Cautionary Tales
in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 3, Summer 2014

Introduction

All activities are associated with risk and organ donation and transplantation is associated with probably more varied risks than other therapeutic interventions. If one accepts a risk of a complication of 1 in 1000, this means that, in 999 cases, the event will not happen but in 1 case it will – but this does not mean that anything has gone wrong, merely that the risk assessment was precise. Of course, risk and error are very different: errors can and do happen, humans can and do make mistakes and processes can fail. When errors or incidents do occur, it is essential that this is acknowledged and recognised, reported, investigated and, where appropriate changes made to reduce the risk of reoccurrence.

As practising clinicians, we are well aware that not all incidents are reported, and often there is a belief that little notice is taken and feed-back is uncommon. We are also aware that relying on incidents gives a biased view of where our risks are, so incident reporting must be complemented by other approaches, including audit, outcome monitoring and observation. The purpose of Cautionary Tales is to provide feedback to health care professionals and others involved in donation and transplantation for several reasons:

- **To show that all incidents are investigated and appropriate action taken**
- **Lessons learned can be shared**
- **Encourage further reporting**
- **Encourage a positive patient safety culture**

In the next edition, we will also list some of the many changes that have been made as a consequence of reported incidents so do please report incidents where things did or could have gone wrong so everyone can learn and reduce harm to patients.

We ask all those involved to report all incidents that did or could result in harm using the online electronic process:

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

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Learning from Incidents

Reliance on back up systems:

Following routine testing of CMV in an organ donor the result of CMV infection was incorrectly recorded as negative instead of positive. An organ was transplanted into a CMV negative recipient who was not given CMV prophylaxis and subsequently developed CMV disease, which was successfully treated. The transplant unit had sent the donor blood for repeat CMV testing in their local labs but no one had checked the results. If this had been done, then the discrepancies in CMV status would have been noticed. The back-up in this case was ineffective, provided false reassurance and wasted resource.

In another case, the donor blood group was tested by conventional serology as A; however, the laboratory testing HLA genotype also tested, by genotyping, the blood group and reported this as B. The serology was repeated on a separate sample and again confirmed as A. After several phone calls, inevitably at night, the staff were informed that genotyping is sometimes incorrect and the donor blood group was A, as confirmed by serology. This additional testing of blood wastes money and may cause confusion. The delay did not, in this case, result in organ loss but the impact of longer cold ischemic times may have been significant. H and I labs have been asked to stop using genotyping for blood group.

Learning point

- Back-up systems only work successfully if appropriate and used effectively. Don't rely on back up to detect errors – focus on getting it right first time.

Reliance on IT Systems:

An H and I laboratory reported to ODT that a particular patient was not active on the renal transplant waiting list although they had requested listing some 7 months earlier. The patient was not listed because of a computer error in the laboratory software which meant the data was not sent to NHSBT. The patient was activated and the waiting time adjusted; subsequent investigation suggested that, in this case, the patient had not been disadvantaged by the error. The laboratory has corrected the software problem.

During retrieval some small lymph nodes were found around donated lungs; although the retrieval surgeons were not unduly concerned, the lungs were placed on EVLP until node histology was available. The liver appearance was also slightly abnormal so the liver implanting team took a biopsy which showed features suggestive of chronic lymphatic leukaemia (CLL). Organs were used for research. Investigation showed that there was a high white cell count present in the donor. The electronic results in the donor hospital contained a comment that the features were strongly suggestive of CLL. Discussions did take place between the ICU staff, SNOD and RCPoC regarding the raised white cell count. However on this occasion the ICU staff were not aware of the cause as they had not been contacted by the local laboratory, and the SNOD did not have access to the hospital's laboratory report system (due to information governance concerns). The bio-chemical profile was taken from the Intensive Care blood result sheet on the night of donation. So no relevant person was aware of a critical piece of information that could have affected several patients had the clinicians not chosen to perform a biopsy of the liver pre-operatively. This incident has led to changes within the local Trust in regards to vital clinical information being verbally communicated to the ICU immediately.

Learning point

- Do not place undue reliance on IT: Check the data and use clinical judgement
- Where there are abnormal bio-chemical markers ensure conversations are had to discuss possible aetiology

Living Donation:

There have been two incidents where low volumes of perfusion fluid were present around kidneys during transport and ice was found in contact with the kidney by the recipient surgeon. In a separate incident, a copy of the HTA A form containing donor identifiable information was attached externally to the organ box. Investigations showed that the addressograph labels that are available in the NORS consumables pack may not be widely available to centres where living donor organs are retrieved, leading to local improvisation.

Learning point

- The standards for packaging and labelling organs for transportation must be consistent for both living and deceased donation and comply with the NORS standards to avoid organ damage.
- Boxes containing organs for transportation must be accurately labelled, using the approved addressograph label, so that the donated organ reaches the correct recipient without disclosing donor/patient identifiable information.

Lesions and biopsies:

In one incident, an implanting surgeon was concerned about a cyst on a retrieved kidney and requested histology prior to implantation. A biopsy was taken which showed a simple cyst. However, the biopsy was not completed under sterile conditions, and therefore the organ could no longer be transplanted.

Learning point

- Maintain organ sterility when taking biopsies
- Consider all organs for transplantation until confirmed by SNOD or Duty Office they are not accepted for transplant

We have had several reports of lesions being identified when the organ is undergoing back table dissection. The National Retrieval group have discussed this on several occasions and agree that the organs should be prepared for implantation by the implanting team and not the retrieval team. Some lesions will therefore not be evident to the retrieval team. If a lesion suggests a malignancy or other problem that might affect other recipients, please inform the Duty office immediately so they can pass on this information to other relevant teams for appropriate action.

Learning point

- Remember that significant lesions may be found on back table dissection
- Inform the Duty Office immediately of any new findings that might affect other recipients of organs or tissues from the donor.

Clinical updates onto EOS:

A surgeon noted that the renal anatomy that was recorded on EOS was no longer present when it was later checked. Investigations showed that the anatomy had been entered onto the wrong donor's record within EOS, the error recognised and corrected. However, the recipient teams were not informed of this error. No harm came to patients in this case.

Some results, especially microbiology, are not always available at the time of offering: for example, a HBV result was initially reported as pending before the report came back as Hepatitis B core antibody positive. In another case, the GP provided significant information regarding the social habits of the donor that raised the possibility that there were increased risk factors. Both incidents were classed as near misses, as no patients were harmed, but in both cases, the correct procedures of contacting the recipient team regarding significant changes or new findings had not been followed.

Learning point

- Report and act on any changes made to donor characterisation once an organ is being considered or has been accepted.

Potential transmission of donor derived conditions:

It is recognised that peanut allergy is transmitted by liver transplantation and we have already described a case where a liver recipient died from thrombocytopenia where the donor had severe ITP. We also described a liver recipient who developed severe problems from acute intermittent porphyria acquired from the donor, whose family were unaware, at the time of donation, of a positive family history.

In a recent case, a potential donor had a family history of Huntingdon's Chorea; he had no symptoms although was too young to show symptoms and had not been tested. There is little information about the risks to recipients, but it was felt that the organs should be offered: they were used in selected recipients and so far at least, none have developed any signs of HC.

In another case, an early protocol kidney biopsy showed unexpected features of lipid storage disease; the kidneys were from an otherwise healthy donor raising the possibility that the donor had a rare autosomal dominant metabolic condition, LCAT deficiency. There were concerns that such lipid disease may affect the recipients. Further and lengthy discussions suggested that these changes were likely to be secondary to hyperlipidemia in the donor rather than indicative of an intrinsic hypercholesterolemic syndrome such as lysosomal acid lipase deficiency, and were likely to resolve in time. By reporting such incidences and following up recipients, we can build a knowledge base to inform clinicians and make best use of offered organs.

Learning point

- Metabolic, autoimmune and other diseases may be transmitted by organ transplantation. NHSBT is building a database of donor transmitted diseases.

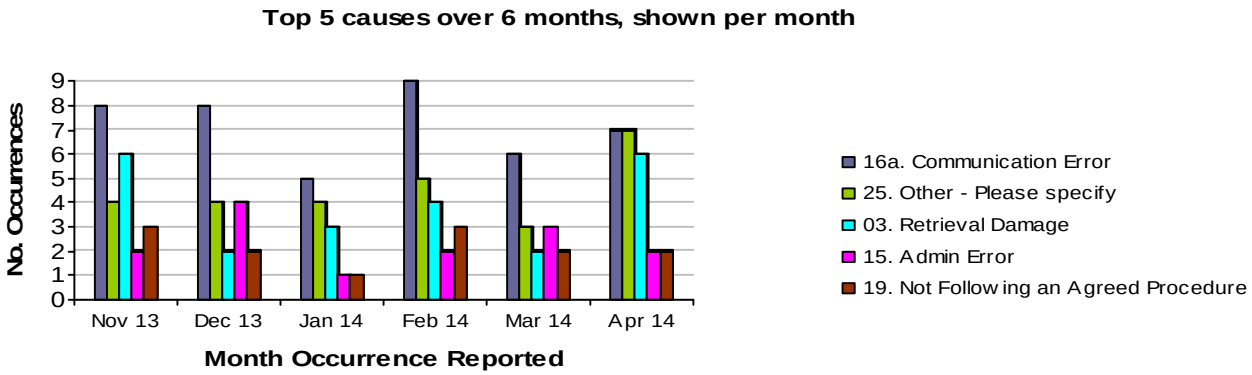
Overview of Incidents Reported to ODT

The number of reported incidents remains constant at approximately 40 per month, but we continue to be concerned that there is significant under-reporting.

Trends and summary of top 5 causes of incidents: November 2013 – April 2014

The main causes of incident to date are:

- Communications
- Other – currently there are too many ‘others’ and we are working to validate this
- Retrieval Damage
- Admin Error
- Not following an agreed procedure



Donation:

Communication remains an important trend; one key issue highlighted is SNODS not contacting tissue typing laboratories to inform of samples being sent. Transcription errors also continue, with many relating to tissue typing material being incorrectly labelled. Whilst neither of these trends have had any direct impact on the tissue typing processes as yet, work is being done to remedy this problem. There are concerns regarding the number of incidents related to failure to contact the GP during the donation process – the key learning from these is that SNODs should always attempt to speak to a GP directly, irrelevant of time of day. Whilst it is acknowledged that out of hours a GP may not be available, some surgeries operate an on call service, and GPs can provide vital previously unknown information.

Retrieval:

The biggest concern relates to retrieval damage. The majority of other incidents within this sub group relate to Scouts and late mobilization of NORS teams with some teams arriving incomplete. These are reviewed in the commissioning meetings and actions taking where required.

Transplantation:

There is a theme regarding issues with organs being used for research. Work is being done to ensure transplant centres are aware of ensuring untransplantable organs are offered for research. There has also been an increase in the number of incidents relating to transplant centres declining organs late in the process when they have previously accepted. Whilst it is accepted that many factors such as new clinical information, recipient status and logistics may change clinical decisions regarding acceptance, it is important to highlight the impact that these changes of decision has on the hospital staff and resources, and most importantly the donor family.

Transplantation Support Services:

There has been an increase in incidents related to recipient outcomes and outcome summary forms and work is being done to improve the whole pathway of organ/recipient outcome follow up.

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