Cautionary Tales
in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 7, July 2015

Introduction

'Humans make mistakes', Yes. Healthcare professionals (even surgeons) are human, and like all humans, are fallible, and mistakes can and do occur. Whilst in day to day life mistakes in the things we do, or forget to do, can be a mere inconvenience, within health care mistakes can have potentially dire consequences for patients.

No one intentionally makes a mistake, however they continue to occur. There are many reasons given as to why mistakes happen, and many of these reasons are related to 'human factors'. It is also frequently the case however that system failures have contributed and management therefore have a responsibility to improve and develop processes to mitigate the risk in the future. For instance, a health care professional makes a transcription error because they have worked 9 hours without a break - why didn't they have a break? What processes and support needs to be reviewed, updated or put into place to avoid this in the future?

NHSBT, like many other organisations, is keen to reduce the likelihood of people or systems making errors and has set up a number of processes to do so. One of the key elements is that when an incident occurs, it is reported, analysed and, where appropriate, actions agreed, implemented and the pathway audited.

All those involved in the donation, retrieval and transplantation pathway want to ensure that organs transplanted are as safe as possible for the recipient, and that donor family care is provided at a high standard. To achieve this we need people to feel able to report all incidents, confident that there will be no accusation of blame, and that incidents will be properly evaluated and investigated, and where appropriate, changes made to practice. Every one shares that responsibility to make things better for all involved.

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

---

The Importance of Audit in Clinical Governance

Learning from incidents and sharing that learning is a vital part of clinical governance and is essential to improve the quality of the care that is given to patients. Clinical audit also plays a key role, but how do audit and learning link together?

When an incident is reported, the circumstances are reviewed, and, where appropriate, changes are made and lessons shared to try and prevent a recurrence. But this can only happen when we *know* that the incident has occurred – there may be many other similar errors that were not identified or recognised and therefore were not reported, or where corrective action was taken locally without consideration that similar errors may be taking place elsewhere.

Clinical audit can be used to assess whether similar incidents have occurred and have not been reported and also to assess whether changes introduced as a result of incidents have been effective. For example, of all incidents reported to ODT between November 2012 and September 2013, 22 were transcription related incidents and occurred across the donation and transplantation pathway: 3 of these were classed as serious incidents. An audit that followed found 35 transcription errors in selected parts of the donation pathway – affecting 1 in every 25 donors. Only a small number of these had been reported.

Clinical audit can also be a useful assurance tool, either by confirming that incidents are isolated occurrences and so unlikely to be system failure or by showing that process and practice changes following incidents are working as intended. The audit described above highlighted some significant issues and resulted in a number of both practice and process improvements, and a re-audit is currently in progress. Early indications are that there has been a significant decrease in these types of incidents and where they have occurred, they are lower in severity.

Analyses of incident trends are used in the development of annual clinical audit programmes within ODT. Following review, a programme of mini-audits designed to provide assurance that donor information provided to transplant centres is consistent with that in the donor files will continue across all regional Organ Donation Service Teams (ODSTs). Also planned are clinical audits designed to assure that donor medical history is accurately provided to transplant centres – together these audits aim to assure, and improve if needed, patient safety.

To be effective, Clinical Audit, Quality Audit and Clinical Governance must work effectively together and ensure that work is integrated. NHSBT has invested in a Clinical Audit team that works across the organisation and is now working with external partners as the work of organ donation, retrieval and transplantation extends beyond NHSBT. For further information about 2015/16 clinical audit plans or any questions about clinical audit in general, contact Marc Lyon, Clinical Audit Manager on 0113 820 8705 or at marc.lyon@nhsbt.nhs.uk

Donor Transmitted Infection and Malignancies

Organ Donation and Transplantation is associated with risk. Organs are 'second hand' and the previous owners may have infections and other conditions that will be transplanted with that organ. All those involved in donation and retrieval work hard to minimise the risk and ensure that transplantation is a safe as possible. However, despite continual improvements, we accept risk will likely never be eradicated completely. This is acceptable because of the risks of not using a donated organ; it is of course essential that risks are balanced and the patient has given appropriately informed consent.

There have been a number of incidents recently where recipients have developed infections and malignancies post transplantation that have subsequently been confirmed as donor derived. On review of all these cases and re-evaluation of the information present at the time of donation, including reviewing chest x-rays and original medical notes, there was no indication that these infections or malignancies were present.

Transmission of HHV8: Two such recent cases involved the Human Herpes Virus 8 (HHV-8) or Kaposi's Sarcoma-associated Herpes Virus (KSHV) which is the underlying infectious cause of all forms of Kaposi's sarcoma (KS). HHV8 is a member of the Herpes virus family and as such, following an initial infection it establishes lifelong latent infection and can reactivate, especially when the host is immunosuppressed. This virus has an extremely low prevalence of HHV8 infection in the general UK population and testing for this infection is not required as routine.

There have been two separate incidents related to recipients developing Kaposi's sarcoma post transplantation. The organs were donated from two unrelated donors in different parts of the country. Following the identification of the cases, the NHSBT microbiology team completed antibody tests for HHV8 on stored donor samples which demonstrated that both donors had been infected prior to donation, and also showed that recipients acquired the infection after transplant. Both incidents were reported to the Human Tissue Authority as Serious Adverse Reactions, not because any error had been made, but because of the potential impact on recipients.

Investigations demonstrated that donor characterisation was appropriately carried out and whilst there were some identified donor characteristics that could account for the HHV8 infection, (sexual history and place of birth), these would not have triggered any specific action at the time of organ offer. A further feature was that in neither case did the clinical team initially attribute the development of KS to a donor derived infection. KS, like some other cancers, occur with increased frequency in the immunosuppressed. The unusual feature was the early development of KS in the graft.

The key learning from both these cases is the importance of early recognition of possible donor derived infection and reporting any suspicion to NHSBT so the teams looking after recipients of other organs from the same donor can be identified and investigated, and the donor characterisation process reviewed. NHSBT contacted all relevant recipient centres advising them of the findings and offering assistance with the testing and follow up plan for the other recipients. So far, 2 of the 5 recipients have been tested, with no evidence of infection.

Other key learning points these cases highlight is the importance of timely reporting and consideration of donor-derived conditions, where appropriate, so that management options for other recipients can be considered.

Learning point

- Whilst risk can be minimised, it is not possible to eradicate
- Any suspected donor derived infection or malignancy reported to NHSBT will be fully investigated to provide reassurance that all information available was communicated
- Where appropriate, the possibility of donor-derived conditions should be considered
- Whilst in many cases the outcome will be accepted as simply a known risk of transplantation that would have been difficult to avoid or predict, the key lessons will be ensuring all recipients are managed appropriately and that NHSBT provides support in diagnosis and advice where requested and appropriate

Please remember, we are all Ambassadors

Recent cases have been reported where behaviour of those involved in donation and retrieval was commented on by not only those involved, but also members of the donor hospital.

Many of those who work within the Organ Donation, Retrieval and Transplantation pathway work long, unsociable hours, often in unfamiliar environments that are highly emotional and distressing and require attention to detail. This can sometimes lead to stressful situations, however please remember that all those involved in any part of the pathway, including NORS Teams and SNODs, are ambassadors for Organ Donation and Transplantation. As such all should act accordingly, especially whilst visiting external donor hospitals and units. Whilst no one aims to cause any distress, heightened emotions can lead to misunderstanding and upset and so please be mindful of this.

Learning point

- All those involved in any part of the pathway are ambassadors for Organ Donation and Transplantation

Retesting of Donor Microbiology

Some Transplant Centres have adopted the practice of repeat donor microbiology testing using the blood sample that is sent with the organ. Whilst acceptance and subsequent transplantation is based on the microbiology results provided by the Specialist Nurse at the time of offering, results of these repeated tests are usually provided post transplantation, sometimes days later.

Whilst this is an individual centre's choice, there have been a number of occasions where discrepancies between the initial test and the repeat test have caused concern. There have been incidents where repeat testing by the transplant unit's laboratory was reported as showing evidence of infection, when the initial result was negative. This has involved significant infection, including HIV. In some of these there was a significant delay in the communication and recognition of the discrepancy.

On all occasions, when further clarity was sort and results repeated and reviewed by senior clinicians and microbiologists, the repeat results were confirmed as negative.

Thus, repeat testing in all cases reported not only raised undue concern but added work for Specialist Nurses, the Duty Office and recipient coordinators.

For those centres where repeat testing is completed it is important that any discrepancies between the initial and the repeat is rechecked, confirmed and interpreted correctly. If, when this has been completed the discrepancy is confirmed it is vital to communicate this to either the Specialist Nurse Team or the Duty Office as soon as possible to allow for other centres to be informed.

Learning point

- Repeat testing of donor microbiology can cause inaccurate results that cause unnecessary workload and concern
- It is important that any discrepancies between the initial and the repeat is rechecked, confirmed and interpreted correctly
- If a discrepancy is confirmed it is vital to communicated this to either the Specialist Nurse Team or the Duty Office to allow for other centres to be informed

HIV Positive Patient? Organ Donation is still an option

HIV infection is still regarded by some as an absolute contra-indication to deceased organ donation. Since 2011 there have been a total of 3 solid organ donors who had HIV infection (not disease), donating a total of 4 organs; all of which were transplanted. All recipients were known to have HIV infection prior to transplantation. Although the numbers are small, whilst three people die every day waiting for a transplant it is vital that the option of donation is explored in every opportunity.

As with all donors, thorough donor characterisation including past medical history is important. However where a potential donor is known HIV positive, an in-depth history of medications and treatment, especially viral load, is also vital to ensure that any centre considering the option of transplantation is as informed as possible to minimise any risk.

There is a high likelihood of transmission of the infection to the recipient and as such SaBTO advise that organs should be used only for those recipients who are already carriers of the virus. Such recipients must be informed and consented regarding the risks of possible super-infection and transmission of other infective agents that may be present in HIV infected patients and whose effects may be exacerbated by

immunosuppression. The advent of highly effective treatment for HIV means not only that more of those with HIV can be considered for transplantation, but the infection can be managed in the context of immunosuppression.

Learning point

- HIV infection is still viewed by some as a contraindication to organ donation. These donors highlight that this is not the case, and patients should continue to be referred to the Specialist Nurses, discussions had and families approached where appropriate
- Potential recipients must be fully informed and consented regarding risks

The Challenges and Limitations of Histopathology

Histopathology is increasingly being used to aid a clinician's decision making regarding organ acceptance prior to transplantation. Histopathology may be used to characterise an unexpected mass or to help decide whether the organ is suitable for transplantation. So for many it provides the vital piece of the picture and helps ensure that organs are used appropriately and, conversely, not discarded inappropriately. At present, the service out of hours is patchy, although we are working with clinicians, pathologists and NHS England to explore how an out of service could be established, Even so, rapid histopathology does have its limitations and as such should be used with this in mind.

Whilst small in number, there have been incidents reported where initial reports suggest that a lesion was benign, when on further evaluation and review the lesion was in fact malignant. No error was made at any stage as the provisional results were provided and accepted with the knowledge that further testing was required. The transplanting surgeon balanced the risk-benefit and importantly the recipient was fully informed prior to consent.

Learning point

- Histopathology can be an invaluable diagnostic tool, however provisional or rapid results need to be utilised with caution with an awareness that any provisonal result has the potential to change

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