Site visit audit report on compliance with HTA requirements

Leeds Teaching Hospital NHS Trust

HTA licensing number 40040

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

9-10 July 2013

Summary of Audit findings

Leeds Teaching Hospitals NHS Trust (the establishment) which includes St James's University Hospital and Leeds General Infirmary was found to have met all assessment criteria.

Particular examples of strengths and 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	Liver	Kidney	Composite tissue - Limbs
Adult living	**DC, OC, P, R**	**DC, OC, P, R**	**N/A**
Adult deceased	**DC, OC, P, R**	**DC, OC, P, R**	**DC, OC, P, R**

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)

Licensable activities carried out by the establishment – Transplant activities

Organ type	Liver	Kidney	Composite tissue - Limbs
Adult	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**
Children	**OC, P, T, I**	**OC, P, T, I**	**N/A**

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)

Background to the establishment and description of audit activities undertaken

St James's University Hospital and Leeds General Infirmary undertake procurement and transplantation of abdominal organs. Transplantation activities for adult patients are carried out at St James's University Hospital and for children at Leeds General Infirmary. An arm transplantation programme has been set up at Leeds General Infirmary and the first transplant took place in December 2012.

Abdominal retrieval surgeons from St James's University Hospital work together with surgeons from Wythenshawe Hospital Manchester, as part of the multiorgan National Organ Retrieval Service (NORS) team to retrieve abdominal organs. There is a weekly rota for each centre to provide a scrub nurse, equipment and perfusion fluids; however each retrieval is attended by a surgeon from Leeds and a surgeon from Manchester.

Last year, the establishment undertook 180 kidney transplants, including 50 from live kidney donors, and 12 paediatric transplants. The establishment also undertook 120 liver transplants including 12 from live liver donors, and 18 paediatric transplants. Each year, surgeons split around 25-30 livers in accordance with established protocols and the liver lobes are transported to other centres for transplantation as required. Transplanted organs are from donations after brainstem death, donations after cardiac death and live donors including altruistic donors. The establishment accepts organs from extended criteria donors. Transplant surgeons have considerable experience in evaluating the risk in accepting these organs for transplantation whilst taking into account the individual recipient's needs and wishes.

Tissue typing and cross matching services are provided by the Tranplant Immunology Laboratory based at St James's University Hospital. The hospital also provides an on-call histopathology service to support transplantation. Transportation of organs for implantation at the establishment is undertaken by a transport provider contracted by the Trust or by NHS Blood and Transplant (NHSBT) commissioned transport providers.

The HTA audited St James University Hospital and Leeds General Infirmary on 9 and 10 July 2013. The audit included round table discussions with key staff who work under the licence and a review of documents and records. Policy documents, patient clinical records, training records and other documentation relating to licensable activities were reviewed. The establishment has a suite of documented procedures for licensable activities. The establishment has also adapted all the National Operating Procedures (NOPs) including the standard operating procedure (SOP) which details how to report serious adverse events and reactions to NHSBT.

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 not applicable. The establishment is not responsible for characterising deceased donors. This activity is carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**N/A**
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. The establishment has adapted NOP 001, NOP 002 and issued SOP 22 which covers the management of donor virology, microbiology and histological information. Information on live donors is obtained from interviews with donors, donor questionnaires, and virology screening. All information is filed in the donor's clinical notes. Characterisation of deceased donors and organs from deceased donors is carried out by the SN-OD under NHSBT's licence.	**None**
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. The establishment has adapted NOP 001 which defines the donor characterisation specified in part B of the Annex to the Directive and issued SOP 22 which covers the management of donor virology, microbiology and histological information. For organs from deceased donors additional characterisation may be requested by the implanting surgeon once the organ has been received at the hospital. These tests could include histopathological examination of biopsies and are undertaken by the on-call pathology services based at the hospital.	**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 adapted NOP 002 and NOP 006. The establishment has issued SOP 25 which covers the management of transplant records. The SOP states that transplant records including patient records and records of investigations relating to transplantation are to be retained for 30 years. All storage cabinets containing paper records such as donor and recipient files are marked with the statement – 'keep for 30 years'.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Tissue typing and cross matching services are provided by the Transplant Immunology Laboratory at St James's University Hospital. This laboratory has Clinical Pathology Accreditation (CPA) and European Federation of Immunogentics (EFI) accreditation. NHSBT is responsible for ensuring that the required tests for donor and organ characterisation for deceased donors are carried out.	**None**

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. Transplant coordinators (TC) receive offers of deceased donor kidneys from SN-ODs or from the NHSBT Duty Office during working hours. Research Fellows are responsible for receiving these offers outside working hours. In the case of liver offers, the on-call liver TC receive offers both during, and outside working hours. Staff record the Electronic Offering System (EOS) number, log onto EOS to obtain further information and liaise with the transplanting surgeon to accept or decline offers as appropriate. TCs complete offer forms which are used to record communications between the TC and NHSBT. The establishment has adapted NOP 001 and NOP 002 which define donor and organ characterisation and transmission of information to the implanting surgeon. The establishment has implemented several SOPs - SOP 23 (Management of kidney offers), SOP 26 (Management of a donor organ) and SOP 20 (Arranging a liver transplant) which outline how information is transferred to the implanting surgeon. Surgeons document information on organ characterisation on the NHSBT split liver form which accompany livers which are split on site and sent to other recipient centres. Surgeons responsible for procurement of organs from live donors work closely with implanting surgeons in order to ensure effective transmission of information. *Advice is offered against this assessment criteria.*	**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 fully met The establishment has adapted NOP 002. The NORS team follow the NHSBT procedure - National Standards for Organ Retrieval from deceased donors- which sets out the requirement to check for consent before organs are retrieved. Consent for donation of kidneys and liver by living donors is checked before procurement. Consent forms are filed in the donor's clinical notes.	**None**
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 fully met. The establishment has adapted NOP 004 and issued a policy document- Medical Devices and Equipment management policy which states that 'all devices hired or purchased must be CE marked'.	**None**
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 fuly met. The establishment has adapted NOP 004. The establishment has a policy which covers the decontamination of reusable medical devices and other hospital equipment. The audit team reviewed the revalidation documentation for the sterile services unit.	**None**
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 fully met. All living donors are invited to attend annual follow up clinics at St James's University Hospital. Letters sent to General Practitioners (GPs) when live organ donors are discharged from hospital, includes specific references to reporting of events such as malignancies or infections which may have a bearing on organ recipients. Liver TCs send annual health questionnaires to liver donors requesting information.	**None**

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 fully met. See assessment under criterion **R2**	**None**
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 fully met. See assessment under criterion **R3**	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. Staff record details of perfusion fluids (type, manufacture and batch number) used during retrieval and prior to implantation in the relevant HTA A or B form. Staff use the 'Operating Sheet Kidney Benching form' to record perfusion fluids used when backbench work is done on kidneys before transplantation. These details are transferred to the HTA B form which is sent to NHSBT. Staff complete details of perfusion fluids used on the 'Destination Form for Kidneys not Transplanted in LTHT' which accompany kidneys which are sent on to other recipient centres. Benching forms are used to record perfusion fluids used before livers are implanted. NHSBT split liver forms are used to document perfusion fluids coming into contact with split livers.	**None**

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 TC is responsible for organising transport of organs from donor hospitals to the establishment using contracted local or NHSBT commissioned transport providers. The Trust commissioned transport provider also transports organs between St James's University Hospital and Leeds General Infirmary. Kidneys arriving at St James's University Hospital are kept in a secure transplantation room. Livers are delivered directly to the anaesthetic room adjacent to the theatres at St James's University Hospital. Staff complete the benching form when organs arrive at the establishment. The form is used to record the time of arrival of the organ, names of medical staff who are responsible for the organ, the donor hospital, a check on the integrity of the organ box, packaging of organs, condition of crushed ice, *etc*. The establishment uses a CE marked kidney transporter (LifePort) in some retrievals which enables kidneys to be perfused and monitored during transport. The establishment has adapted NOP 003 and has a documented procedure (TFT SOP – Transportation of Human Tissue) which covers the packing of organs and labelling of transport boxes. *Advice is given against this assessment criterion*	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion if fully met. The establishment uses NHSBT kidney boxes and the LifePort kidney transporter to transport kidneys. Proprietary cool boxes are used to transport livers and limbs. The establishment intends to use validated transport boxes when they are issued by NHSBT.	**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. See assessment of criterion **TP1** above. The NORS team follow the NHSBTprocedure - National Standards for Organ Retrieval from deceased Donors - which states that retrieval surgeons and SN-ODs are responsible for ensuring that organ boxes are labelled correctly. Where a LifePort transporter is used, the establishment places relevant documentation in a file which is attached to the kidney transporter.	**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. The establishment has adapted NOP 003 and has a documented procedure TFT SOP which details information which must accompany the organ during transportation. Following retrieval by the NORS team transported organs are accompanied by the HTA A form which is an organ specific form which has been checked and signed by the retrieval surgeon. The SN-OD also uploads information about donor characterisation onto EOS.	**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. The establishment has adapted NOP 003 and has a documented procedure TFT SOP which also applies to the establishment's transport provider and all third parties employed by this provider. Transport requirements are detailed in the NHSBT procedure -"NHSBT Specification for the Provision of Transport for Human Organs". Retrieval surgeons are responsible for reporting any serious adverse events which occur during transport when they accompanying retrieved organs back to the establishment for implantation.	**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 fully met. The establishment has adapted NOP 002 and has a series of documented procedures which cover the requirements for donor identification and collection of information prior to implantation. • SOP 20 – Arranging a liver transplant • SOP 23 – Management of kidney offers • SOP 26 – Management of an organ within the Leeds Teaching Hospitals • SOP 22- Management of Microbiology, Virology and Histological Information. Surgeons review information provided by the TC and /or Research Fellows and information on printed EOS forms. Urgent cross-match reports are sent by the laboratory. The implanting surgeon signs to acknowledge receipt of the cross-match reports. Before each liver transplant, the surgical team goes through the 'safe surgery checklist' which is modelled on the World Health Organisation surgical checklist, and includes checking of the donor and recipient's blood group. There are plans to implement an equivalent checklist before each kidney transplant.	**None**
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 fully met. Staff complete the benching form when the organ arrives at the establishment. The form is used to record the time of arrival of the organ, and checks on the integrity of the organ box packaging of the organ and condition of crushed ice. This form is reviewed before implantation.	**None**

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 fully met. The implanting surgeon undertakes a risk/benefit analysis if any of the information required to characterise the donor including information specified in Annex A of the Directive, is not available. The risk/benefit analysis is documented in the recipient's clinical notes. In these situations, the recipient is made aware of the relevant risks.	**None**

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. The establishment has adapted NOP006 and has an SOP 25 – Management of Transplant records which covers this requirement.	**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. Each deceased donors is assigned a unique NHSBT ODT number, which is recorded on EOS and the HTA A form. Live donors and all recipients are identified by their name, NHS number and date of birth.	**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's SOP 25 – Management of Transplant records states that all records transport records are retained for 30 years.	**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. The establishment has adopted NHSBT Standard Operating Procedure SOP3888/1 -Reporting an Organ Donation or Transplantation Incident to NHSBT and staff are aware of the reporting requirement. The establishment has an incident reporting SOP 21 – Governance audit and incident reporting for organ donation and transplantation. Organ transplant incidents are discussed during regular multidisciplinary team meetings and at clinical governance meetings.	**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. See assessment under 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. The establishment has a SOP 24 – Assurance of internal and external providers who support organ donation and transplantation process. The document states that the testing laboratory and transport providers have been informed of the importance of informing the transplant team of any incident that occurs during donor testing and the transport of organs.	**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. The establishment issues competency certificates to surgeons who are signed off following assessment by senior surgeons. Staff training records were reviewed during the audit.	**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. TCs train ward staff who receive kidneys at St James's University Hospital, and are responsible for contacting the Transplant Immunology Laboratory and placing the kidney boxes in the secure transplant room. Staff attend external meetings on a regular basis.	**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. The establishment has adapted NOP 005 which details the medical activities performed under the guidance of a registered medical practitioner.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	N/A	The establishment has detailed local procedures which cover licensable activities and has adapted or adopted NOPs as appropriate. The establishment is advised to consider consolidating these documents in order to minimise duplication and reduce the number of documents and the effort required to keep them up to date.
2.	CT6	The establishment is advised to consider implementing the use of a communication log when kidney offers from SNODs and NHSBT Duty Office are received out of hours by Research Fellows. Notes are usually written on the EOS printout and the time when the information was received may not always be recorded. A formal system of recording information will help to ensure that all information relating to kidney offers received by Research Fellows is documented and provided to implanting sugeons. A formal system of recording information will also enable effective audits of the acceptance and rejection of organs offered to the establishment.

3.	TP1	The establishment has a robust system in place for recording the receipt of organs at St James's University Hospital. The establishment is advised to consider implementing a similar system when organs are transferred from St James's University Hospital and received at Leeds General Infirmary. The local transport provider uses a transport form to document the time of pick up and delivery of the organ and record the name of the person who transported the organ. Each transport form has a unique number which can be recorded and used by the establishment to retrieve the relevant transport record form, if required, in order to obtain information relevant to traceability.

Concluding comments

There is excellent communication between living donor coordinators, transplant coordinators, surgeons, clinicians, scientists and theatre staff who work well together as a team. The Trust's Human Tissue Manager has oversight of all HTA licences held by the Trust. There are several examples of good practice.

Regular audits are undertaken of all offers of organs and outcomes following transplantation. Surgical competencies are assessed and documented by senior surgeons. There are good systems in place to follow up living donors with information provided to GPs and letters sent to donors along with annual medical questionaires. The HTA was informed that the establishment plans to implement an EOS-type form to cover donor and organ characterisation during transplants from living donors.

The secure dedicated transplant room at St James's University Hospital has clear signage and instructions on the notice board which details steps to be carried out when kidneys arrive at the hospital. The 'Deceased Kidney Donor Materials for Transplant Immunology' form and the 'benching' form act as prompts to ensure that ward staff alert laboratory staff who collect samples for cross matching. The forms document the checking of blood groups and the tracking of kidneys between the transplant room and theatres where back bench work takes place. The 'destination form for kidneys not transplanted at LTHT' is used to record information on kidneys when they are sent away to other transplant centres. Staff complete analogous forms when livers which are received in the anaesthetic room, are split, and sent to other transplant centres.

The establishment has an on call histopathology service which supports the transplant team. The tissue typing laboratory has clear protocols in place to report cross match results; laboratory policy requires staff to provide implanting surgeons with urgent cross match reports instead of verbal updates. The laboratory uses unambiguous phrases like 'compatible – proceed to transplant' or 'incompatible' and does not use terminology such as 'reactive','non-reactive', 'positive', or 'negative'. The pharmacy at St James's University Hospital is responsible for stock control and monitoring storage conditions of perfusion fluids used to preserve organs.

The HTA has given advice in relation to reviewing documented procedures in order to minimise duplication, to implement a communication log to be used by research fellows who receive kidney offers out of hours, and to improve the recording of transport of organs between St James's University Hospital and Leeds General Infirmary.

The audit team was impressed with the professionalism of staff and their commitment to improve transplant outcomes. The audit team would like to thank all the staff who attended the meetings over the two days for the work they did to prepare for the audit, and for their

courtesy during the audit.

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

Report sent for factual accuracy: 8 August 2013

Report returned with comments: 6 September 2013

Final report issued: 8 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.