Cautionary Tales

in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 5, March 2015

Introduction

Learning from incidents and sharing that learning is vital for Clinical Governance to be effective. NHSBT is reliant on those who report and those involved in investigations to ensure that the processes are reviewed, improved as necessary and good practice is highlighted. That an incident has been noted and been reported does not mean any error has occurred, and it is hoped that reporting incidents is seen as a positive way to improve standards and the quality and safety of organ donation and transplantation. Over the years incident reporting has increased, changes to practice have been made and the hope is we have moved towards a 'no-blame' culture. Whilst this may seem just a buzz word, when used in relation to incident reporting it is a vital term, although 'no-blame' does not mean 'non-accountable'.

We continue to encourage all those involved in the donation and transplantation pathway to report any incident via the online form as soon as practicable, to allow for investigation, analysis, wider shared learning and so to better outcomes for patients. The form can be accessed through the ODT website www.odt.nhs.uk or directly on https://www.organdonation.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx

Following recent enquiries, we were told that it would be more helpful if Cautionary Tales was issued more frequently to allow for timely feedback of incidents. Therefore from this edition, Cautionary Tales will be published bi-monthly rather than quarterly. We are also looking at how we can incorporate other aspects of feedback we have received to ensure learning from incidents is shared and beneficial to all.

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

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Duty of Candour:

The Mid Staffordshire inquiry identified the principles of openness and transparency as the cornerstone of healthcare and now, in addition to our own longstanding ethical duty and individual organisation's existing contractual duty, all providers of regulated healthcare must comply with the statutory Duty of Candour.

Set down in the Health and Social Care Act 2008 (Regulated Activities), as well as in the Care Act 2014, those who fail to comply with this mandatory requirement risk enforcement by the CQC and relevant professional regulatory body. There will also be organisational penalties. But it should not be feared.

Its aim is for greater transparency and accountability across the NHS. It relies on incidents being recognised, reported and appropriately investigated. This in turn should result in shared learning to avoid a similar future occurrence.

In its Saying Sorry leaflet, the NHS Litigation Authority urges openness and transparency, asking health organisations to create a culture in which all staff report patient safety incidents, give apologies, and explain to patients when things go wrong. The NHSLA's risk assessments are no more, instead we have a new safety and learning service to promote learning from claims and reducing harm.

Having set out their commitment to a duty of candour, the GMC and NMC will soon publish guidance for all health professionals and their duty to be open and honest. It will cover the need to learn from near misses, as well as when actual harm is caused. It will also advise on apologising to patients and those close to them.

Duty of candour should not be viewed in isolation but as part of a wider change of culture. It is not something to fear, and is likely something many of us already do. This alongside other cultural changes will lead us to a safer NHS.

Transplant recipients' deaths following kidney transplant:

In December 2013, two patients died after receiving kidney transplants from the same donor.

The donor presented with symptoms and signs of encephalitis for which no cause had been identified at the time of death. Donor characterisation was done according to protocol and the organs were offered; both kidneys were accepted for transplantation.

Following transplantation, both recipients made an initial recovery with good graft function but their condition deteriorated rapidly. NHS Blood and Transplant, Public Health England and University Hospital of Wales, Cardiff worked closely to diagnose the infection in a timely way to identify the infectious organism and identify any effective treatment.

Sadly, both recipients died a few weeks after their transplants, prior to the identification of the infective organism, which was subsequently shown to be Halicephalobus gingivalis, an extremely rare infection that has only been reported in humans five times previously.

NHSBT carried out its own investigations and the University Hospital of Wales commissioned an independent review. Public Health England convened a meeting of the relevant agencies to review working practices and agree plans for management should a similar incident occur. NHS Blood and Transplant also commissioned an external review by Professor Donal O'Donoghue and Dr Kevin Gunning to ensure that all aspects had been considered by the reviews and there was a joined up overview of key learning. Following this review and the original investigations, action plans were agreed.

There was an inquest into both deaths which concluded in December 2014. The Coroner ruled that both recipients had died due to the unintended consequences of a necessary medical intervention. Whilst there were no gross failing on the part of any organisation involved in the care of the donor or recipients, it was felt improvements could be made and a Regulation 28 Report to Prevent Future Deaths was issued by the Coroner. That report, together with NHSBT's response, will in due course be published here http://www.judiciary.gov.uk/subject/prevention-of-future-deaths/ and also on the ODT website.

Learning point

There were many learning points identified and some of the key ones are below:

- The decision to accept organs from a donor where there is a question over the suitability of the organs for that recipient should not be made by one person. There must be discussion with at least one other consultant transplant surgeon and an appropriate physician
- Accepting clinicians should review all information on EOS prior to acceptance to ensure they are aware of any significant findings
- On routine offering centres provide the reason for declining the offer. This information is then recorded by the Duty Office. Currently information regarding the most common reason for declining the organ is included on the fast track offer. A full review of the information provided with all fast track offers will be undertaken
- Full and rigorous systematic patient assessment including a full medical, behavioural, social and travel history by Specialist Nurses is invaluable to allow accepting centres to make an informed decision. Delivery of the 'Donor Registration Transformation' project will change the way in which Specialist Nurses record and transmit data electronically to transplant centres. This will simplify the work of the nurses, reduce the risk of errors in recording the data and increase the amount of data available to transplant centres via EOS
- Recipients must give informed consent and details of all discussions with the patient, their family (if appropriate) and colleagues should be fully documented in the patient records

All key documents can be found in the link below:

http://www.odt.nhs.uk/odt/governance-and-quality/reports-on-incidents/

Severe post-operative haemorrhage in a living kidney donor:

A recent case has been reported in which a living kidney donor who had an elective laparoscopic donor nephrectomy had a cardiac arrest secondary to massive intra-abdominal bleeding. This massive bleed was found to be due to two surgical Weck Hem-o-lok clips having slipped from the renal artery stump.
Despite the donor having a second cardiac arrest and requiring further surgery, they recovered fully and were discharged home.

A full Root Cause Analysis has been completed following this incident. Two key learning points raised were:

Learning point

- Weck Hem-o-lok ligating clips should not be used to ligate the renal artery in laparoscopic donor nephrectomies because of potential serious risks to the donor
- Local policies and procedures must be developed to inform staff how to respond in the event of a massive haemorrhage. Clinical staff must be alert to the correct procedure for activating the massive haemorrhage protocol regardless of the patient's location within the hospital

A more comprehensive report has been disseminated to relevant renal centres

Bats and Organ Donation…

Whilst contact with bats is not a common finding for organ donors, cases do occur where there has been actual or suspected contact. A small number of bats in the UK have been found to carry the Lyssavirus, which is the causative agent of rabies. The risk of exposure to the Lyssavirus from a bat bite or other contact however is low and therefore the risk to recipients is even lower.

In a recent case a donor was reported to have been in contact with a bat (in a branch of WH Smith!) although it was not certain whether the donor had been bitten. All centres were informed of this incident: abdominal organs were retrieved and transplanted. Following discussions with one of the Consultant Microbiologists in NHSBT, advice was sought from Public Health and wildlife experts. Whilst it was accepted that the risk of infection and so transmitted infection was very low, risk could not be completely excluded due to some uncertainties in the history. The decision was made to explore the possibility of obtaining brain tissue samples from the donor. Thanks to the efforts of the SNODs involved, and many clinicians and scientists, samples were taken and these were later confirmed as negative, eliminating any risk of transmission via the donated organs.

Learning point

- If a donor is known to have had contact with a bat – explore the nature of the contact, the date, whether the bat was alive and whether medical treatment was sought or given
- Review the rationale for Patient Assessment Questions to ensure the appropriate questions are asked and implications understood
- Consider brain biopsy – whilst this may often not be possible, it should be considered and explored where possible
- Seek advice early from expert microbiologists in NHSBT, Public Health Bodies or locally

Deviation from agreed clinical procedures and communication of unusual findings:

Agreed clinical procedures are written on evidence based best practice and therefore should usually be followed. The varied nature of our work means however that there can be situations where there are valid clinical reasons for not following the standard practice. In such cases, the reasons for not following the protocol should be clearly documented. One example where it was not appropriate to follow procedures was when, due to donor instability, withdrawal of life-sustaining treatment took place on the ICU which led to a long period

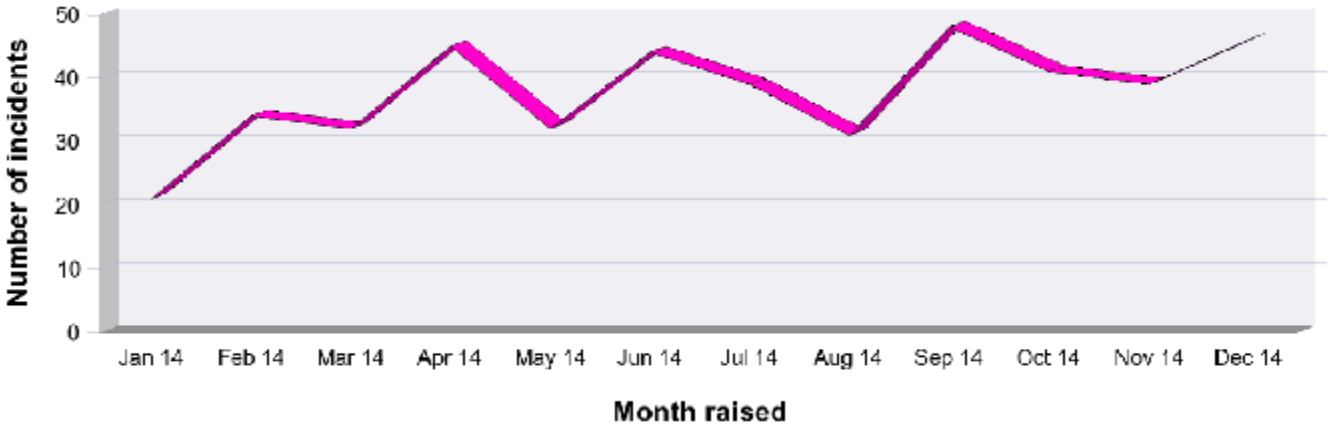
between asystole and perfusion. Because of this prolonged interval, on removal of the liver the retrieval team did not utilise in-situ portal perfusion as the priority was to remove the liver as soon as possible. Whilst the rationale was sound, this deviation was not relayed to the accepting transplant centre.

There have been a number of examples when unusual and unexpected findings have been noted at retrieval but these have not been communicated to the recipient centres. Examples include nodules and cysts seen on organs, condition of the retrieved organ, unusually short ureter of a retrieved kidney, fatty change in the liver and, in one recent case, an unexpectedly large liver which may have affected the graft outcome.

Learning point

- If there is a deviation from standard practice that may affect the quality of the retrieved organ or suitability of its use for the intended recipient, ensure this information is communicated to the recipient centre as soon as possible
- If something at retrieval appears unusual, or there is something that is relevant to implantation, may affect the health of the recipient or alter their management, you should ensure this information is passed on to the transplanting centres as soon as possible. This may be done through the SNOD, the Duty Office or from surgeon to surgeon but please ensure the SNOD is aware and that both the unexpected finding and all subsequent actions are fully documented

Overview of Incidents Reported to ODT



Donation: There has been an increase in the number of incidents relating to tissue donation within this sub group. Many processes related to tissue donation are not formalised and this is an area that has been highlighted as need of review this year. The trends in microbiology transcription errors continue: copies of all SNOD Teams virology reports have been collated to ascertain if the lay out of the reports and the terminology utilised could be a contributing factor. Whilst this review is not yet complete, it is clear that some of the reports received are complex, none are standardised and these factors may contribute to the continued errors.

Retrieval: Retrieval damage continues to account for most reported incidents within the retrieval sub group; however damage report rates remained static in the current 6 months compared to the previous 6 months. The reports of heart valve damage have reduced significantly since new guidance and training has been introduced, with only 1 incident in the last 3 months.

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