Cautionary Tales
in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 13, October 2016

Introduction

Communication is the key in many areas of health care, and organ donation and transplantation is no exception. This edition of Cautionary Tales again highlights the importance of simple communication pathways to ensure that transplantation is safe.

Last edition we looked at the ODT Hub project and the IT systems that are being developed to support the donation and transplantation pathway. Whilst digital technologies are changing the way we do things, giving us new means of transacting and participating, the impact of clear concise communication when disseminating information can not be underestimated.

ODT receive incidents from all those within the pathway from Transplant Surgeons and SNODs, to Laboratory Technicians and Transport Providers. To ensure all incidents are reviewed thoroughly and robustly with all the relevant individuals it is important to ensure that they are always reported via the reporting system. It is appreciated that it is tempting to email a colleague and leave it at that, however by reporting via the online system all information can be captured, important lessons learnt and shared with all.

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

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Histopathology

As with many things during organ donation and transplantation, histopathology is, in general not straightforward. Often many obstacles need to be overcome; from locating appropriate on-call staff, transport of the sample, to ensuring timely dissemination of results.

Over the past 18 months we have shared a number of cases highlighting the importance of the inclusion of donor identifiable data on final results. There have again been a number of cases where histopathology results were sent to NHSBT with recipient details but no donor identifiable data included. It is critical that it is clear that the results being forwarded are from the donor and not the intended recipient and as such donor ID must be included.

A trend that has also come to light recently is that of timely dissemination of results, irrelevant of the findings. Any concerning findings are in general reported to the Duty Office or SNOD team in a timely way. However there have been a number of cases where benign results have been significantly delayed. Whilst this does not normally have clinical significance for the recipient, knowledge of a benign result can avoid unnecessary concern for the clinical team and additional workloads in seeking the results.

Many of you may be aware that a National Histopathology Audit was previously completed reviewing the provision of the services. Work is currently underway to build on the outcome of this audit and to

explore how the provision of histopathology services could be improved for organ donation. Roberto Cacciola, Associate National Clinical Lead for Organ Retrieval, has been working with a number of senior clinicians, histopathologists, NHS England and other stakeholders to develop a proposal for a 24/7 national digital histopathology service. A bid has been submitted to the National Institute for Health Research (NIHR) for funding to support this work and, if successful, the service will launch in April 2017.

Learning point

- To ensure that there is no confusion, three points of donor ID MUST be included on donor histopathology results. This will allow other centres to 'link' to their recipients safely
- All results, both malignant and benign, should be forwarded to the Duty Office to ensure timely dissemination to any other accepting centres

Serious Adverse Events and Reactions (SEAERs)

Acting on behalf of the HTA, NHSBT manage the system for reporting, investigating and transmitting information regarding SAEARs as part of the wider incident reporting system.
This makes life as easy as possible for all involved as there is only one reporting system.

Most of you will be aware that there is a requirement for all UK establishments licensed under the Regulations to report SAEARs to NHSBT via the NHSBT on-line form. Recently there have been a number of cases that have only come to light following 'corridor conversations' or email trails and were never reported as potential SAEARs.

Whilst there is clearly a regulatory requirement, many SAEARs have potential considerations for wider patient safety. Informing NHSBT will ensure that SAEARs are not only reported to the HTA in a timely way, but recipient centres are informed where necessary and any national learning can be followed up.

Learning point

- All UK establishments licensed under the Regulations are required to report SAEARs to NHSBT via the NHSBT on-line form
  https://www.organdonation.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx
- Full guidance can be found in the following link:
  https://www.hta.gov.uk/sites/default/files/Guidance_-_SAEARs.pdf
- Non reporting of a SEAER may also have significant clinical implications to other recipients

False Positive Pregnancy Testing

The possibility exists that female patients who could be considered as potential organ donors may be pregnant. Currently, if a potential donor family advise that a potential donor could not be pregnant no further action is taken and pregnancy testing is not performed following consent.

In a recent case, during a young women's admission and prior to the consideration of organ donation a serum human chorionic gonadotrophin plus beta subunit (hCG+β) was completed. The hCG+β was measured at 26 IU/L but two urine pregnancy tests gave a negative result.

As the family had stated during the Patient Assessment that they did not think that she could be pregnant a repeat hCG+β was not completed.

The hCG+β levels were not noted pre retrieval and the donation proceeded. The following day the level of 26 IU/L was questioned and concerns were raised that the donor had been pregnant, although at very early stages.

During admission the patient had received the clotting product OctaplasLG® (due to her age she had not received UK sourced FFP). As such, following the concern raised post donation regarding the possibility of pregnancy a pre transfusion sample was obtained for testing. This retest was hCG+β <0.1 IU/L thus ruling out pregnancy.

OctaplasLG® is made from the donations of 630-1520 individuals which may include women. hCG is produced by the placenta during pregnancy with peak levels reaching around eight weeks gestation. Inter-individual variation is high but hCG+β levels of greater than 100,000 may be observed after week seven. Therefore even allowing for the high number of donors used for a batch of OctaplasLG® one female donor at seven-eight weeks gestation may result in a product with hCG+β levels of ~100 IU/L. A bag of the same batch of octaplasLG® received by the organ donor was tested: hCG+β levels were found to be 102 (IU/L) - confirming octaplasLG® as the source of hCG+β.

This was an extremely rare event, however whilst it is a case of interest it also highlighted a number of key learning points which are listed below.

Dr Alex Manara, Regional Clinical Lead for Organ Donation in the South West, has been working with the Joint Standards Committee of the Faculty of Intensive Care Medicine and the Intensive Care Society over the issue of pregnancy testing. It has been agreed that the possibility of pregnancy should be considered whenever a female patient of child bearing age is admitted to ICU, irrespective of any potential for organ donation. We expect that guidance to perform a pregnancy test on admission will be incorporated into the next revision of the Faculty's Guidelines for the Provision of Intensive Care Services (GPICS) and will provide a further update when this is published.

Learning point

- Consideration must always be made when completing pregnancy testing on patients who have been transfused
- Where possible, if a potential donor has been transfused serum hCG+β should be completed on a pre transfusion sample
- Any results related to a potential donor must be collated and recorded as part of donor characterisation, and clarity sought where any unclear results are found
- SNODs should be aware of the possible use and transfusion of Human Products other than those that are routine such as RBC, FFP and Platelets

Zika and Organ Donation

Recently a potential donor was deemed at risk of Zika virus due to known travel history. With expert help and with the close co-operation of the Specialist Nurse team, donor hospital, donor family, retrieval teams and recipient centres, a risk assessment was performed indicating that in this particular case, the risk of Zika virus was low.

In this case, whilst the areas of travel were included on EOS, initially the risk of Zika was not. Following the learning from this, SNODs now ensure that as well as the travel history previously documented, any additional risk listed on the Geographical Disease Risk Index (GDRI) are also clearly documented on EOS. This will allow for transplant centres to review and make an informed decision.

Testing for Zika virus is possible but only at a single reference laboratory during normal working hours. Due to this restriction, unlike Malaria and T Cruzi, testing for Zika virus is not routine. Therefore a complete risk assessment should be carried out by accepting centres to allow a balanced decision between the risk of Zika virus transmission and the risk to the patient in not receiving a transplant.

This is still a new, evolving situation and it is difficult to predict all possible scenarios. However we have updated the Zika virus information and this can be found on the ODT website at www.odt.nhs.uk.

Learning point

- Additional risks referenced on the GDRI due to a donors travel history must be included on EOS to allow transplant centres to review
- Potential donors will not be tested for Zika virus as routine
- Advice has been updated to aid transplant centres in making a risk-benefit decision and can be found here: www.odt.nhs.uk