Specialist and Screening Services

Area 062
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB
Telephone 0131 275 6575
Fax 0131 275 7614
www.nsd.scot.nhs.uk

Draft for Discussion

Subject: **Management of Adverse Events and Clinical Governance of Organ Retrieval and Transplantation Services within NHS Scotland**.
File ref: 07 Health Support Ser\Specialist & Screening\Spec\Transplants\SORT\Papers
Authors: Dr. Mike Winter, Medical Director
Dr. Craig Wheelans, National Medical Advisor
Date: 6th April 2016

INTRODUCTION

This paper offers a process to describe the shared management of Adverse Events and the Clinical Governance of organ retrieval and transplantation services within NHS Scotland. Whilst the focus is on activity within NHS Scotland, the paper recognises the overarching authority of the HTA (Human Tissue Authority), and the delegated responsibilities held by NHS Blood and Transplant (NHS BT) on its behalf.

COMMISSIONING ARRANGEMENTS

The surgical retrieval of donor organs in Scotland is commissioned by NHS BT on behalf of the Scottish Government; and is delivered by the Scottish Organ Retrieval Team (SORT), which operates as a single paired team. This is recognised as a part of the UK wide National Organ Retrieval Service (NORS).

The core staff, including the Lead Clinician and Theatre Practitioners, are employed by NHS Lothian, supporting the work of the two surgical teams. The clinicians responsible for the retrieval of abdominal organs are based and employed by NHS Lothian and the cardiothoracic team is based and employed by the NHS National Waiting Times Centre (Golden Jubilee National Hospital). Both teams operate under organ retrieval licenses issued to their host NHS Board by the HTA through their contract with NHS BT.

Organ transplantation in Scotland is commissioned by NSD (Na*tional* Specialist Services and Screening Directorate of NHS NSS) on behalf of the NHS Boards in Scotland. The commissioned providers of transplantation are:

1. Golden Jubilee National Hospital (NHS National Waiting Times Centre) - cardiac transplantation.
2. Royal Infirmary of Edinburgh (NHS Lothian) - abdominal organ transplantation (liver, pancreas, islet cell and kidney (adult)).
3. Queen Elizabeth University Hospital & Royal Hospital for Children (NHS Greater Glasgow & Clyde) - adult and paediatric renal transplantation service.
4. Freeman Hospital (NUHT) – lung transplantation

RETRIEVAL

Within NHS Scotland, it is recognised that the NHS Board within which a clinical activity takes place is responsible for the Clinical Governance oversight of that activity. In most cases, this will include responsibility for the employment of all clinical staff involved in delivering the procedure.

When considering organ retrieval, all staff employed within SORT are licensed to undertake retrieval in any donor hospital, and it is recognised that they work alongside colleagues who are employed by that local NHS Board.

Any concerns in relation to issues arising during an organ retrieval procedure will normally be managed by NHS Lothian as the provider of the core infrastructure and managerial functions for SORT. NHS Lothian also provides pharmacy support. NHS Lothian is the employer of most SORT staff and of the abdominal surgical retrieval team. Any issues in relation to work of the cardiothoracic surgical team are managed by the NHS National Waiting Times Centre.

NHS BT regards the SORT Lead Clinician as the principal point of contact for any reported concerns regarding retrieval activity undertaken by SORT. The SORT Lead Clinician requires the authority to oversee all activities in relation to organ retrieval in Scotland, and it is mandatory that they are involved in any initial discussion to determine the level of review required to manage a reported concern.

The SORT Lead Clinician will also be responsible for the co-ordination of any investigation of a concern relating to retrieval activity. In order to allow the Lead Clinician to deliver these responsibilities there will be the requirement for support and guidance to be provided by the NHS Lothian Clinical Governance Team and relevant senior medical management (e.g. Associate Medical Director).

It is mandatory that any concerns in relation to retrieval activity, or the quality of any organ made available for transplantation, are reported to NHS BT. NHS BT will then take the lead on any subsequent investigation in partnership with the NORS team involved in the retrieval of that organ – in Scotland that would be with SORT. NHS BT will also make contact with NSD to allow meaningful national support to be provided to the team undertaking the required review. To date this has been an informal arrangement and, in light of recent experience, would merit being changed into a formal transparent and published responsibility. It is accepted that NHSBT, as the commissioner of retrieval activity, will be the recipient of any formal report; however, NSD has an opportunity to ensure lessons learned within the retrieval programme can be shared with the organ transplant programme and vice versa.

TRANSPLANTATION

Where there is an issue in relation to a transplant procedure, the lead responsibility for managing the incident remains with the NHS Board within which the transplant takes place.

It is a requirement of National Designation in Scotland that NSD be informed of any significant events, and senior staff from NSD are available to support the NHS Board in deciding the level of review which needs to be undertaken and to assist in the investigation in relation to a significant event. NSD has an important secondary role in supporting the NHS Board in making this report to NHS BT, and ensuring lessons learned are shared widely across the transplantation community in Scotland and, through the partnership with NHSBT, to teams across the UK.

In line with the license under which transplantation activity takes place, the final report on any issue in relation to transplantation is required to be submitted to the Human Tissue Authority via NHS BT, which acts as the clinical adviser to the HTA.

ROUTINE MONITORING OF OUTCOMES

All transplant centres within the UK participate in a clinical outcomes audit managed by NHS BT. The data is analysed and outcomes reported on a regular basis, and should a centre be identified as being outwith a standard variation, both the transplant centre and the commissioning team (NSD) are notified. In reality, the variation has usually been identified by the local team ahead of the formal notification from NHS BT, and as a result initial review and immediate actions may already have been taken.

STANDARD PROCESS FOR MANAGEMENT OF AN ADVERSE EVENT

All NHS Boards in Scotland have committed to the management of adverse events through a learning process of report and review, as advised by HIS, in the framework document published in April 2015.

This describes a six phase approach (see BOX 1 below) with an emphasis on learning and promoting best practice; a culture of openness about failures; and encouraging personal, professional and organisational accountability.

Box 1

Management of Adverse Events in NHS Scotland - HIS

The stages described include:

1 The need to undertake a risk assessment, and to seek to avoid harm through embedding a positive and safety culture
2 When an event happens, to consider the immediate actions needed to minimise the impact of those affected and to reduce any future harm
3 To have a process of early reporting and notification
4 To undertake an initial assessment and categorisation
   - o category 1 – an event that may have contributed to or resulted in permanent harm – the expectation is that a root cause analysis or equivalent will be undertaken.
   - o category 2 – an event that may have contributed or resulted in temporary harm – the level of review will be determined by the local team
   - o category 3 – an event that had the potential to cause harm but no harm occurred (near miss) – the level of review will be determined by the local team
5 To undertake an appropriate level of review and analysis proportionate to the category of event that has been identified
6 Publication of reports and sharing of learning – with specific reference to ensuring that all who have been affected by an incident (patients, family and staff) are advised of the outcome and changes agreed as a result of the review.

SUMMARY

Provider organisations responsible for organ retrieval and transplantation services in Scotland will continue to hold the responsibility for the identification, management, investigation and reporting of Adverse Events as well as the overall Clinical Governance for the way in which services are delivered.

The resources of existing clinical governance and patient safety programmes will be utilised to minimise the risk of harm. Use of such existing resource will aim to reduce duplication of effort and reduce confusion in the procedures and protocols which required to be followed in the event of concerns being raised.

It will be a mandatory requirement in terms of organ retrieval and transplantation to involve the Commissioners at an early stage of any significant event within organ retrieval and organ transplant programmes. In Scotland this will involve both NSD and NHS BT, although a single report in the format required within their own NHS Board will be used as the reporting tool.

When a complex event is identified (usually at stage 4 above when incident is categorised as either a category 2 or 3 event), there will be an agreement between all of the provider units involved and the commissioners as to the level of review which will be needed to understand the event.

It is expected, as per the HIS document, that the group to review the event will have representatives from all of the stakeholders groups, and that a single report will be provided under the authority of the NHS Board that has agreed to take responsibility for the delivery of same. Prior to publication, any such report will be reviewed by all stakeholders involved, e.g. the NHS Boards, NSD and NHS BT (on behalf of HTA).

The algorithm at annex 1 offers a diagrammatic representation of the approach being suggested.

Dr Mike Winter
Medical Director