Site visit audit report on compliance with HTA requirements

Central Manchester University Hospitals NHS Foundation Trust

HTA licensing number 40043

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

18-19 June 2013

Summary of Audit findings

Central Manchester University Hospitals NHS Foundation Trust (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	Kidney	Liver	Pancreas
Adult living	**DC, OC, P, T, R**		
Adult deceased	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**
Paediatric deceased	**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
Adult	**OC, P, T, I**	**OC, P, T, I**
paediatric	**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 both kidney and pancreas transplants in adult and paediatric patients.

The establishment also provides staff to the National Organ Retrieval Service (NORS) teams which additionally undertake liver retrievals.

Tissue typing and cross matching are performed by the establishment's own CPA accredited laboratory. 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.

Transportation of organs is carried out by a specialist courier company whose service is contracted by the establishment. Representatives of the transport company also attended the visual tour part of the audit and showed the audit team the vehicles that are used to transport the NORS team and 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.	This criterion is not applicable.	**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 National Operating Procedure (NOP) NOP1 which defines donor characterisation as specified in part A of the Annex to the Directive. Donor and organ characterisation information is collected during several pre-assessment visits of a potential living donor as part of the donor work-up. The establishment uses a 'living donor checklist' which specifies the testing that is required and help to assure the establishment that all relevant donor tests and questionnaires have been completed. Characterisation information is collected in the donor's clinical notes. Although the living donor checklist is used to ensure that suitable testing is completed, the serology testing section does not individually list each of the mandatory serology screens that should be performed. Advice has been given about this below. Advice has also been given with regards to the consent form used to capture living donor consent for virology testing, which currently does not list syphilis as one of the diseases that will be screened for.	**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. For deceased donor organs additional characterisation tests will usually be arranged by the Specialist Nurse Organ Donation (SNOD) at the retrieval centre.If necessary however, extra tests, most commonly histopathological analysis of organ sections may be taken at the establishment upon receipt of the organ. The establishment does not have an out of hours pathology service so steps to preserve an organ while awaiting histological analysis may be taken, such as the use of a hypothermic perfusion device. For living donor cases, if additional tests are required, these will be carried out at the establishment. Living donors are reviewed by the nephrologist who discusses medical and social history with potential donors as part of the donor work up. Advice has been given below with regards to developing a list of prompting questions for potential living donors which includes any other considerations that may affect a donor's suitability or inform further testing, such as recent overseas travel.	**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 Trust's record management policy states that all transplant records are kept 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. 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 donors is gathered during donor work-up by the nephrologist. Results of the nephrologist's donor and organ characterisation screens are summarised in a letter which is sent to the implanting surgeon at the point where a living donor is referred to them. The retrieving and implanting surgeons also discuss donor and organ characterisation information prior to implantation. For a deceased donor organ, the recipient coordinator receives a phone call from NHSBT. The recipient coordinator collects the donor identification number and logs onto the Electronic Offering System (EOS) to collect further data about the donor including information on donor characterisation. Donor and organ information is passed verbally to the on call transplant surgeon so they can decide whether or not to accept the offer of an organ. If the organ is accepted the recipient coordinator will start to make arrangements for the transplant. If necessary to gather further information the recipient coordinator will liaise with the retrieving surgeon and SNOD. A virtual cross match between the deceased donor and recipient may be performed. This is made possible by regular monitoring of the immune status of recipients and gathering information on potential sensitizing events when recipients attend the renal clinic or attend prior to transplant surgery. The establishment has a protocol which defines which recipients may be suitable for virtual cross matching such as whether the recipient has had an antibody screen in the last three months. The implanting surgeon reviews the donor and organ characterisation information prior to surgery for both deceased and living donor organs. This check is also recorded on the establishment's 'Transplant Surgeon Donor/Recipient Check List'. The establishment has also adoptred NOP001 and NOP006 which include details of information that should be reviewed prior to implantation of an organ.	**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's NORS team verify the consent paperwork relating to deceased donors prior to scrubbing into theatre. Once in theatre consent documents are checked against the donor's wrist band ID to verify the identity of the donor. For living donors, the consent for donation of kidneys is collected during the live donor work up by the retrieving surgeon or registrar. Consent to undergo the retrieval procedure is verified prior to surgery as part of the World Health Organisation (WHO) surgical safety checklist. In living donor cases, consent regarding the fate of organs should they not be implanted into the intended recipient is also sought during donor work up.	**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 a medical devices management policy which sets out the requirements for maintainance and repair of medical devices. Additionally, when purchasing medical devices for the Trust, new devices are subject to a series of acceptance checks including one that confirms that medical devices meet the requirements of the Medical Devices Regulations. If the Trust wish to purchase a new device which is non CE marked a consultant must make an application to the MHRA for approval.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	The criterion is fully met. Certificates demonstrating that the Trust's decontamination services department has been assessed and meets the accreditation requirements for moist heat sterilisation of theatre trays, procedure packs, dressings and supplementary instruments 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 criteria is fully met. The establishment indicated that live donors spend five days at the establishment post operatively to recover. Following this, they are seen by the retrieving surgeon and the live donor coordinator at six weeks post operation prior to being discharged. Between leaving hospital and the six week review, live donors are also contacted via telephone by the live donor coordinator so that their recovery is monitored. Live donors are also booked into the live donor follow up clinic at the establishment for annual reviews. A donor may choose to have their annual follow-up appintments at the hospital where they underwent work-up prior to donation. The local live donor coordinators are advised on the type of monitoring that a live organ donor should be subject to on an annual basis. Additionally the local centre performing the monitoring of the live donor is made aware of the requirement to alert the establishment should the donor present with any indication that may have consequences for the recipient or be as a result of the retrieval surgery. Alternatively, where a live donor is returning overseas following donation, the establishment indicated that they are discharged with a letter for their local clinician which sets out the required monitoring that a live organ donor should be subject to on an annual basis. Advice has been given regarding amending this discharge letter below.	**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. Evidence that batch numbers and expiry dates of perfusion fluid used when perfusing organs is appropriately recorded on the appropriate HTA A and B forms was reviewed as part of the traceability exercise performed during the audit.	**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. NOP 003 covering the packing and transport of organs on ice has been adopted by the establishment. The 'National Standards for Organ Retreival From Deceased Donors' retrieval guidance used by the NORS retrieval teams, and the packing instructions included with transport boxes, also give details of how to pack organs prior to transport. Where organs have arrived at the establishment, been rejected and are being transferred to another transplant centre on ice, there is guidance for the medical/nursing transplant team on how to complete the establishment's 'receiving an organ checklist'. This guidance includes details of re-packing and re-icing and the sealing of transport boxes. Procedures for the use of the establishment's hypothermic perfusion device which is also used for the transport of donation after circulatory death (DCD) donor kidneys is included within the equipment packs that are taken to organ retreivals by the NORS retrieval team.	**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.	**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 have adopted NOP003 which outlines the information specified in paragraph 68 of the framework document. The establishment have also determined that it is the responsibility of the recipient coordinator to re-label transport boxes where organs were not accepted by the establishment and were being sent onward to alternative centres. The 'National Standards for Organ Retreival From Deceased Donors' document, which outlines procedures relating to NORS activity, states that it is the responsibility of the retrieving surgeon and the SNOD to appropriately package and label organs prior to transport. For kidneys transported on ice in NHSBT kidney transport boxes, instructions are provided with the boxes and standardised labels are used which contain the information that must be included on the shipping container. The establishment's hypothermic perfusion device is not currently labelled with 'Organ in Transit'. Advice has been given below regarding the labelling of the hypothermic perfusion device.	**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. Deceased organs are accompianied by a report on the organ and donor characterisation which is held in NHSBT's electronic offering system (EOS). If the establishment resends organs on to another transplant centre or transfers organs from living donors, there is guidance for establishment staff detailing the requirements for completing the establishment's 'organ receipt form'. This form includes a dedicated section to record confirmation that all relevant paperwork is placed with organ in the transport box.	**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 agreement between the transport provider and the establishment states that the transport provider must be aware of the establishment's serious adverse event reporting procedure. Further advice about the content of this agreement is provided below.	**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 adopted NOP001 which defines the minimum information specified in Annex A and B of the Directive which must be verified before proceeding to implantation. NOP001 is further strengthened by a 'Organ Offer Pathway' flowchart developed by the establishment that outlines the steps taken when accepting an organ offer. Additionally, the establishment has developed a 'Transplant Surgeon Donor/Recipient Checklist'. This records that the implanting surgeon has pre-operatively verified the donor/organ characterisation information. Check boxes record that EOS, virology results and donor blood group have been reviewed. Advice has been given below to the establishment on combining all of these relevant documents together.	**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 establishment has adopted NOP003 which details the checks that should be performed on organs prior to proceeding to implantation. Additionally, the establishment has developed a 'Receiving an Organ' checklist which includes space to record all relevant transportation information such as time of receipt of organ, details of courier, when checks on ice level are performed, checks of the appropriate paperwork and that the tamper proof seals have been checked. This checklist is supported by a guidance document for medical/nursing transplant team members on how to complete it.	**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 any of the information specified in Annex A of the Directive is not available the implanting surgeon is responsible for performing a risk benefit analysis. The risk benefit analysis is discussed with the recipient and is recorded both in the recipient's clinical notes and on the consent for transplant form.	**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 living donor and recipient coordinators are responsible for the return of HTA A and B forms. The establishment has developed two guidance documents, one for living donors and the return of the HTA A form and one for deceased donor organs and the return of HTA B forms.	**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. Refer to I3	**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 Trust uses an electronic incident reporting procedure via an on-line incident reporting system to record any adverse events or reactions. Additionally the establishment have adopted the NHSBT SOP388/1 which details the procedure for reporting adverse events or reactions to NHSBT.	**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 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. The Trust have a corporate and clinical mandatory training policy in place for all staff. There is a transplant specific version of the 'Junior Medical staff in training – medical device user' training pack which on page eight records the use of hypothermic perfusion equipment as a required competency for members of the NORS team. Evidence of consultant appraisal and continuing professional development (CPD) was reviewed during the audit. Consultants also sign off registrars when they are deemed to be competent to practice unsupervised. NORS team nursing staff also have competency based assessments as part of their induction. Advice has been given below regarding the development of a new competency based training and assessments programme for living donor coordinators.	**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 See GN1 Specific training on the use of hypothermic perfusion devices provided by the consultants following their training from the supplying company. Additionally the supplier undertakes refresher training at regular intervals. Advice has been given below regarding the recording of the orientation tours of the department given to the transport provider's drivers.	**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. Transplant activity is overseen by consultant-level staff. The establishment has also adopted National Operating Procedure 005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation'.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The establishment is advised to amend the living donor checklist and expand the section that is used to record when donor serology screens are performed by listing all of the mandatory tests that are required, rather than a single check point labelled serology. Additionally, the consent form used to capture living donor consent for serology testing does not include syphilis as one of the diseases that will be screened. The establishment is advised to amend the consent form so that it clearly identifies all diseases that will be tested.
2.	CT3	The establishment is advised to develop a prompt list of questions for potential living donors which includes any other considerations that may affect a donor's suitability or inform further testing, such as recent overseas travel. In addition, the establishment is also advised to amend the clinical screening form used to collect some living donor screening information so that there is a dedicated space to record the responses to questions regarding previous intravenous drug use.
3.	R4	Where a live donor is returning overseas following donation, the establishment indicated that they are discharged with a letter for their local clinician which sets out the required monitoring that a live organ donor should be subject to on an annual basis. The establishment is advised to amend this discharge letter so that it advises a local clinician, who may be seeing a live donor for follow up, 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	The establishment is advised to label the hypothermic perfusion device with the information specified in paragraph 68 of the framework document, and to develop an operating procedure to describe how this should be done.
5.	TP5	The establishment is advised to amend the agreement with its transport provider to state that any unplanned or unexpected occurrence during transport of an organ must be notified to the establishment immediately. The transport provider and establishment verbally stated that this reporting would be the case and the agreement between both parties does mandate that the transport provider should be familiar with the establishment's serious adverse event reporting procedure.
6.	I1	The establishment is advised to append all relevant documents which support NOP001 to the documented procedure so that they can all be easily referred to by establishment staff when using NOP001.
7.	TC1	The establishment returns HTA A and HTA B forms to NHSBT by recorded post. The posting of the forms is recorded in a receipt book recording the charging for the postal service. The establishment is advised to reference the recording of deliveries in the receipt book within the two guidance documents that have been developed to support the return of the two forms to NHSBT.

8.	GN1	The establishment is advised to continue with its plans for the development of a new competency based training and assessments programme for living donor coordinators.
9.	GN2	The establishment is advised that when giving orientation tours of the department to the transport provider's drivers, each driver's attendance should be recorded and maintained in the establishment's training records so that the establishment is aware of which drivers have received this training.

Concluding comments

During the audit evidence was seen that the establishment has reviewed its documents and prcedures to asses compliance with the Regulations. The establishment has taken a pro-active approach to governance and has undertaken reviews of the NOPs to assure itself that all areas of activity are reflected in the procedures. In addition to reviewing the NOPs the establishment has also developed many in-house documented procedures to further strengthen the NOPs.

The establishment also has a very close working relationship with the transport company who has been contracted to provide transport services for the NORS team.

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

Report sent for factual accuracy: 24 July 2013

Report returned with comments: No comments received

Final report issued: 23 August 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.