HTA
Human Tissue Authority

Organ Donation and Transplant Sector Regulation

A look back review, March 2014

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Foreword

Organ transplantation is a growing field and saves thousands of lives each year. It is the only treatment for end-stage organ failure, and the most cost-effective treatment for renal failure.

In 2011, 30,000 organs were transplanted in the European Union (EU), many of which were shipped across borders. The European Union Organ Donation Directive 2010/53/EU (EUODD) was introduced in 2012 to bring all EU countries up to the same high quality and safety standards when transplanting organs. The EUODD means that UK citizens will benefit from the availability of better quality organs from across Europe.

It has now been 20 months since the Human Tissue Authority (HTA) was appointed as the UK's Competent Authority under the EUODD, and we began licensing this sector. In this short time we have seen some significant changes to the regulatory landscape.

Following consultation with professionals, we developed the UK's first formal framework for the donation and transplant of organs. Under this framework we have licensed and audited all of the UK's 37 establishments involved in various aspects of organ donation and transplantation.

We audit establishments against specific criteria and gather evidence through a combination of inspection, review, and interviews with staff involved in each aspect of the 'organ pathway'. These audits are carried out by a core team of expert HTA inspectors who meet regularly to review, discuss and compare findings. I am pleased to say that this document summarises the outcome of the first round of HTA audits.

The review shows that we have found good compliance across the sector. However in this ever-changing field, it is important that we are not complacent. We will continue to provide advice, support and guidance to make sure standards are maintained, and we will take regulatory action wherever necessary.

The review also outlines the positive feedback we have received: in most cases respondents rated their experience of an HTA audit as good or excellent. I am particularly pleased that 88% of respondents felt that the HTA's audit process has improved working practices.

The HTA strives to be flexible and responsive. We have a strong track record of listening to professionals, our stakeholders and the public, learning from what they say and adapting to improve our regulatory approach.

We will continue to work closely and positively with colleagues across the transplant community to ensure appropriate standards in the quality and safety of organs intended for transplantation.

Baroness Diana Warwick Chair, HTA (March 2014)

Executive Summary

The European Organ Donation Directive (EUODD) standards of quality and safety of human organs intended for transplantation requires member states to identify a Competent Authority to oversee the requirements of the Directive.

In 2011, the UK Government and the Welsh and Scottish devolved Governments appointed the HTA as the Competent Authority for the EUODD in England, Wales, Northern Ireland and Scotland. The appointment is complementary to the other work of the HTA in regulating human tissue under the Human Tissue Act 2004 and the European Union Tissues and Cells Directives.

Following transposition of the EUODD into UK law, establishments conducting activities involving the procurement and transplantation of organs applied for and were issued licences in August 2012.

In December 2012, the HTA commenced on-site audits of the 37 establishments licensed under the new regulatory framework.

The audits were scheduled on the basis of self-assessed compliance against predicted assessment criteria. Those with the lowest predicted self-score were audited early in the cycle.

A review of all audits conducted has shown that there is a high level of compliance across the sector with the new regulatory requirements. The average number of shortfalls identified during an audit was less than one (0.7) across the 37 licensed establishments and 26 of these had no shortfalls.

In addition to assessing compliance with legal requirements, the HTA has a statutory remit to provide advice and guidance. During the course of the audits, the HTA identified opportunities to provide establishments with advice and to share learning to support further improvements to practice, in total 112 pieces of advice were provided.

This review summarises the findings of the audits conducted and provides an overview of the serious adverse events and adverse reactions (SAEARs) reported during the first year of licensing.

Introduction

Organ transplantation is a growing field of medical treatment and the number of organs transplanted has steadily increased across the European Union (EU) over the years. Transplantation is currently the only treatment for end stage organ failure, such as liver and heart and is generally accepted as the best treatment both for quality of life and cost effectiveness for renal failure.

Legislation

The EUODD aims to ensure a high level of health protection throughout the EU by establishing common standards of quality and safety of human organs intended for transplantation. It is anticipated that this harmonisation of standards will facilitate the exchange of organs and expand the pool of organs available, ensuring a better match between donor and recipient. Measures such as ensuring robust systems of traceability should also help to prevent associated illegal or fraudulent activities such as organ trafficking.

In order to meet these aims, a Competent Authority has been appointed in each member state, to regulate the quality and safety standards of the Directive.

Human Tissue Authority

The HTA has been in existence since 2006 and was established by the Human Tissue Act 2004 to regulate the removal, storage and use of bodies, body parts and tissues for post mortem, research anatomical examination and public display and transplantation. In 2007, the remit of the HTA was extended when the European Union Tissues and Cells Directive (EUTCD) was transposed into UK law. Under the EUTCD, the HTA licences establishments that procure, test, process, store, distribute, import and export human tissue or cells for the purpose of human application. Under the Human Tissue Act 2004, the HTA also regulates through an independent assessment process, the donation of organs from living people and the donation of bone marrow and peripheral blood stem cells from children and adults who lack capacity to consent.

In 2012, the HTA became the UK Competent Authority responsible for ensuring the quality and safety of organ donation and transplantation (ODT) under the EUODD.

The criteria used to assess establishments in the ODT sector are based on the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Q & S Organ Regulations). The Q & S Organ Regulations are the statutory instrument that transposed the EUODD and were developed in consultation with professionals already working in the field of organ donation and transplantation. All establishments that carry out activities under the Q & S Organ Regulations are licensed by the HTA. The HTA issued the first ODT licences in August 2012.

National Health Service Blood and Transplant and HTA – collaborative working

The EUODD requires organ donation and transplant establishments to have in place a core set of operating procedures. In order to minimise the burden on establishments the HTA, in collaboration with National Health Service Blood and Transplantation (NHSBT) commissioned the development of a suite of national operating procedures (NOPs) which were made available to the sector to adapt to local practices. The NOPs detail the mandatory requirements for all procedures which require documentation under the Q & S Organ Regulations. Where establishments did not have equivalent documentation in place, they were encouraged to adapt the NOPs to their own requirements. The NOPs cover the following activities:

- Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation; (http://www.hta.gov.uk/_db/_documents/NOP001DonorAndOrganCharacterisationAssessmentAndAllocation.doc)

- Verification of donor identity, consent/authorisation and organ and donor characterisation in deceased and living donation and transplantation; http://www.hta.gov.uk/_db/_documents/NOP002VerificationIdentityConsentDonorAndOrganCharacterisation.doc)

- Packaging, labelling and transport of organs in deceased and living donation and transplantation; http://www.hta.gov.uk/_db/_documents/NOP003PackagingLabellingAndTransportOfOrgansForTransplantation_201207064559.doc

- Management of procurement material and equipment in deceased and living donation and transplantation; http://www.hta.gov.uk/_db/_documents/NOP004ManagementOfProcurementMaterialsAndEquipment.doc

- Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation; http://www.hta.gov.uk/_db/_documents/NOP005ActivitiesUnderTheGuidanceOfAMedicalPractitioner.doc

- Transfer and storage of donor and organ characterisation information and storage of traceability data. http://www.hta.gov.uk/_db/_documents/NOP006TransferStorageDonorAndOrganCharacterisationInformationandStorageOfTraceabilityData.doc

To further reduce regulatory burden, the HTA has established a service level agreement (SLA) with NHSBT. The SLA sets out a number of functions that NHSBT will perform on behalf of HTA to assist HTA in meeting its obligations as a Competent Authority. The most significant

function that NHSBT carries out under the SLA is the management, reporting and investigation of SAEARs. The assisted function requires NHSBT to:

- manage a system to report, investigate, register and transmit information about SAEARs associated with organ donation and transplantation;
- notify the HTA of any SAEAR associated with organ donation and transplantation, the steps being taken to manage the SAEAR and confirmation that all actions associated with the SAEAR have been concluded.

NHSBT receive incident reports from the ODT sector via a dedicated portal and forward serious adverse events (SAE) or serious adverse reactions (SAR) to the HTA. The HTA's system captures the date that the incident took place, the date it was reported to NHSBT, the date NHSBT determined the incident to be a SAEAR and the date NHSBT reported the SAEAR to HTA. Any investigation will be managed by NHSBT, except where there is a potential conflict of interest, when the investigation will be overseen by the HTA. Follow-up information, in the form of an investigation report, should be provided within 90 days of reporting. The HTA will review the follow up information and agree with NHSBT to close the case when satisfied that all appropriate actions have been taken.

The audit process

The HTA's authority to carry out audits is defined in the Q & S Organ Regulations Part 4, regulation 13 (3), which states that audits may be carried out at intervals that the Authority considers appropriate to ensure compliance with licensing conditions and directions.

The HTA defines 'audit' as a process encompassing desk-based assessment, on-site assessment and analysis of information to evaluate and assess whether the conditions and directions of a licence and the HTA assessment criteria have been met. For the purpose of this review 'audit' will refer to a site visit audit.

The focus during an audit is to review operational policies, procedures and practices. This involves review of documentation (documented policies and procedures, organ receipt log books, medical notes, HTA A and B forms, information relating to donor and organ characterisation), and round table discussions / interviews with a range of staff at the transplant centre or procurement organisation. This process allows the HTA to identify any shortfalls, to provide advice and to identify areas of good practice.

The audit report

Following an audit, findings are recorded in a report which undergoes internal quality assurance (QA) to ensure consistency across the sector. The internal QA consists of a review by the support auditor, the Head of Regulation for the ODT sector, and a final review by the Director of Regulation. Once internal QA is completed, the draft report is sent to the establishment contact for an accuracy check. Following receipt of any comments the report is

finalised and published on the HTA website.

HTA audit assessment criteria

The assessment criteria used by the HTA covers the following areas:

- Donor and organ characterisation (CT);
- Retrieval of organs for transplantation (R);
- Organ preservation (P);
- Making arrangements to transport an organ (TP);
- Implantation (I);
- Traceability (TC);
- Serious Adverse Events and Reactions (S);
- General (GN).

Classification of shortfalls

Where shortfalls are identified these are classified as minor, major or critical.

Minor shortfall

A minor shortfall is a shortfall, which cannot be classified as either critical or major and can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next audit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within three to four months of the issue of the final audit report.

Major shortfall

A major shortfall is:

- a shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a living donor or a recipient;
- a shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a living donor or a recipient;
- a shortfall which indicates a major deviation from the Quality and Safety of Organs Intended for Transplantation Regulations 2012 or any HTA Directions,
- a combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the organ or organs to be transplanted.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within one to two months of the issue of the final audit report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

Critical shortfall

A critical shortfall is:

- a shortfall, which poses a significant direct risk of causing harm to a recipient patient or to a living donor; or a number of 'major' shortfalls, none of which are critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

- A notice of proposal being issued to revoke the licence.
- Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- A notice of suspension of licensable activities.
- Additional conditions being proposed
- Directions being issued requiring specific action to be taken straightaway.

Advice and Guidance

Advice and guidance are provided where a standard is met, but it is felt that improvements can be made or good practice can be shared.

Licensed establishments included in the review

Thirty seven licensed establishments are included in this review and encompass all ODT establishments currently licensed by HTA. The review reflects the diversity of ODT establishments and the range of activities that are undertaken e.g. multi-organ transplant centres, centres that carry out living donor transplants (kidney and liver lobe), private hospitals often treating overseas patients, adult and paediatric centres and NHSBT, in their role in deceased organ donation and retrieval.

Establishments that carry out any of the following activities are now required to be licensed by the HTA: (see Appendix 1 for list of licensed establishments).

- Procurement Activities:

  donor characterisation;

  organ characterisation;

  preservation of an organ;

  making arrangements to transport an organ; and

  retrieval of an organ.

- Transplantation Activities:

  organ characterisation;

  preservation of an organ;

  making arrangements to transport an organ; and

  implantation of an organ.

Review of the ODT sector

This review summarises the findings of audits carried out in the ODT sector to date and provides an opportunity to give feedback to the sector.

Findings of Audits carried out to date

Shortfalls or advice of all audits in the ODT sector have been collated against the relevant assessment criteria.

Shortfalls

There were 0 critical, 0 major and 28 minor shortfalls identified against individual assessment criteria for the audits included in this review.

This equates to an average of 0.7 minor shortfalls per establishment audited. However, 70% of the establishments included in the audit review were not found to have any shortfalls (26 /37), while six establishments (16%) were found to have only one shortfall. There were two establishments with three shortfalls and three establishments with greater than three shortfalls (four, five and seven respectively).

The maximum number of shortfalls found in one establishment was seven. This was one of the early audits and the establishment had a low score on the predicted compliance assessment matrix. However, it should be noted that establishments audited later in the schedule will have benefitted from shared learning and the opportunity to read audit reports from other establishments.

These considerations may account for improved regulatory compliance and fewer shortfalls identified in some of the establishments audited later in the schedule.

Number of shortfalls	0	1	3	>3
Number of establishments	**26**	**6**	**2**	**3**

Table 1: Summary of the frequency of shortfalls at audited establishments.

The assessment criteria most frequently associated with a shortfall were related to making arrangements to transport an organ (TP), with nine establishments found to have shortfalls against these assessment criteria. This was followed by shortfalls related to serious adverse events and reactions reporting which affected seven establishments (see Figures 1 & 2).

All establishments were found to have met the general assessment criteria (GN). This standard relates to staff members in the chain from donation to transplantation being suitably qualified, competent and trained to perform tasks, and provided with on-going training in order to carry out their tasks. All establishments had systems in place for continuous professional development and evidence of training, competency assessment and appraisal.

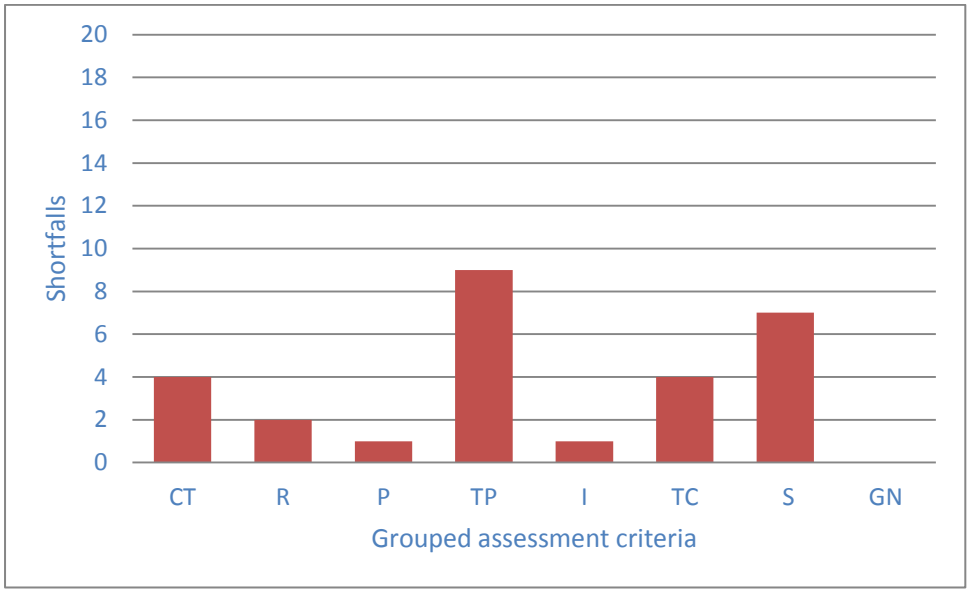


Figure 1. – The number of minor shortfalls found in each group of assessment criteria.

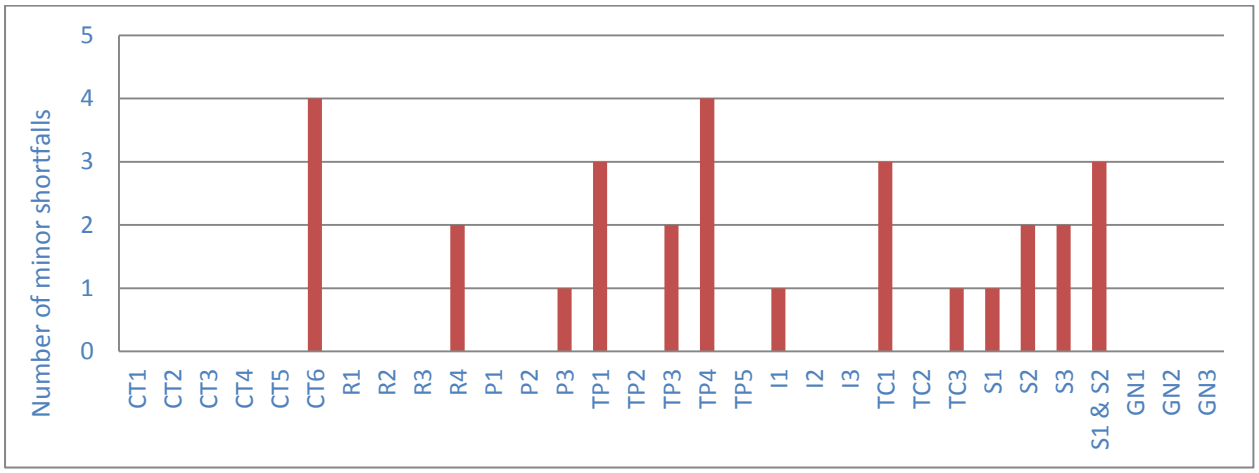


Figure 2. – The number of minor shortfalls found against each assessment criterion.

Common themes – Shortfalls

Donor and organ characterisation

The four shortfalls under donor and organ characterisation were all under criteria CT6. This relates to the information relevant to the organ reaching the implanting surgeon within a time period that will not compromise quality and safety. This assessment criterion requires an operating procedure to be in place. Each of the four establishments were found to be working in accordance with the requirements of the assessment criteria, but did not have a written procedure that reflected this.

Retrieval of organs for transplantation

There were two establishments found to have a shortfall under R4. In both cases this shortfall was in relation to the living donor discharge letter and the requirement to highlight the need to notify the centre if a donor developed any form of malignancy or transmissible disease within a time frame that could affect the recipient.

Organ preservation

One establishment was found to have a shortfall in relation to recording batch numbers of perfusion fluids, P3. The shortfall was discovered during a review of the HTA B forms and related specifically to when kidneys were re-perfused on the backbench prior to implantation. In such instances the batch numbers had been omitted from the forms.

Making arrangements to transport an organ

Three establishments were found to have a shortfall against TP1 which relates to the integrity of an organ being maintained during transport and the transport time being suitable, for example, in the rare instances where a kidney from a living donor would be re-offered into the national pool. In all three cases, the shortfalls against this standard related to the establishment not having appropriate documented procedures such as a re-offer of an organ or transporting living donor organs to other centres for transplant.

The TP3 assessment criterion relates to the specific requirements of the labelling of the shipping container and states that a documented procedure is required to demonstrate how this requirement is met. Two establishments were given shortfalls in relation to this assessment criterion due to the absence of appropriate documented procedures.

Four establishments were given a shortfall under TP4 which relates to the requirement to have an operating procedure in place to demonstrate that transported organs are accompanied by a report on donor / organ characterisation. As with TP1, the shortfalls related to having a procedure in place to reflect situations that were not routine practice, such as a re-offer of an organ or transporting living donor organs to other centres for transplant.

Implantation

Only one establishment was found to have a shortfall against I1. This related to the requirement for a documented procedure to verify the identity of the donor and donor / organ characterisation information prior to implantation. The majority of establishments audited used a modification of the World Health Organisation (WHO) surgical safety checklist for this purpose.

Traceability

Three establishments were found to have shortfalls against TC1, which relates to completion of HTA A and B forms and return of these to NHSBT within seven days. The shortfalls were, again, in relation to having a documented procedure outlining how this would be done in practice and identifying who was responsible for returning the forms.

There was only one establishment found to have a shortfall against TC3 which related to not having a record of transported organs – specifically living donor organs – leaving the establishment for implantation at another centre.

Serious adverse events and reactions

Five establishments did not have procedures for the management and reporting of serious adverse events and reactions. In a number of cases a shortfall was found against S1 and S2 for the same issue of not having awareness of identifying and managing SAEARs and not having a documented procedure that staff were familiar with.

Two establishments were found to have shortfalls for not having instructed testing laboratories to report serious adverse events. The criteria of S3 requires that establishments using third party laboratories are informed of any incidents that may impact the quality or safety of an organ.

Summary

The common theme of all shortfalls found (with exceptions of keeping a record of the time and date organs leave an establishment and information provided in discharge letters), relates to having appropriate written procedures that reflect local practice and outline roles and responsibilities. Establishments are required to have clear written procedures in place to support practices and people working under the licence. Many people are involved in the organ pathway from donation to transplantation and follow-up and documented procedures provide consistency and clarity to the overall process.

Advice

There were a total of 112 pieces of advice offered following the audits. The remit of the HTA is to give advice, not only to identify further areas for ongoing process improvement, but also to share good practice identified during audits of ODT establishments.

Advice was provided to 26 establishments. Nine establishments were provided with between one and three pieces of advice, eight establishments were provided with between four and six pieces of advice and nine establishments had greater than six pieces of advice. The maximum number of advice items provided was 12.

Number of pieces of advice	0	1-3	4-6	>6
Number of establishments	**0**	**9**	**8**	**9**

Table 2: Summary of the frequency of advice provided during audits.

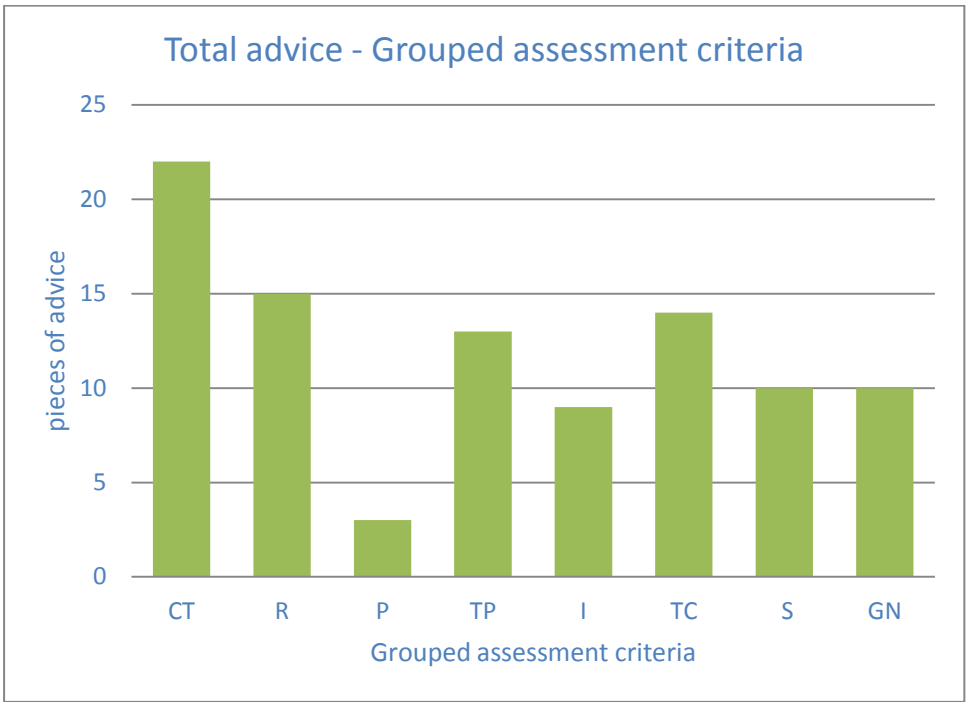


Figure 3: The number of pieces of advice provided for each group of assessment criteria.

Common Themes - Advice

Retrieval

There were 12 establishments that were provided with advice and guidance in relation to the assessment criteria under retrieval of organs for transplantation (R4) specifically to the information provided in the discharge letter. For this assessment criterion, the narratives for the shortfalls and the advice appear very similar. All transplant centres are required to provide follow up information to NHSBT in relation to living donors. Advice relates to ensuring that when patients are discharged back into primary care the donor's general practitioner is made aware of the requirement to report any serious adverse events such as the development of malignancy or a transmissible disease.

Donor and organ characterisation

Seven establishments were provided with advice against CT2. The advice relating to this assessment criterion was quite varied. Some advice related to having a checkbox to make sure all the mandatory donor data set specified in appendix A were captured, even if the answer was 'no'; for example, when considering if a donor had a history of intravenous drug use. Advice was also given in relation to transcription errors and to limit the amount of forms in use that capture duplicate information.

The advice provided in relation to this assessment criterion was also varied and included implementing a system to identify medical notes that were required to be retained for 30 years to prevent destruction. In other cases advice was specific and related to typographical errors in a records retention policy.

The majority of advice provided against this criteria related to amending NOPs or local procedures to reflect current practice. In some cases advice was provided to version control the documents. Advice provided against this assessment criterion was frequently specific, for example: ‘a trans-bronchial bronchoscopy is carried out in all lung retrievals however this additional test is not listed in the NOP document’.

Making arrangements to transport an organ

Advice against TP1 related to including more specific detail in documented procedures outlining the packaging of organs – often the advice was offered when living donor organs were being sent to other centres for transplant.

Implantation

Information was provided in relation to written procedures and in several cases a recommendation was made to include the mandatory donor / organ characterisation information in a checklist so that all information could be verified as required by I1.

Traceability

The assessment criterion of TC1 relates to the return of HTA A and B forms and advice was provided in relation to developing some form of tracking system to ensure all HTA A and B forms were returned, especially if implantation was taking place at another centre – for example a paediatric centre within the same Hospital Trust.

Advice was provided against TC3 relating to labelling of hypothermic and normothermic perfusion devices in accordance with the mandatory labelling requirements for organ boxes. Lifeports are used to perfuse kidneys during transport and are currently always accompanied during transport. A number of establishments have found difficulty with the labelling requirements because there is no obvious repository on the Lifeport for the label.

Serious adverse events and reactions

Advice against S1 and S2 predominantly related to providing training to staff members on how to identify SAEARs and specifying who will be responsible for reporting at the licensed establishment and clearly indicating those roles and responsibilities in written procedures.

Assessment criteria with no advice provided

There were four criteria with no advice provided. The criteria were CT1, R1, P2 and I3. No shortfalls were identified against these criteria.

CT1 is specific to NHSBT's licence as it relates to transmission of donor and organ characterisation information for deceased donors. NHSBT was found to be fully compliant against this criteria during their audit.

R1 relates to consent or authorisation and is relevant to NHSBT National Organ Retrieval Service (NORS) teams for deceased organ donation. This standard covers deceased donor organ retrieval (checking consent/authorisation) and living donor programmes (seeking and verifying consent or authorisation).

P2 pertains to reusable instruments used in organ preservation being subject to a validated cleaning and sterilisation procedure, which is documented. All establishments included in this review were found to be fully compliant with this criteria.

I3 is an implantation criteria and relates to situations where information specified in annex A is not available and a clinical risk benefit analysis is carried out. Our experience from the audits so far is that all information in annex A is provided or collected. In the event that this information is not available, the clinical risk benefit is documented in the recipient's medical notes. It is often difficult to see evidence of this unless the establishment can specifically remember a case and access the medical notes on site.

Finally, general pieces of advice were given in relation to reviewing all documented procedures and also making sure all documentation was in place for an establishment considering setting up a new programme, for a novel procedure or addition of activities.

Audit findings

There does not appear to be a correlation between prediction and actual compliance, however, this may be due to the fact that the spread of data was relatively confined since most establishments in this sector were already meeting the majority of the assessment criteria when the predicted compliance score was determined, and all shortfalls identified during the audits were minor. In most cases the shortfalls identified related to establishments not having a suitable documented procedure in place that reflected local practice.

There is no requirement for establishments in the ODT sector to be audited within a specific mandatory time frame. As such, any future audit strategy in this sector needs to be in accordance with the compliance and potential regulatory risks of the sector. This review has provided evidence that the sector are meeting the majority of the assessment criteria, with half of all establishments included in this review found to be meeting all assessment criteria fully.

Future audit strategy

Unlike the European legislation governing the human application sector, the EUODD does not set a prescribed timeframe for conducting audits. The EUODD states that the Competent Authority shall ensure that '…procurement organisations and transplant centres are controlled or audited on a regular basis to ascertain compliance with the requirements of the Directive'.

The findings from this review have been used to underpin the development of a future audit strategy for the ODT sector. In developing the strategy, compliance in the ODT sector was compared with compliance information from the human application sector and post-mortem sector. This comparative data indicates that the level of regulatory compliance in the ODT sector is high and that regulatory compliance is more comparable to that of the post mortem sector, where audits take place on an approximately three yearly basis. Taking into account the good level of compliance within the ODT sector balanced against the high impact of a risk materialising, it has been agreed that the HTA will conduct a further round of audits commencing in December 2015 – three years after the first round of audits commenced.

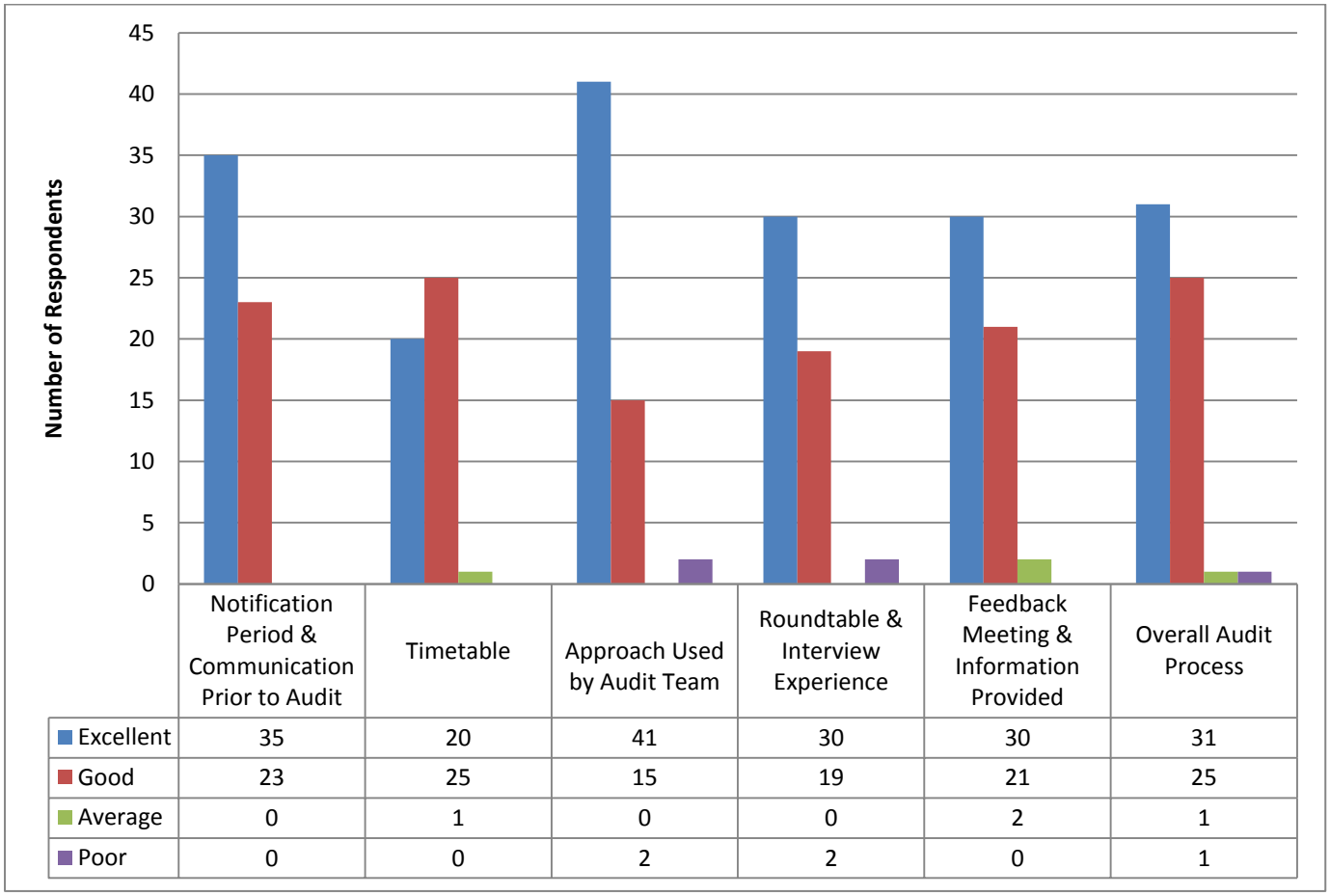
In the intervening years the HTA will maintain regulatory oversight in the sector by implementing a combination of the following activities:

- mandatory compliance updates via the portal, including a specific compliance update in relation to organ boxes when new boxes are validated and rolled out (anticipated by April 2014);
- a risk based compliance update against all assessment criteria;
- retaining the option to carry out an audit when information is received e.g. via a whistle blower, substantial changes occur to existing governance arrangements, or a SAEARs report indicates the need to do so;
- monitoring the return of HTA A and HTA B forms via quarterly reports provided by NHSBT;
- presenting an overview of regulatory requirements for organ donation and transplantation at NHSBT Specialist Nurse Organ Donation (SNOD) training days which take place biannually;
- a workshop to increase awareness of SAEARs, with a focus on identification and management. Additional workshops or training days will be added if a need is identified.

With specific reference to quality and safety of organs intended for transplantation, practice within the sector is not expected to change significantly other than an increase in the number of donations.

Establishment evaluation of audit

All staff members that are involved in the audit process are invited to provide feedback on their experiences and views of the process. Feedback is requested in relation to communication prior to the site visit, agreeing the timetable, interviews, feedback and whether the audit has improved practices (see Figure 4).



	Notification Period & Communication Prior to Audit	Timetable	Approach Used by Audit Team	Roundtable & Interview Experience	Feedback Meeting & Information Provided	Overall Audit Process
Excellent	35	20	41	30	30	31
Good	23	25	15	19	21	25
Average	0	1	0	0	2	1
Poor	0	0	2	2	0	1

Figure 4. Establishment Evaluation of Audit

Respondents are asked to score (excellent, good, average, poor) the following categories; the approach used by the audit team, the overall audit process, the notification period and communication prior to the audit, the timetable developed, their roundtable experience, feedback information provided and whether the audit has helped improve ways of working.

Implementation of the Q & S Organs Regulations in the UK has, for the majority of establishments, not resulted in a need to make significant changes to practice. However, the vast majority of establishments audited have provided feedback that the HTA audit process has improved the way they work (51 of 58, 88%).

Overall, feedback was positive and in most cases respondents rated their audit experiences as

excellent or good. It was especially encouraging that feedback suggested the audit process had improved working practices. Feedback was provided by 79% of establishments, representing 29 of the 37 licences audited.

Changes to licensed activities

Establishments must inform the HTA, in advance, of any changes which will take place to their ODT licence. This could include, for example, changes to the named contacts on the licence, to the corporate body (for example, if there is a merger of Trusts or Health Boards), or to the transplantation activities being carried out. If an establishment intends to procure or implant a new organ or composite tissue type, then it must submit a completed self-assessment against the licensing criteria to the HTA at least one month before this activity is due to begin. A focussed audit will be conducted to find out more about the proposed activity, the findings of which will be recorded in a report published on the HTA website. In particular assurance will be sought that new, or updated, operating procedures are in place to support the proposed transplantation activity.

Serious Adverse Events and Reactions

For completeness, this report considers SAEARs reports received in the last 17 months from the commencement of the legislation to February 2014. Many of these cases are still active and therefore it should be noted that the status of these SAEARs may, on rare occasions change following an NHSBT-led investigation and discussion with relevant experts and organ advisory boards.

Serious adverse events

Serious adverse events have been categorised as follows:

- **Malignancy event** – which relates to situations where a tumour is identified post transplantation that was not apparent at the time of donation. This may come to light during a post-mortem of the donor or from histological results that were not available before implantation.
- **Packaging and labelling** – which relates to any events where transplantable organs are lost due to inappropriate packaging or labelling of the organ.
- **Perfusion** – this relates to an event associated with perfusion of an organ that makes an otherwise transplantable organ unusable.
- **Retrieval damage** – any surgical or handling damage sustained during retrieval which resulted in an otherwise transplantable organ becoming unusable.
- **Transcription error** – this relates to miscommunication of critical donor or organ characterisation information that has the potential to impact on the quality and safety of a donated organ or recipient.
- **Transmissible disease** – discovery of a transmissible disease in the donor that was not known at time of donation and presents a risk but the recipient is not showing any clinical signs of infection.
- **Incorrect Testing**

There were a total of 41 serious adverse events (SAEs) reported in the 12 months post licensing. The most frequent SAEs related to retrieval damage, followed by SAEs relating to undiscovered malignancies that have not yet had clinical consequences (see Figure 5).

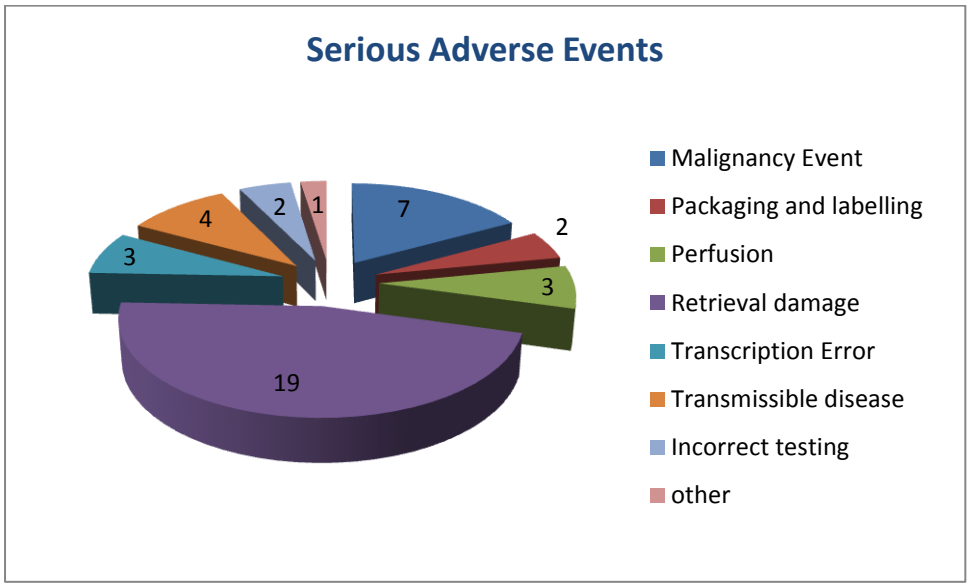


Figure 5: Number of reports of serious adverse events in each defined category.

Nineteen potentially transplantable organs were reported as lost due to damage sustained at retrieval. In most cases this was considered to be a consequence of surgical damage. However, it is often difficult to fully attribute some damage, for example a tear on the intimal surface of the vessels, as being sustained during retrieval – since fluctuations of blood pressure resulting from brain death may have the same consequences.
In order to put this figure into context, it is worth noting that there were 3,082 deceased donor organ transplants from 1212 deceased donor organ retrievals in the 2012/13 business year.

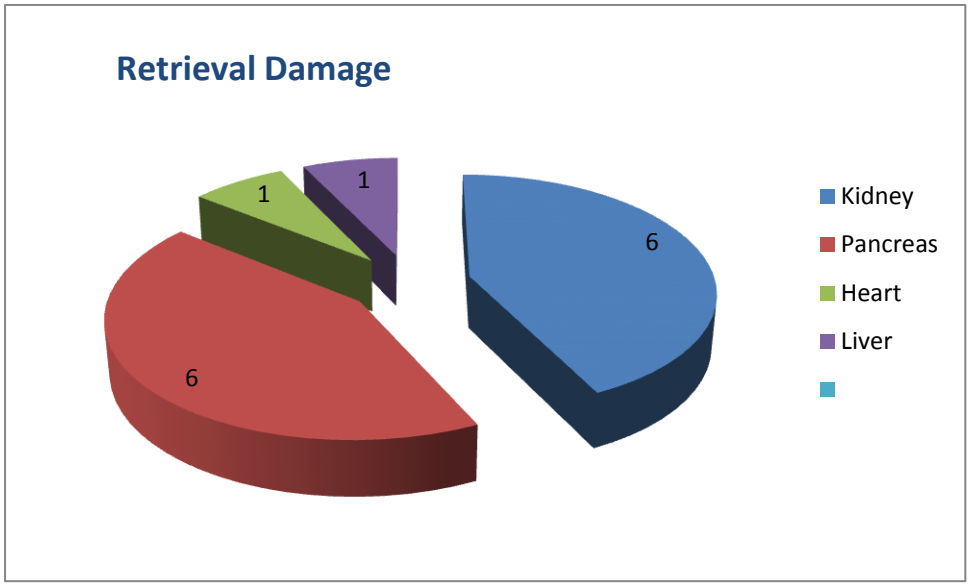


Figure 6: Organs lost as a consequence of retrieval damage.

Types of organs affected by retrieval damage are illustrated in Figure 6, below. Organs most frequently lost due to retrieval damage tend to be kidneys or pancreata. Cardiothoracic organs are much less likely to be considered un-transplantable since due to the short cold ischaemic time, the recipient will be prepared for surgery with the thoracic cavity opened prior to the organs arriving. The surgeon will usually opt to repair the organ on the back bench rather than refuse it for transplant. The implanting surgeon may have some capacity to decline to use damaged kidney or pancreatic organs on the basis of risk / benefit since intended recipients may not be in an immediate life threatening situation.

Additional reasons to explain the distribution of organs lost due to retrieval damage may be when organs are retrieved from donors after cardiac death, removal of organs needs to happen very quickly, creating greater potential for damage to certain organs (for example the pancreas may be sacrificed in favour of the liver).

The next most common SAE category was malignancy event with seven cases (17%), followed by events relating to perfusion of organs (10%) and transcription events (7%). There were four reported SAEs relating to transmissible disease and two cases relating to perfusion and labelling.

Serious adverse reactions

There were a total of 20 serious adverse reactions (SARs) reported in the first 12 months of licensing. This is significantly fewer cases than the number of serious adverse events reported, which may indicate that systems are in place to prevent SAEs translating into SARs. A similar profile in the ratio of number of SAE: SAR is seen in SAEARs for tissues and cells.

These reactions are classified into the following categories for trending purposes:

- **Donor reaction** – relates to any unintended consequence for a living donor that prolongs hospitalisation or increases morbidity / mortality.
- **Transmissible disease** – relates to transmission of a disease from donor to recipient. Examples of this include malignancy or metabolic disorders such as porphyria.
- **Transmissible infection** – as above, but when the transmitted agent is a bacteria or virus. This will also include transmission of prion infections such as Creutzfeldt-Jakob Disease (CJD).
- **Surgical removal of graft** – when a transplanted organ is removed, usually as a consequence of vessel damage or perfusion issues. Removal for primary graft non-function would not be included in this category unless the non-function was attributable to a serious adverse event.
- **Aborted procedure** – relates to situations where a recipient has been anaesthetised or a procedure commenced but is then aborted due to unforeseen circumstances.
- **Incompatible HLA –** this relates to when a mix up of donor/recipient information or a transcription error results in transplantation of a donor organ with incompatible HLA type.
- **Prolonged hospitalisation –** when a recipient requires addition time as an in-patient, most often as a consequence of an identified SAE.

The types of SAR reported are distributed throughout the defined categories with one or more for all seven categories. The most frequently reported SAR was surgical removal of graft with three instances (25% of cases). Two were owing to retrieval damage (surgical) and one instance where an implanted kidney was removed as incorrect perfusion fluid had been used (see Figure 7).

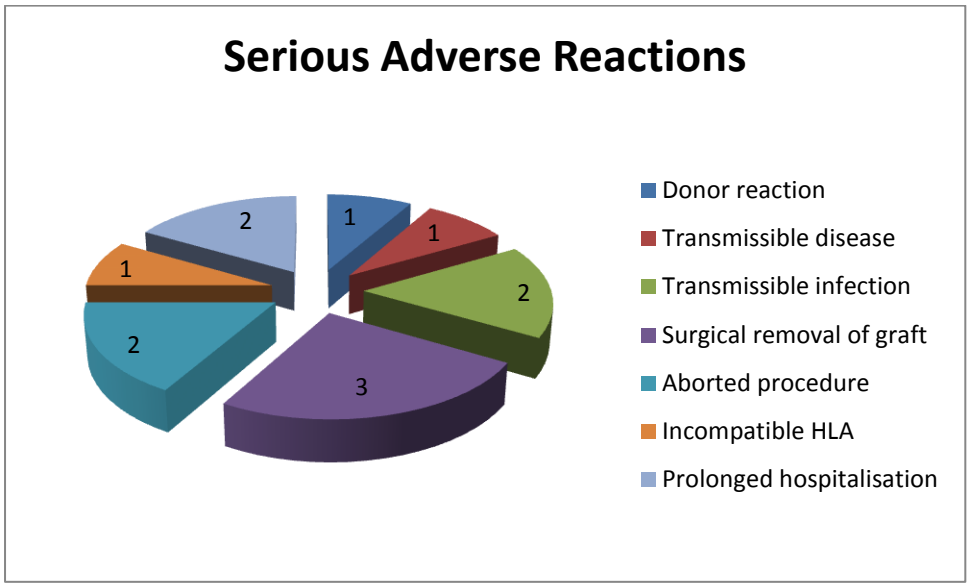


Figure 7: Number of reports of serious adverse reactions in each defined category.

SARs categorised as 'surgical removal of graft', 'aborted procedure', and 'prolonged hospitalisation' may be attributable to SAEs that relate to retrieval damage (four cases) and incorrect packaging and perfusion of organs (three cases; poorly packaged or wrongly perfused organs resulting in clinical consequences for the recipients).

The majority of events related to packaging and labelling, perfusion and retrieval damage, these combined together account for 64% (18/28) of SAEs and 58% (7/12) of SARs.

Comparing the number of reports of SAEARs in the ODT and human application (HA) sectors, there were a total of 28 SAE and 12 SARs in the ODT sector, which compares to 107 SAEs and 28 SARs in the HA sector. A ratio of one SAR per 2.3 SAE in the ODT sector and one SAR per 3.8 SAE in the HA sector (total number of HA licences 164; total number of ODT licences 37). The frequency of SARs to SAEs in the ODT sector is greater than that of tissues and cells. This is likely to be an indication of the greater risks that are acceptable with life-saving treatments being delivered within a restricted time frame.

SAEARs Reporting – NHSBT Assisted Functions

The time taken to report SAEARS to NHSBT and also from NHSBT to HTA has been collated and data displayed as quarterly results. The Framework Document states there is a requirement to report any suspected SAEARs to NHSBT within 24 hours (or immediately if a risk to patient safety). NHSBT are required to report to HTA any incidents that fall into the SAEARs category by the next working day. It is worth noting that any SAEARs reported to NHSBT on a Friday evening will show as having been reported three days later.

Figure 8 and 9 show the time taken to report SAEARs from the sector to NHSBT and from

NHSBT to HTA for SAEs and SARs respectively.

These data indicate that there has been a positive improvement over time on the number of days taken both for the sector to report to NHSBT and also for NHSBT to report to the HTA. The bar graphs have large error bars, indicating a wide spread of data. For NHSBT's reports to HTA, this is reflective of a small number of cases that appear to have taken significant time to determine whether they fall into the classification of a SAEAR. Often this process will involve consultation with NHSBT's Medical Director and relevant organ advisory groups. HTA now capture the date that NHSBT determine an incident as an SAE / SAR, rather than the date the incident occurred, making it much easier for NHSBT to achieve the next working day reporting time frame.

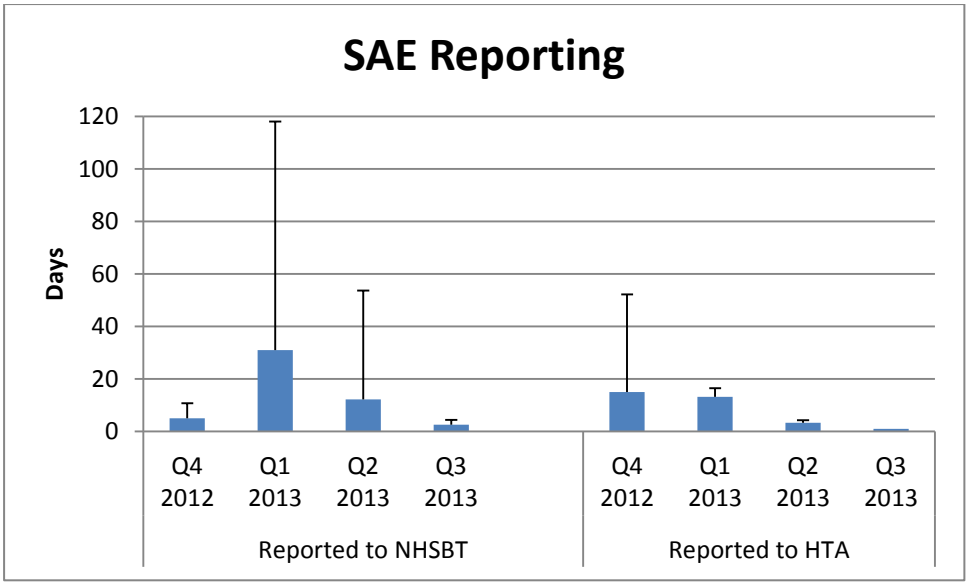


Figure 8: Time taken for SAEs to be reported from the sector to NHSBT and from NHSBT to HTA.

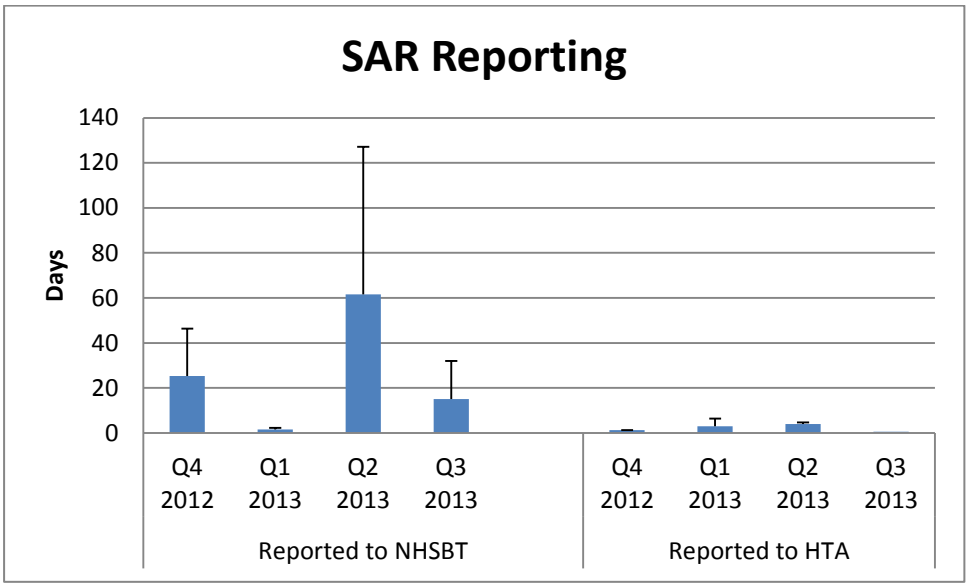


Figure 9: Time taken for SARs to be reported from the sector to NHSBT and from NHSBT to HTA. (One case of a donor reaction was identified on audit, almost three months post-occurrence and it is this case that is responsible for the large error bars in the Q2 reporting to NHSBT figures).

Acknowledgments

The HTA would like to thank staff at the 37 licenced establishments for offering their help, cooperation and assistance throughout the audit process.

Appendix 1: List of licensed establishments included in this review

Licence number	Establishment / Organisation	Audit date
40049	University Hospital's NHS Foundation Trust, Bristol	25/09/12
40054	University Hospitals of Leicester NHS Trust	29/1/13
40052	Bart's Health NHS Trust	30/1/13
40011	BUPA Cromwell Hospital	26/2/13
40039	University Hospitals Coventry and Warwickshire NHS Trust	28/2/13
40044	Imperial College Healthcare NHS Trust	6/3/13
40045	Newcastle upon Tyne Hospitals NHS Foundation Trust	26/3/13
40019	Royal Brompton and Harefield NHS Foundation Trust	18/4/13
40029	Guy's and St Thomas' NHS Foundation Trust	23/4/13
40035	The London Clinic	25/4/13
40055	Plymouth Hospital NHS Trust	30/4/13
40036	London Bridge Hospital	9/5/13
40028	Golden Jubilee National Hospital	9/5/13
40037	Cardiff and Vale University Local Health Board	15/5/13
40024	NHS Lothian	21/5/13
40031	Royal Liverpool and Broadgreen University Hospitals NHS Trust	5/6/13
40034	Sheffield Teaching Hospitals NHS Foundation Trust	13/6/13
40043	Central Manchester University Hospitals NHS Foundation Trust	18/6/13
40025	Royal Free London NHS Foundation Trust	26/6/13
40056	NHS Blood & Transplant	8/7/13
40040	Leeds Teaching Hospitals NHS Trust	9/7/13
40053	University Hospital of South Manchester NHS Foundation Trust	24/7/13
40033	Papworth Hospital NHS Foundation Trust	31/7/13
40022	NHS Greater Glasgow & Clyde Health Board	20/8/13
40050	St George's Healthcare Trust	29/8/2013
40051	Birmingham Children's Hospital NHS Foundation Trust	10/9/13
40067	London Independent Hospital – BMI	10/9/13
40023	King's College Hospital NHS Foundation Trust	18/9/13
40048	North Bristol NHS Trust	24/9/13
40032	Cambridge University Hospitals NHS Foundation Trust	1/10/13
40046	Belfast Health and Social Care Trust	17/10/13
40038	Oxford University Hospitals NHS Trust	20/11/13
40020	Portsmouth Hospitals NHS Trust	26/11/13
40041	Great Ormond Street Hospital for Children NHS Foundation Trust	28/11/13
40042	University Hospital Birmingham NHS Foundation Trust	10/12/13
40079	BMI The Priory Hospital	11/12/13
40017	Nottingham University Hospitals NHS Trust	15/1/14

Appendix 2: Assessment Criteria

Donor characterisation and organ characterisation (CT)
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.
CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.

Retrieval of organs for transplantation (R)
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.

Organ preservation (P)
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.

P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.

Making arrangements to transport an organ (TP)
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP2) The organ shipping container is suitable for transport of the specified organ.
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.

Implantation (I)
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.
I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.

Traceability (TC)
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.

Serious adverse events and serious adverse reactions (S)
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.

General (these activities apply to all licensable activities) (GN)
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.
GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.