Site visit audit report on compliance with HTA requirements

Oxford University Hospitals NHS Trust

HTA licensing number 40038

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

20-21 November 2013

Summary of Audit findings

Oxford University Hospitals NHS Trust (the establishment) was found to have met all assessment criteria.

Advice has been given to the establishment in relation amendment one of the establishment's SOPs, labelling of certain transport devices, GP referral letters for living donors and some forms used by the establishment to collect information.

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	Kidney	Pancreas	Liver	Small bowel	Composite-abdominal wall	Composite -Skin
Adult living	**DC, OC, P, T, R**					
Adult deceased	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, 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	Kidney	Pancreas	Small bowel	Composite - abdominal wall	Composite -Skin
Adult living	**OC, P, T, I**				
Adult deceased	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**

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

The establishment carries out kidney, pancreas and small bowel transplants. The small bowel program includes composite tissue, abdominal walls, which may be used if necessary on the recipient. As part of the pancreas program, a second composite tissue may be retrieved. Vascularised skin from the donor's forearm is removed and transplanted onto the pancreas recipient's forearm. This composite tissue transplant is used as an early marker for organ rejection in the recipient so that anti rejection treatment can commence earlier, with the aim of saving the graft. Live donor kidney transplants are also performed at the establishment. Live donor work up and organ retrieval surgery takes place at the establishment although some live donor suitability assessments may initially take place at the donor's local hospital.

Tissue typing and cross matching are performed by the Trust's laboratory which was visited as part of the audit and holds current CPA and EFI accreditation. Other characterisation tests such as additional histopathological tests and donor serology testing are performed by the establishment's pathology laboratory and hospital testing laboratory respectively, which also hold current CPA accreditation.

The establishment also participates in the National Organ Retrieval Service (NORS) with staff retrieving kidneys, pancreases, livers, small bowels and composite tissue – abdominal wall and vascularised skin. The establishment holds a contract with a specialist courier company for transport of organs.

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.	The establishment is not responsible for obtaining information relating to a deceased donor. This will be 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 adopted NOP1 which defines donor characterisation as specified in part A of the Annex to the Directive. For deceased donor organs this information is collected under NHSBT's licence. The establishment is responsible for characterising living donors and living donor organs under its licence. The establishment has developed an 'Oxford Living Donor Pathway document' which acts as an SOP for living donor coordinators to follow and includes details of mandatory tests. In addition, there is a series of checklists to ensure that all of the necessary characterisation tests are performed. The three main checklists are the Clinic 1 History sheet, Live Donor Clinical Pathway document and the Final Live Donor Checklist. Donor and organ characterisation information is collected during several pre-assessment visits of a potential living donor as part of the donor work-up. Potential living donors are asked medical and social history questions as part of their early assessment, including questions on IV drug use, previous malignancies and recent travel.	**None**

	Although there are spaces for drug use history and social history, advice has been given below regarding adapting the Clinic 1 History sheet further to include specific spaces for answers to questions relating to IV drug use, travel history and any previous malignancies. This will help ensure that all necessary characterisation questions are put to the potential donor and record that they have been answered. Finally there are checks that other characterisation information has been received and reviewed by the establishment such as the donor's medical history form their GP.	
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. For deceased donor organs additional characterisation tests may be arranged by the SNOD under NHSBT's licence. These tests can be performed at the retrieval centre. However, extra tests, most commonly histopathological analysis of any suspect lesions on organs can be undertaken at the establishment upon receipt of the organ. The establishment does not have access to 24 hour histopathology services and if necessary implantation will not proceed until appropriate analysis can be undertaken. For living donor cases, if additional tests are required, these will be carried out at the establishment as part of the living donor work up.	**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 developed an operating procedure relating to the management of transplant related documentation and return of HTA-A and HTA-B forms to NHSBT. The 'Procedure for Processing and Archiving of HTA-A and HTA-B Forms' states that documents relating to transplantation will be put into permanent storage with a minimum period of 30 years.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The CPA accreditation status of all laboratories used by the establishment for donor and organ characterisation was reviewed during the audit. All laboratories had current, non-conditional accreditation.	**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. Characterisation information for living kidney donors is gathered during donor work-up by the nephrologist. When all relevant assessments are completed the nephrologist signs the donor off as being suitable for donation. The Donor work up is reviewed by the retrieving surgeon who will also have been involved in multidisciplinary team (MDT) meetings during donor work up. Once satisfied that all characterisation assessments have been performed and the donor is suitable the nephrologist, retrieving surgeon and transplant coordinator sign a checklist recording all of the required assessments. The implanting surgeon then reviews all of the characterisation information and also attends further MDTs such as the radiology meeting to discuss the donor anatomy with the retrieving surgeon. For deceased donor kidney and pancreas offers the transplant coordinator is alerted to a possible donor organ by NHSBT. The coordinator takes the donor ID number and logs onto NHSBT's Electronic Offering System (EOS). Some donor data can then be transcribed onto a donor offer form or the coordinator may print off information from EOS. Additionally the establishment's transplant coordinators have access to EOS via iPads and can access any required information at any time. The coordinator then contacts the implanting consultant surgeon who then accepts or rejects the offer of the organ. Following this, if accepted, donor bloods are requested from the retrieving hospital for tissue typing. The coordinator then alerts the laboratory to the donor and the recipient's referring nephrologist. Kidneys and pancreases are received onto the renal ward where time of receipt and donor hospital details are recorded. Before implantation the surgeon checks EOS, the paper work accompanying the organ and the condition of the organ. These checks are recorded on the Deceased Donor HLA Typing and Cross-Matching Report.	**None**

	Small bowel and abdominal walls follow the same pathway apart from during the early stages of the pathway the transplant coordinator verifies that there is an intensive care unit bed available post transplant and that the organs are taken directly to theatres upon arrival at the establishment. When the establishment transports kidneys from living donors in paired/pooled exchange transplants or following an altruistic living donation, donor and organ characterisation data is contained within the organ transport box. Additionally some characterisation information will have been shared with the relevant recipient centre prior to the retrieval of the organ taking place. Advice has been given to the establishment regarding this transfer of characterisation information to other recipient centres for cases where kidneys from living donors in paired exchange transplants or following an altruistic living donation are transferred.	

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. If procuring a deceased donor organ as part of the establishment's National Organ Retrieval Service (NORS) team activity then prior to the procedure, the lead surgeon reviews all paper work with the SNOD which includes donor consent. The NHSBT NORS surgical safety checklist includes a check step that consent documentation had been verified. In living donor retrievals the donor consent is verified before commencing the procedure as part of the establishment's World Health Organisation (WHO) surgical safety checklist.	

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 had an email from the Trust's procurement department stating that although the Trust does not have any specific document relating to CE marking, the checking of CE marking status is integral to any procurement process undertaken by the Trust.	**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 fully met. The establishment held certificates demonstrating that the Trust's decontamination services department has been assessed and meets the accreditation requirements for sterilisation processes were reviewed during the audit.	**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. Live donors are telephoned by the living donor coordinator during the first week following their discharge post surgery. Live donors are then seen at six weeks following their discharge post surgery at the establishment. After this six week visit, live donors commence a cycle of annual appointments at the establishment or if necessary, a local hospital nearer to their home. Advice has been given to the establishment below with regards to amending the letter sent to living donors' GPs when discharging living donors.	**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. Refer to 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. Refer to 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. During the audit a review of transplant related records was undertaken. As part of this exercise, HTA-A and HTA-B forms were reviewed and evidence was seen that the establishment is recording the details of perfusion fluid being used.	**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 establishment has adopted and adapted NOP003 to reflect the roles and responsibilities of staff at the establishment who may be involved in packaging an organ that is being sent on to another recipient centre. In addition, while undertaking NORS retrievals, the establishment staff follow the National Organ Retrieval Service guidelines with regards to packing of organs. When using a hypothermic mobile perfusion device for transporting kidneys the establishment staff follow the manufacturers guide and in house produced procedures on how to correctly pack the organs. There is a laminated instruction card to act as a reminder of the procedure if needed which also includes details on cleaning the device. Organs are usually packed by the consultant surgeon who has retrieved the organ. Advice has been given to the establishment (see below)with regards to labelling of the hypothermic mobile perfusion device.	**None**

TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses NHSBT's kidney transport boxes which have been deemed suitable for transportation of kidneys. The hypothermic perfusion device used for transport of some DCD donor kidneys is CE marked. Livers and small bowels are transported in proprietary cool boxes. The establishment will switch to using the approved NHSBT transport boxes as soon as these become available nationally. The establishment labels the large organ boxes with the information specified in paragraph 68 of the framework document by using spare kidney box labels which contain fields for all of the required information.	**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 establishment has adopted NOP003 which contains details of the labelling requirements specified in paragraph 68 of the framework document. Refer also to TP1 and TP2	**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 adopted NOP003 details what information must accompany the organ during transportation. When the establishment transports kidneys from living donors in paired exchange transplants or following an altruistic living donation, donor and organ characterisation data is contained within the organ transport box. Additionally some characterisation information will have been shared with the relevant recipient centre prior to the retrieval of the organ taking place.	**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 Trust has a documented agreement with the transport provider. Section 1.4 details that the service provider must be compliant with the requirements contained within the relevant national operating procedures and that transport staff are aware of how to report incidents in accordance with NHSBT's SOP 3888/1. The transport provider has also sent an email in preparation for the audit assuring the establishment that they have policies in place regarding the reporting of serious incidents and near misses.	**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 produces a Deceased Donor HLA Typing and Cross-Matching Report (the Report) for each donor organ. The Report contains donor and organ identification details in addition to HLA type and blood group. The implanting surgeon cross checks the Report against information from EOS and the HTA-A form accompanying the organ. The cross checking is then recorded on the Report and countersigned by the implanting surgeon.	**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. The implanting surgeon performs checks on the organ prior to implantation which include checks that the organ has been packaged and transported in a way that does not affect its quality or safety. These checks are recorded on the establishment's Deceased Donor HLA Typing and Cross-Matching Report	**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. If the implanting surgeon considers there to be any potential risks associated with the organ they will undertake a risk-benefit analysis. This will weigh up the risk associated with the organ against the benefit to the recipient or the risk to the recipient of not going ahead with the transplant. If any risks have been identified the surgeon will discuss these with the recipient and record the conversation in the recipient's clinical notes.	**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's 'Procedure for Processing and Archiving of HTA-A and HTA-B Forms' document details how and within what timeframe, HTA- A and HTA-B forms are returned to NHSBT.	**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. Deceased donors are traceable by their NHSBT donor number, available in EOS. Recipients and living donors are traceable by name, hospital 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. Kidneys and pancreases from deceased donors are delivered to the establishment's renal ward. Senior staff check that the box is sealed and undamaged and place the organ box into a fridge on the ward. Records of receipt are kept on an organ receipt register kept by the fridge. Advice has been given below regarding the column headings used on this fridge receipt record. Small bowels are taken directly to theatres by the NORS team and arrival is recorded in theatres. If organs are sent onto other implanting establishments the collection of the organ by the courier is recorded on an Organ Transport Form by a transplant nurse.	**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 would manage serious adverse events in line with the Trust's incident policy. Additionally, if a serious adverse event or a serious adverse reaction occurs that relates to transplant this would be discussed by the consultant surgeons to determine if it is a reportable incident to NHSBT. The establishment has adopted SOP3888/2 and demonstrated an awareness of the reporting procedure. This SOP describes the procedure for reporting incidents to NHSBT, relevant timeframes and follow up actions required.	**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 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 close working relationship with the in house laboratories undertaking testing and would be alerted directly if there were any incidents relating to testing. Also refer to TP5	**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. Consultant surgeons undertaking liver retrievals have been evaluated and signed off as being competent by consultant surgical staff at another licensed establishment undertaking such retrievals. This allows independent scrutiny of surgical technique. All trainee surgical staff are observed by consultant level staff during training while undertaking procedures. Consultants feed back to junior staff on performance following each procedure. Transplant coordinators undergo a two week induction. Following induction they undergo a period of observation before being signed off as competent by the lead nurse. Evidence of continuous professional development for nursing staff was also reviewed during the audit. The establishment is also involved in organising retrieval workshops where trainee staff can practice surgical technique and receive training on other aspects of retrievals, such as packing organs and completing paperwork.	**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 GN1	
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. Transplant activity is consultant-led with a consultant surgeon present at retrieval and implantation. The establishment has adopted NOP005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation' which describes how activities are performed under the advice and 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.	CT2	As part of the live donor work-up, potential living donors are asked medical and social history questions as part of their early assessment. Included in these questions are questions around IV drug use, previous malignancies and recent travel. Although there are spaces on the Clinic 1 History record sheet for drug use history and social history, the licence holder is advised to adapt the Clinic 1 History sheet further to include specific spaces for answers to questions relating to IV drug use, travel history and any previous malignancies. This will help ensure that all necessary characterisation questions are put to the potential donor by acting as a checklist in addition to acting as a record that they have been answered.
2.	CT6	The licence holder is advised to specify in the 'Paired Exchange Transplant' procedural document what donor characterisation information is to be transferred to the implanting centre, how this will be transferred, and by whom.
3.	R4	Where a live donor is being discharged by the establishment following donation, the establishment sends a letter to the donor's local clinician to alert them that their patient has been a live organ donor. The establishment is advised to amend this discharge letter so that it includes a reminder notice to a local clinician of the requirement to alert the establishment should the donor present with any indication that may have consequences for the recipient, such as development of a malignancy or transmissible infection, or be as a result of the retrieval surgery.
4.	TP3	When using the hypothermic perfusion device for the transport of DCD kidneys the device is not labelled with all of the information specified in paragraph 68 of the framework document. The device is however, always transported back to the establishment by the establishment's NORS team and does not go to any other implanting centre. The licence holder is advised to develop a system for labelling the hypothermic perfusion device with the information specified in paragraph 68 of the framework document. The licence holder may wish to consider attaching a laminated card to the device which contains mandatory information that does not change between retrievals i.e. The information specified in paragraph 68 (c), (d) and (e). Other mandatory information and accompanying paperwork may be attached to the device in a sealed envelope.
5.	TC3	Kidneys and pancreases from deceased donors arrive at the establishment's renal ward. Senior staff check that the box is sealed and not damaged and place the organ box into a fridge on the ward. Records of receipt are kept on an organ receipt register kept by the fridge. The record sheet has fields for several pieces of data relating to the organ such as transport container tag number, ODT number and other information regarding retrieval hospital and times of arrival. The establishment's current process is that the receiving nurse logs the date, time and donor hospital details on the record sheet in addition to the transport box tag number. In a number of instances, it was observed that the donor's ODT number, rather the security tag number, had been entered into the register. The licence holder is advised to amend the receipt record sheet so that it only contains columns to hold the information available to the receiving nurse. This may help reduce the risk of the wrong identifying number into the wrong

		column on the organ receipt record.

Concluding comments

During the audit, evidence was seen that the establishment has reviewed its documents and procedures to assess compliance with the Regulations. The establishment has taken a pro-active approach to governance and has undertaken reviews and updates of the NOPs to assure itself that all areas of activity are reflected in the procedures. In addition to reviewing and updating the NOPs the establishment has also developed in-house documents describing their procedures.

The establishment holds weekly meetings that are attended by staff involved with transplant activities and reviews all organ offers that were accepted and rejected. This review helps the establishment to continually assess its acceptance and rejection criteria to assure itself that they remain appropriate.

Finally, the establishment has developed good documented procedures around recording the checks performed on organs and their associated paperwork prior to implantation. The use of the Deceased Donor HLA Typing and Cross-Matching Report to record the various checks performed by the implanting surgeon prior to surgery helps ensure that accurate records of checks are maintained and also acts as a checklist for the implanting surgeon who is completing the checks.

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

Report sent for factual accuracy: 19 December 2013

Report returned with comments: No comments received

Final report issued: 28 January 2014

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.