Cautionary Tales
in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 10, January 2016

Introduction

Following your feedback, during 2015 we have revised and simplified the incident reporting form. We know that often completion of an incident form can be bottom of the list when care of donors, donor families, transport, implantation and care of recipients are priority. Nevertheless, without these reports we are unable to improve and develop practice, learn lessons and make the process better for all those involved.

Often people think that an incident is a 'one off' or 'nothing to worry about' and feel that there is no benefit of reporting. However what may seem a one off in one centre may in fact be a wider issue across all centres. Near misses too, should also be reported as this will allow us to put measures in place to prevent recurrence of the incident and so prevent actual patient harm.

Reporting incidents is crucial in ensuring this wider oversight and, as illustrated by the cases in this edition, will allow learning and better outcomes.

Those incidents that seem simple, irrelevant or annoying may actually lead to a straight forward and helpful change. Those who are actually doing the work are also the best placed to suggest change.

https://www.organdonation.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx

---

The £10,000 Chest X-Ray….

Assessment of organs is always a challenge and doing this remotely is even harder. Surgeons will use all available options to make an informed decision regarding accepting or declining an organ: either way, the decision may lead to potential harm for the recipient. A recent case has highlighted that a common-sense use of technology can avoid unnecessary costs, use of resources and potential distress to patients and donor families alike.

Lungs were offered from a DCD donor who had active respiratory movement on CPAP. There was a history of heavy smoking and an abnormal chest x-ray. Despite best efforts, a bronchoscopy could not be organised. With this information, and because a flight would be required to mobilise the NORS team, the recipient centre declined. The second centre then accepted and the NORS team were flown to retrieve.

On arrival at the donor hospital, the NORS surgeon reviewed the chest x-ray and discussed the findings with the accepting surgeon. The anonymised image was then sent to the accepting surgeon who subsequently declined. The Cardiothoracic NORS team stood down prior to withdrawal of treatment.

Clearly no error was made; however this case shows the sensible use of photos and other images can allow better assessment and more effective use of resources.

Learning point

- The use of images may be a useful way to assess organs and the mobilisation of retrieval teams
- Transfer of chest x-rays and other images is acceptable as long as the principles of consent, annoyminity and confidentiality are considered
- Guidance and Principles – Donor Organ Photographs provides further guidance: http://www.odt.nhs.uk/pdf/guidance_and_principles_donor_organ_photographs.pdf

Perfusion fluid Incidents - Quarantining and others lessons

Quarantining fluid

Quarantining of fluid is not something that is undertaken lightly and is usually done following wide discussions and with significant evidence of adverse consequences. In the cases below, a decision to quarantine was made because of the seriousness of the outcomes and that donor transmitted infection in multiple recipients is uncommon.

A number of reported incidents regarding 'microholes' in 1 litre and 2.8 litre bags of Perfadex led to the quarantining of batches of both. The MHRA and HTA were notified and the bags sent to the manufacturers for examination. Following this, it was found that one of the 1 litre bags developed holes during the sterilisation process when the inner bag stuck to itself and tore during cooling to form a hole. The MHRA are continuing their investigation with the manufacturer to find out why these holes may form and whether there is a method to reduce recurrence. The other incidents were found to be handling issues.

Many of you will also be aware of the recent incident that led to the quarantining of specific batches of University of Wisconsin (UW) perfusion fluid. Initial investigation confirmed that Candida albicans contributed to the loss of one kidney graft and the death of a liver recipient. Candida was also grown in the transport fluid of the combined kidney/pancreas graft but the recipient had no adverse effect. Because of the significance of these findings and that there was no clear source of the Candida, a decision was made to quarantine the batches used during the retrieval to allow for the full investigation and microbiology testing to occur. Following discussions with the manufacturers, all countries that had received the UW from the same batch were also requested to quarantine the fluid. NHSBT worked closely with the recipient centres, manufacturers, NORS and SNOD team to look into the source of the infection. The HTA and the MHRA were kept informed throughout.

Thanks to everyone involved, the donor history and retrieval procedure was fully reviewed, perfusion fluid tested, swabs taken of ice containers and recipient isolates collated. Following extensive investigation and testing, it was confirmed that no Candida was isolated in any perfusion fluid, ice preparation at NORS centre, nor was there any evidence of Candida infection in the donor. The conclusion was that the infection with Candida may have arisen during the retrieval procedure.

Infection in perfusion fluid

The incident above also highlights a further issue. The detection of microorganisms in the transport fluid surrounding an organ is not uncommon. For example, a study in 2005 (Wakelin et al, Transpl Int;17:680-6) found that organisms were isolated from about 17% samples taken prior to allograft implantation and 45% of samples taken at retrieval. Broadly similar findings have been reported by others.

This raises some quandaries for clinicians.
Should preservation fluid be routinely cultured? An informal survey of UK transplant units shows there is no consensus on routine culture of preservation fluid. This is clearly a clinical decision and will be discussed with partners.

If culture of preservation fluid grows bacteria, should this be reported to all centres and should the fluid be quarantined? Given the relatively high frequency of positive cultures, the low impact and the number of

transplant units involved, such a policy would be a bureaucratic nightmare (or delight if you are a true bureaucrat!) and would flood clinicians with information that is probably unhelpful and may mask essential information. Our current advice is that non-standard bacterial infections should be reported to NHSBT to allow for wider dissemination as necessary and the findings discussed with a transplant microbiologist.

Should all recipients be offered antifungal treatment? Practice varies between centres and between organs. Again, this is a clinical issue that needs discussion between clinicians and microbiologists. However, clinicians should be aware that Candida is present in the gastro-intestinal tract. Retrieval of the pancreas involves transecting the duodenum and this almost inevitably leads to some contamination of the field by Candida; equally a nick in the integrity of the gastro-intestinal mucosa may lead to bacterial and/or fungal infection. Transplant clinicians should bear this in mind in the prophylactic antimicrobial regimen.

The HTA form

A final note on perfusion fluid. The HTA B forms currently read "Was the organ perfused after receipt?" It has been highlighted that because of the wording of this, some transplant teams are not recording the perfusion fluid batch number and type if they have only *submerged* the organ (i.e. put it in a bowl with some perfusion fluid, but not actively perfused it). Advice has been sought from the HTA who have confirmed that the perfusion fluid details must be recorded whenever it is used, not only when active perfusion has taken place.

Learning points

- There is a possible risk of fungal contamination if the pancreas is retrieved
- When positive ***fungal*** cultures are grown from transport fluid, this should be communicated as new clinical information to allow for this information to be disseminated to other recipient centres who received organs from the same donor
- Any breaches of the gut during organ retrieval should be communicated to any accepting recipient centres
- Ensure any concerns with perfusion packaging are reported to the manufacturers as well as NHSBT. Whilst NHSBT will ensure information is communicated to all centres, the manufacturers will ensure full investigation of packaging
- To allow full traceability, perfusion fluid used to perfuse *and* submerge organs should be documented on the HTA A and B forms

Organs retrieved for non UK residents

When there is no suitable recipient in the UK for organs donated in the UK, these organs are offered for transplantation in other jurisdictions. There is an established process for organs retrieved in one country being offered elsewhere. This is a reciprocal arrangement and the annual balance is published on the ODT website. Between 1st April 2014 and 31st March 2015, 9 organs were accepted and transplanted outside the UK, including the Republic of Ireland. Whilst this is not a common occurrence, occasionally surgeons from the accepting centre will wish to attend the retrieval.

Whilst the accepting surgeons may attend the retrieval, there are two clear principles that must be followed:

- The retrieval should not be delayed or prejudice the chance of donation by awaiting the arrival of the accepting surgeon.
- The retrieval must be done by members of the NORS teams. Surgical members are required to be assessed as competent before being allowed to retrieve within the UK and must be aware of, and follow national guidance. Whilst a visiting surgeon may be experienced, they will not be signed as competent within the UK framework.

The importance of adhering to this guidance was highlighted in a case where the heart was accepted for a non UK patient and the lungs accepted for a UK patient. The visiting surgeon led on the retrieval of the heart and

when the NORS surgeon continued, it was highlighted that the pulmonary vein had been cut too short and the lungs were deemed untransplantable. An otherwise transplantable organ was lost.

Whilst the visiting surgeon may not have made an error as such, the retrieval was not carried out in the manner a UK surgeon would have. A clear discussion and agreement of the requirements may have prevented this occurring.

Learning point

- Visiting surgeons can attend a retrieval; however it is the NORS surgeon who should carry out the retrieval
- Worldwide, organs are a precious resource, and therefore discussions should be had with all parties prior to a retrieval to ensure the possibility of transplantation is maximised, where ever the transplant may be occurring

Donor derived Transitional Cell Carcinoma

Transplantation is associated with many risks, including transmission of donor diseases, which may be infectious, malignant, metabolic or autoimmune. Cancers from donors may be donor transmitted (where the cancer is transplanted with the organ) or donor derived (where the cancer develops in the transplanted organ).

Two cases were recently reported regarding two renal recipients from the same donor developing a transitional call carcinoma. Whilst this in itself is not unusual, the time frame between diagnosis and transplantation was relatively short, and both recipients developed the same complication.

Following the initial report, the full donor history was reviewed, including original source, to ascertain if there were any omissions or whether there was any relevant information that was not available or highlighted at the time of donation. Whilst the donor had a lengthy medical history, this was communicated, and it is not felt that any of this information could be related to the subsequent diagnosis and there were no indications of a pre-existing renal tract malignancy.

Expert advice was sort from an uro-oncologist and a specialist pathologist. They felt that there was some intrinsic instability in the urothelium in both kidneys which, under immunosuppression, led to synchronous primaries in the recipients.

There was no evidence of renal tract malignancy in the donor, who by chance, had undergone multiple investigations relatively soon before their death. All the relevant information was provided to the recipient centres, who made entirely appropriate decisions. These cases were reported to the HTA as Serious Adverse Reactions, and both the HTA and NHSBT believe that it was a very unfortunate instance of donor-derived urothelial tumours, occurring in both recipients from a single donor.

Learning point

- Malignancy from the donor may be donor derived or donor transmitted
- Conditions associated with unstable epithelium may lead to donor derived cancers
- Donor cancers are an accepted risk of transplantation that cannot be absolutely mitigated

Heart Valve Damage

If neither the heart nor lungs are retrieved from a multi-organ donor, the heart and importantly aortic and pulmonary valves will often be removed by the NORS team. When the lungs alone are removed, in either a

DCD or DBD donation, there is clearly still scope for retrieval of both valves. The aortic valve is obviously not a problem, but there have been a number of recent incidents reported by tissue banks that the pulmonary artery is too short for the valve to be used.

For most applications involving pulmonary valve implantation, only the artery up to the bifurcation is required. (Complex reconstructions involving main pulmonary arteries cannot be performed with the valve if the lungs are being retrieved). When lungs are retrieved from the donor, the division of the pulmonary artery should be at the level of the bifurcation.

The cannulation site will obviously be included in the specimen, but this is unavoidable. However, the implantation of the lungs will not be jeopardized by this distal division, and importantly more usable pulmonary valves will be supplied to tissue banks

Both organs and tissues are a limited resource, and all efforts should be made to both maximise these and ensure that the wishes of the donor and their family to help others is carried out.

Learning point

- When lungs are retrieved from a donor, the division of the pulmonary artery should be at the level of the bifurcation
- Implantation of the lungs should not jeopardized the retrieval of usable pulmonary valves

Care of potential lung DCD donors

Following a number of incidents, NHSBT has worked with key stakeholders and recently issued a Safety Alert - available on:

http://www.odt.nhs.uk/pdf/Lung_DCD_Safety_Briefing_Dec_2015.pdf

The key points to highlight from this are:

- DCD lung retrieval requires careful planning and close collaboration between all of those involved in the care of the patient, including the organ retrieval team.
- Protection against airway soiling: If the patient has been extubated as part of treatment withdrawal, the airway should be re-intubated as soon as possible after death has been confirmed.
- Lung ischaemia: The lungs should be inflated with a **single** vital capacity breath of oxygen-enriched air. **A minimum period of ten minutes from the onset of irreversible asystole** must elapse before performing this manoeuvre.
- Ventilation: Cyclical ventilation of the lungs is **not** allowed until the retrieval team have started to flush the lungs and have vented the left atrium.

Learning point

- Donation and retrieval teams must be aware of the legal and ethical issues surrounding organ donation and follow them
- SNODs and others must feel empowered to raise concerns if there are concerns that the guidelines are not being followed

If you have any comment, feedback or suggestion regarding the Cautionary Tales, please contact **clinicalgovernance.odt@nhsbt.nhs.uk**