of very late decision making. At a heart-only retrieval, the heart was declined after knife to skin as a result of re-interpretation of the TOE.

Another was declined 45 minutes before cross-clamp, for logistic reasons. There was an offer to delay retrieval, but all other centres declined on function

One heart was declined *after* cross-clamp because of new onset of AF. There was poor communication between the accepting centre and the SNOD, but the donor was aged 22, 180cm tall and 100 kG, so potentially a very good heart. No other centre was able to use the heart

There remain issues with damaged heart valves, and complaints about the suture in the PA. The decision to leave only the PA bifurcation on the lungs when not retrieving the hearts is still ignored on occasions – there was an 8mm PA on one heart.

There has not been a meeting of the heart valve bank group since the last CTAG, so a decision about our offer to remove the suture is awaited. The group meet on September, and the issue is on their agenda. Any decision will be relayed to CATG members