Site visit audit report on compliance with HTA requirements

NHS Blood & Transplant

HTA licensing number 40056

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

8 – 11 July 2013

Summary of Audit findings

NHS Blood & Transplant (the establishment) was found to have met all assessment criteria.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria :

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

Organ type	Heart	Lung	Liver	Kidney	Small Bowel	Pancreas
Adult deceased	**DC, OC, T**	**DC, OC, T**	**DC, OC, T, P**	**DC, OC, T, P**	**DC, OC, T**	**DC, OC, T, P**
Paediatric deceased	**DC, OC, T**	**DC, OC, T**	**DC, OC, T, P**	**DC, OC, T, P**	**DC, OC, T**	**DC, OC, T, P**

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

Background to the establishment and description of audit activities undertaken

NHS Blood & Transplant (NHSBT) is a Special Health Authority with responsibilities for organ donation and transplantation across the United Kingdom. The Organ Donation and Transplant (ODT) Directorate manages the National Transplant Database, the NHS Organ Donor Register and provides a dedicated 24 hour service that assists with the identification, referral and progression of organ donation from deceased donors, and ensures that donated organs are matched and allocated to patients in an unbiased way. NHSBT perform the matching and allocation in altruistic and paired / pooled living donations and maintain records of traceability.

The directorate has a main office site at Stoke Gifford in Bristol and twelve regional organ donation services teams throughout the UK - South East, South Central, South West, South Wales, London, Eastern, Midlands, North West, Yorkshire, Northern, Scotland and, Northern Ireland. The Duty Office of NHSBT, which is based in Bristol, acts as a point of contact for Specialist Nurses in Organ Donation (SNODs), transplant teams and courier services which transport organs.

The audit team visited the Duty Office, Data Services, Commissioning and Quality Assurance, and Clinical governance departments in Bristol. In addition, the Scotland, North West and Midlands regional offices were visited. During each visit the audit team interviewed various members of staff and reviewed documentation relating to the practices and procedures taking place. In addition, an audit of donor records was undertaken. More details of the records audit are provided against assessment criteria CT2 below.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
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.	This criterion is fully met. The Specialist Nurse-Organ donation (SNOD) acts under the guidance and supervision of the associate medical director of the ODT directorate, NHSBT. The SNOD approaches the family of the deceased following a referral from a member of staff at the hospital where the potential donor is being treated. Following the end of a detailed consent process and if consent has been given by the family of the donor, the SNOD will start gathering the required donor characterisation information by holding discussions with the deceased's family, treating clinician and undertaking a review of the relevant clinical records. Information about donor and organ characterisation are recorded on a number of forms including, a core donor data form, patient assessment form and an organ donor clinical pathway document. In addition, once the family have consented to the use of the donor's organs, the SNOD will initiate the process of requesting relevant medical information from the donor's General Practitioner (GP). The collection of this information is facilitated by the use of a form which is sent to the deceased's GP via secure fax. All relevant clinical and donor history data is entered onto the establishment's Electronic Offering System (EOS). Where any data, such as the donor's clinical history from their GP, is not available this is also recorded in EOS so that the implanting surgeon may make an informed decision on the acceptance or rejection of any organs offered to them.	**None**

CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. Donor and organ characterisation information is collected and recorded using a number of paper forms and documents in addition to electronic data capture systems. 'Management Process Document' procedures describing the use of the donor and organ characterisation information collection systems are in place and are supplemented by Standard Operating Procedures (SOPs) and information documents. A number of the characterisation documents and related procedures have been recently implemented. It was understood during the audit, that as the new documents and procedures are becoming embedded in routine practice, the establishment plans to undertake a review to identify which aspects of the procedures and data capture systems work well and which aspects may benefit from further development or streamlining. During the time at the Duty Office three electronic donor records were reviewed for each of the three regional offices that were visited, the Scottish office, the North West office and the Midlands office. Information relating to around 20 donor data points were taken from the National Transplant Database (NTxD). During visits to the various regional offices the paper donor records were reviewed and the original hand written donor data compared against the electronic data stored in NTxD. In addition to the three donor records chosen per regional office, at the North West and Midland regional offices an additional donor from each office was selected at random from the files and the same 20 data points reviewed against the data held in NTxD via EOS. Some discrepancies were found during this audit. There were five donors where serology results for Epstein-Barr Virus or toxoplasma were shown as awaited in NTxD but were present in the paper donor records, meaning that NTxD had not been updated to reflect the serology screening results when they became available.	**None**

	Additionally there were three donor records where the height, weight or girth measurements had been incorrectly transcribed between the paper files onto NTxD. There were no clinical consequences for any recipients as a result of these discrepancies. The establishment has already identified the potential for transcription errors to occur and has initiated a detailed audit of paper donor files against information held in NTxD. This audit looks at key data points which also cover areas where errors were found such as virology results, blood group results, donor height and past medical history data. Advice has been given to the establishment below regarding the internal audit that is being undertaken. Additionally, during the audit it was found from interviews with establishment staff that there was variation in the approach to the conducting of haemodilution calculations. The audit team reviewed the establishment's procedures relating to haemodilution calculations (SOP3630 and INF831). The INF831 document states that whenever there is a risk to the reliability of a virology screen a haemodilution calculation must be performed. One factor highlighted in INF831 as posing a potential risk to the validity of serology results if the receiving of blood transfusions by the donor during their treatment. During the audit of paper donor files a case was found where a donor had received a blood transfusion of two units of blood. According to the INF831 document this should have triggered a haemodilution calculation to be conducted; however no calculation had been performed. Advice has been given below about the procedural documents relating to haemodilution calculations.	

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.	This criterion is fully met. Where additional donor or organ characterisation tests are required and undertaken, the results are recorded both in paper donor clinical records and on the establishment's electronic donor database. Should any anomaly requiring further investigation be discovered following retrieval of the organ, such as investigation into a nodule found on an organ which may be malignant, additional testing can be performed at either the retrieving hospital or at the implanting centre. The location of where additional testing takes place may depend upon various factors, for example, the availability of an out of hours pathology service and is determined on a case by case basis.	**None**
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.	This criterion is fully met. The establishment has a national Transplant Directorate Policy regarding the management of transplant related records which refers to an organisational wide policy on record retention. The establishment's documented procedures (SPN189 and SOP3863) stipulate that transplant related documentation and records will be kept for the required time periods.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion was not assessed. This assessment criterion is subject to on-going discussions between NHSBT and the HTA regarding suitable mechanisms to review and act on the Clinical Pathology Accreditation (CPA) status' of the laboratories which are frequently used by the establishment for conducting donor and organ characterisation tests. The establishment has developed a Management Process Description (MPD) which describes the procedures for checking the CPA status of the frequently used testing laboratories and the actions to take should a testing laboratory not have full accreditation. At the time of the audit, however, this MPD had not been fully implemented. Staff at the establishment's regional offices follow the first section of the MPD which gives details on how to determine the CPA status of the frequently used testing laboratories and how to report these statuses to the establishment's national quality management team. Following reporting the accreditation status to the national quality management team no further action is taken. Actions to be taken following the determination of the accreditation status is subject to the outcome of the on-going discussions between the HTA and the establishment.	**Not assessed**

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.	This criterion is fully met. Organ and donor characterisation information is available to the implanting surgeon via the establishments EOS system which allows the implanting surgical team to review all of the relevant donor and organ information via the internet. Donor and organ characterisation information is uploaded into NTxD of which EOS is a user accessible portal allowing the entering and viewing of relevant information. SNODs upload donor and organ characterisation information onto NTxD via EOS as it becomes available. To facilitate the rapid access of donor and organ information to implanting surgeons and recipient centres the establishment launched EOS mobile in January 2013 so that some key donor and organ information can be viewed via mobile devices. In the months following the launch of EOS mobile 93% of organ offers were reviewed by recipient centres via EOS. All transplant centres are able to access EOS however not all have yet trained staff to use the EOS system. Where a transplant centre does not have staff who are able to view EOS (either due to staff training or a computer system failure), the establishment has procedures to allow manual organ offers and transmission of donor and organ characterisation information to be made. If manual offers or transfer of characterisation information is used, any information given verbally over the phone is always followed up with a secure fax to the recipient centre.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Retrieval of Organs for transplantation		
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.	This criterion is not applicable. This criterion is not applicable to the establishment as this is the responsibility of the retrieving surgeon.	**N/A**

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.	This criterion is not applicable. This criterion is not applicable to the establishment as equipment used in organ retrievals is supplied by the National Organ Retrieval Service teams (NORS) who undertake activity under the licence held by their own hospital.	**N/A**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is not applicable. This criterion is not applicable to the establishment as equipment used in organ retrievals is supplied by the National Organ Retrieval Service teams (NORS) who undertake activity under the licence held by their own hospital.	**N/A**
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.	This criterion is not applicable. The establishment does not have a role in living donor follow up which is undertaken under the licence held by the retrieving hospital.	**N/A**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Organ preservation		
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.	This criterion is not applicable. This criterion is not applicable to the establishment as equipment used in organ retrievals is supplied by the National Organ Retrieval Service teams (NORS) who undertake activity under the licence held by their own hospital.	**N/A**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is not applicable. This criterion is not applicable to the establishment as equipment used in organ retrievals is supplied by the National Organ Retrieval Service teams (NORS) who undertake activity under the licence held by their own hospital.	**N/A**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is not applicable. This criterion is not applicable to the establishment as the responsibility to record details of perfusion fluids coming into contact with organs is that of the retrieving surgeon acting under the licence held by their own hospital.	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
Making arrangements to transport an organ		
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.	This criterion is fully met. The establishment has produced a guidance document for NORS teams to follow should they be responsible for packing organs. Additionally the organ packing guidance could be followed by a SNOD should they be packing any organs. The establishment has a contract in place with a transport company stipulating that any deviations from the planned transport schedule must be reported to the establishment immediately. Additionally the contract stipulates that any adverse events during transport must be reported to the establishment immediately.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment only has responsibility for kidney/pancreas transport boxes. These boxes have been validated as being suitable for transport of these organs. These boxes are also sealable with a uniquely identifiable security tag (details of which are recorded on the accompanying paper documents) so that the recipient centre can assure themselves that the box has not been tampered with/opened during transport.	**None**
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.	This criterion is fully met. The guidance documents created for use by the NORS teams includes details of how organ boxes should be labelled. Additionally, the kidney/pancreas transport boxes supplied by the establishment have labels as part of a labelling and packing kit included with them. The labels require completion, however some core data is pre-populated. This helps to assure that the organ boxes are labelled in accordance with the information specified in paragraph 68 of the framework document.	**None**

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.	This criterion is fully met. Donor and organ characterisation information is available for recipient centres to access via EOS. Should an establishment not be able to access EOS for any reason SOP3925/1.1 details a manual offering process and manual transfer of characterisation data process. To receive characterisation data, SNODs can fax the Core Donor Data form to the duty office for entry onto the NTxD. To disseminate characterisation information the SOP details the process by which characterisation information can be faxed to recipient centres in addition to giving information over the telephone.	**None**
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.	This criterion is fully met. Refer to criterion TP1.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Implantation		
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.	This criterion is not applicable. This criterion is not applicable to the establishment as it is not involved in implantation activity.	**N/A**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is not applicable. This criterion is not applicable to the establishment as it is not involved in implantation activity.	**N/A**
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.	This criterion is not applicable. This criterion is not applicable to the establishment as it is not involved in implantation activity.	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
Traceability – (*these criteria apply to all licensed activities*)		
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.	This criterion is fully met. Completion of the HTA A and B forms is the responsibility of the retrieving and implanting surgeon respectively. During the organ retrieval process the SNOD may facilitate the recording of some information required on these forms by completing the HTA A form themselves prior to the retrieving surgeon finalising and signing the form. Details of how to do this are included within the establishment's procedure SOP3648.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. As a donor record is created within the NTxD, a unique donor identifier is also created automatically by the system. This process is described within SOP3828.	**None**
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.	This criterion is fully met. The establishment has recently implemented an Organ Transport Record form which records dates, times and courier details for when organs are both sent and received. During the audit of paper donor records described above in the background section of this report however, cases were found where the Organ Transport Record had not been completed correctly or had not been completed at all. It is recognised that the Organ Transport Record and it's use is a new process and is still becoming embedded. Advice has been offered against this criterion below.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.	This criterion is fully met. SOP3888 and 3842 give details of how to report serious adverse events and/or reactions. The documents also include details of the timeframes in which incidents including serious adverse events and reactions should be reported and when follow up reports of the incident are required. During the audit at the duty office the audit team reviewed the actions taken following some recent incidents (one of which has been reported to HTA as a serious adverse event). It was noted that swift action had been taken to review the incidents and develop a 'Duty Office Review' action plan to address the root causes of the incidents.	**None**
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.	This criterion is fully met. Refer to assessment criterion S1.	**None**
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.	This criterion is fully met. Refer to assessment criteria TP1. In addition to stipulating within the transport provider's contract the requirements for reporting adverse events to the establishment, the regional office staff have initiated meetings with the frequently used third party testing laboratories. During the meetings with the testing laboratories the establishment staff review any adverse events and also remind the laboratories about the requirement to alert the establishment of adverse events.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
General – (*these criteria apply to all licensed activities*)		
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.	This criterion is fully met. Establishment staff involved in the chain from donation to the transplantation or disposal of an organ have been appropriately trained and are competent and qualified to undertake their tasks.	**None**
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.	This criterion is fully met. Refer to assessment criterion GN1.	**None**
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.	This criterion is fully met. Medical activities are performed under the guidance of the associate medical director of Organ Donation and Transplant or the relevant specific advisory group.	**None**

Advice

The HTA advises the establishment to consider the following to further improve practices:

No.	Assessment Criterion	Advice
1.	CT2	The licence holder is advised to review the SOP and information documents that relate to haemodilution calculations to ensure that they are sufficiently clear and detailed to result in a consistent approach to the undertaking of haemodiltion calculations and when they are necessary. Once reviewed the licence holder is also advised to undertake further training of establishment staff about when conducting a haemodiltion calculation is necessary.
2.	CT2	The establishment has already identified the potential for transcription errors to occur and has initiated a detailed audit of paper donor files against information held in NTxD. This audit looks at key data points which also cover areas where errors were found such as virology results, blood group results, donor height and past medical history data. Once this audit is completed, the licence holder is advised to identify, implement and train establishment staff on appropriate measures to mitigate the risk of transcription errors occurring and/or on systems to identify potential transcription errors in the future.

3.	TC3	During the audit of paper donor files an example was found when an organ transport form had not been completed fully. Additionally, a further example of where a transport form had not been included in the file was also found. As the use of these transport forms is a new procedure the licence holder is advised to audit compliance with procedures relating to the use of the transport forms to give assurance that they are being used as intended.

Concluding comments

Areas of strength and good practice were identified during the audit.

It was noted that the establishment has made good progress in complying with the HTA's assessment criteria since the pilot audit carried out 12 months previously. Just ahead of the implementation of the Directive and Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012, the establishment agreed to take part in a pilot audit as the HTA were developing the audit strategies for the sector. The Eastern regional office was visited as part of the pilot audit. At that stage many of the establishment's documented procedures were in draft as the establishment was preparing to be licensed and developing new processes. During this audit in 2013 it was found that processes have been developed, implemented and are supported by multiple documented procedures.

During the visit to the Scottish regional office the audit team were informed about the meetings that had been set up with relevant stakeholders such as the surgical transplant teams and the testing laboratories. These meetings facilitate the efficient transfer of information between the establishment staff and the third party stakeholders.

At the northwest regional office it was noted that robust procedures to track the packs that SNODs use to collect donor information and record consent had been implemented. The office keeps a record of all packs made and the versions of documents within them. This allows them to recall any packs that are in the field at donor hospitals should any of the documentation change. This helps to ensure that the latest versions of documents are being used by SNODs.

At the Midlands regional office it was considered that the meetings held with the theatre staff at retrieval and implanting hospitals to inform them about the need for record keeping and other implications of the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012 to be good practice.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent for factual accuracy: 7 August 2013

Report returned with comments: 21 August 2013

Final report issued: 9 September 2013

Appendix: Classification of the level of shortfall

Where the HTA determines that an assessment criterion is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an assessment criterion, it works on the premise that a lack of evidence indicates a shortfall.
The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.
Or
A number of 'major' shortfalls, none of which is 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:

(1) A notice of proposal being issued to revoke the licence

(2) 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.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.
A shortfall in the carrying out of licensable activities which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient
or
A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;
or
A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;
or
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 quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 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.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which 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 3-4 months of the issue of the final audit report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final audit report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.
Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit audit.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.