Cautionary Tales
in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 6, May 2015

Introduction

Incidents can potentially be seen in isolation and sometimes the 'bigger picture' can be lost. It is important therefore to ensure that incidents are reported; we will then ensure that each incident is reviewed and lessons learnt alongside other aspects of good governance.

Within ODT we work closely with the Clinical Audit Team to ensure any trends noted are linked into the audit schedule. This allows any wider issues to be identified so that we can audit the pathway or process to reassure everyone that the errors are mitigated. In future editions of Cautionary Tales we will highlight the role of audit and how the findings from audits integrate with incident reporting to improve patient safety.

Over the past few months there has been a significant decrease in incident reporting. Currently it is felt that this may be associated with a reduction in organ donation, retrieval and transplantation activity; however this decrease will be monitored.

With over 1200 potential donors and 6000 potential recipients each year, we do require some information in order to identify the donor and/or recipients, and a clear background of the incident so we can investigate appropriately. So while we have tried to get the minimum data set as small as possible, please complete as much as you can. Messages and grape vine discussions that 'an issue should be logged' can be difficult to trace and follow up with any confidence, so please do use the Incident Reporting form:

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

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Improvements to the Incident Reporting System

We are constantly looking at how we can improve the incident reporting system to ensure it is quick and easy to report any incidents. We are well aware that clinicians, nurses, scientists, administration staff and managers have many competing demands on their time, and conflicting priorities, and therefore we want to ensure that submitting an incident is as straight forward as possible.

With this in mind we have made the following improvements:

- The submission form is now active for 30 minutes prior to logging out (instead or 15 minutes). This allows submitters longer to complete the form
- The classifications defining where in the pathway the incident occurred, have been widened, and now include the tissue pathway, recipient registration and offering
- The classifications defining the cause of an incident have been reduced and simplified
- Once a form is submitted, there is now a save option which will allow submitters to generate a PDF copy of the report.

We listen to your feedback regarding the reporting system, and whilst we may not be able to accommodate all your requests, we aim to make the system as easy to use as possible.

If you have any feedback or suggestions regarding the on line form, please contact clinicalgovernance.odt@nhsbt.nhs.uk

Incidents with Coroner involvement

We know that there are significant regional variations across the UK in regards to involvement of the Coroner, and Procurator Fiscal (PF) in Scotland. However, there have been a number of recent incidents involving the Coroner where lessons learnt can help fulfil the wish to donate without adversely impacting on the judicial process. In this context, the prospective audit of Coroner/PF referrals has now finished; the findings are being analysed and, when completed, new proposals will be circulated for discussion with all interested parties.

One of these incidents related to a case where the SNOD asked the medical team caring for the patient whether the patient's death should be referred to the Coroner. The medical team felt that as there was a clear cause of death, referral was not required. Following organ donation, further enquiries were made by hospital staff and the clinicians agreed that the case should have been referred as the circumstances of the death were less certain than previously believed. The case was subsequently referred to the Coroner and an inquest held. The family took great comfort that donation proceeded and in this case the Coroner stated that they would likely have agreed to donation proceeding even if he or his officers had been contacted prior to retrieval.

In a second case, the Coroner was of the understanding that they had given consent for all organs except the heart to be retrieved for donation. The SNOD however understood that full consent had been given without any restrictions. The Coroner had discussed donation with the Medical Practitioner rather than the SNOD so this may have contributed to the misunderstanding. Again in this case there was no direct adverse impact on the inquest as the heart was donated for heart valves and therefore the Coroner was able to gain a full report from the Tissue Establishment.

Learning point

- Responsibility for referral to the Coroner/PF lies with the clinicians caring for the donor.
- However, the SNOD must work closely with the clinicians to ensure that any potential donor does not fall within a category that requires reporting. A full list of these categories and further information can be found here: http://www.odt.nhs.uk/donation/deceased-donation/organ-donation-services/role-of-hmc/
- If there is any doubt whether to report, it is advised that the responsible clinician should discuss the case with the Coroner/PF.
- Ensure that when seeking consent from the Coroner for organ and/or tissue donation to proceed, each organ and tissue is discussed and agreed, and this conversation is clearly documented, noting any restrictions where necessary.
- Unlike England, Wales and Northern Ireland, the Procurators Fiscal in Scotland have an agreed protocol in place. More details can be found here: http://www.odt.nhs.uk/donation/deceased-donation/organ-donation-services/role-of-procurator-fiscal/

Ocular Incident Management

From the 1st April, the ocular tissue pathway, which incorporates the consent and authorisation of potential eye donors, along with retrieval, processing, and supply, is now being wholly managed by Tissue Services. The change was introduced to simplify accountability and allow end-to-end visibility and planning of the supply chain, enabling improved planning to meet the needs of patients.

Now, every incident relating to the ocular pathway will be managed by the Quality Assurance Team within Tissue Services and not the ODT Clinical Governance and Quality Team. Whilst all incidents will continue to be investigated, the QA Team within Tissue Services will not routinely send an outcome response to the reporter, although relevant incidents will be discussed at OTAG.

Learning point

- It is important to be aware that whilst ocular incidents should still be reported via the same on-line system, they will be managed by the QA Team within Tissue Services and reporters will not receive a response.

Ice Cross-contamination Risk

It has been highlighted through a number of unrelated incidents that there is a risk of infection and cross contamination of organs from organ transport boxes. These incidents have varied from the isolation of a Pseudomonas species from the retrieval box and from ice machine samples. In other incidents, ice used in a heart retrieval grew a mixture of Pseudomonas, Stenotrophomonas and Cupriavidus and a recipient who developed a theatre acquired mediastinitis from which Enterobacter sp. was isolated. It is unclear if the potential contamination came from the ice used to pack the organs, or from the box itself.

Learning point

After review and discussions with Public Health Microbiologists, the following points have been highlighted to mitigate the risk of cross-contamination:

- Organ Transport Boxes should be cleaned inside and out with water and detergent, then with a chlorine based disinfectant.
- The outside of the box should be wiped with a Cliniwipe or Tristell wipe before the box is taken into theatre.
- Some companies recommend that ice machines must be completely emptied of ice once a week and the interior disinfected. Please ensure that ice machines are maintained in line with the manufacturer's/supplier's guidance.

Urgent Heart Acceptance and Decline

When a Transplant Centre accepts an Urgent Heart offer, the Duty Office record this acceptance to stop further offers being made for the same patient. If the offer is later declined, the Transplant Centre should contact the Duty Office who will then re-activate the patient. If the Duty Office are not informed that a Centre has subsequently not used the organ for that patient, that patient will not receive further offers.

In a recent incident, when the Duty Office contacted the Centre to enquire of the outcome of the transplant, they were informed that the heart was declined on inspection at retrieval. As soon as this was realised the patient was reactivated on the Urgent list.

On investigation it was found that the Duty Office had not been informed of a subsequent decline, however in this case the patient listed on the Urgent Heart list had luckily not missed a heart offer whilst deactivated. This incident has highlighted the importance of the need to inform the Duty Office if an accepted offer is subsequently declined.

Learning point

- An accepting centre must advise the Duty Office if they subsequently decline a previously accepted organ. This is especially important in Urgent Heart patients.
- All those involved in the donation, retrieval, offering and transplantation pathway must have a clear understanding of their responsibilities; Work is underway to provide clear guidance.

Pre and Post Transfusion Samples

We have had a number of recent incidents where post transfusion samples that have been used for microbiology testing have produced significantly different microbiology results to the pre transfusion sample. On one occasion CMV IgG, Toxoplasma IgG and Hepatitis B core antibody were all negative on the pre transfusion sample and were all found to be present in the post transfusion sample.

Following investigation, it was found that the patient had received not only three units of red cells, but also immunoglobulin. Following discussions with Clinical Microbiology it was felt these were ‘passively acquired antibodies’.

Blood donors are not routinely screened for some microbiological markers, including anti-HBc, anti-HBs, CMV IgG, EBV IgG and toxoplasma IgG. Antibodies can be acquired passively through transfusions, and so antibody may be found in a post transfusion sample. Their presence is transient and do not necessarily indicate that the patient is infected.

Learning point

- A post transfusion/haemodilution sample is **not** required if an adequate pre transfusion/pre haemodilution sample is available, and testing such samples may give misleading or confusing results.
- Ensure all blood product/component information is included on EOS and microbiology request forms to allow for accurate interpretation of results by transplant centres/microbiologists.
- It is important to note that any samples sent with an organ may be a post transfusion sample and therefore may produce differing results if compared with the original pre transfusion sample. These results need to be interpreted within this context.

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