Site visit audit report on compliance with HTA requirements

Cambridge University Hospitals NHS Foundation Trust

HTA licensing number 40032

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

1, 2 & 4 October 2013

Summary of Audit findings

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

Advice has been given to the establishment in relation to the labelling of large organ transport boxes and amendment of one of the establishment's SOPs relating to the return of HTA A and B forms.

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
Adult living	**DC, OC, P, T, R**		**DC, OC, P, T, R**	
Adult deceased	**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	Liver	Small Bowel
Adult living	**OC, P, T, I**		**OC, P, T, I**	
Adult deceased	**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, liver and small bowel transplants. The small bowel program includes multi-visceral and modified multi-visceral transplants. Modified multi-visceral transplants being a multi-visceral transplant without the liver. Live donor kidney and liver transplants are also performed at the establishment although at the time of the audit only one live liver transplant had taken place. 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 an external laboratory with current CPA 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 have current CPA accreditation.

The establishment also participates in the National Organ Retrieval Service (NORS) with establishment staff being involved in the retrieval of kidneys, livers and small bowels. The establishment is responsible for the transportation of organs which is undertaken by couriers working under a contract with the establishment.

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 (SNOD) 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. Donor and organ characterisation information is collected during several pre-assessment visits of a potential living donor as part of the donor work-up. Initial visits can be either at the establishment or at a potential donor's local hospital. If any characterisation tests as specified in part A of the Annex to the Directive are undertaken at a referring hospital, these are repeated at the establishment by its own CPA accredited laboratories. A checklist is used to help ensure that all necessary characterisation tests and assessments have been performed. Included in these checks are checks to ensure that potential donor medical history is obtained from their GP and that information from the GP has been received. The checklist also includes checks that consent and necessary independent assessments have been carried out. As part of the donor consent process a donor lifestyle and health questionnaire is completed during a meeting between the donor and transplant coordinator. The transplant coordinator talks through the questionnaire with the donor and is able to answer any questions that the potential donor may have.	**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 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 benefits from a 24-hour histopathology service, meaning that where histopathology services are not available at the donor hospital, samples can accompany the organ to the establishment for analysis. 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 Trusts records management policy, details that all records pertaining to transplantation will be maintained for a 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. Results of the nephrologist's donor and organ characterisation screens are reviewed by the implanting surgeon at a multidisciplinary team (MDT) meeting. The retrieving and implanting surgeons also discuss donor and organ characterisation information prior to implantation. Characterisation information for living liver donors is gathered during a multidisciplinary donor work up. As the donor work up is via a multidisciplinary approach the information is passed to the implanting surgeon during this process, which takes around seven months to complete. 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 and logs onto NHSBT's Electronic Offering System (EOS). Information from EOS is then transcribed onto a donor offer form. The transplant coordinator will then discuss the offer with the implanting surgeon to assess suitability. The implanting surgeon then discusses the organ with relevant specialists such as the nephrologist. A collective decision on acceptance or rejection is then reached. When the implanting surgeon arrives at the theatre they review the paperwork that accompanies the organ. Another check on the organ identity, donor blood group and conditions of transport is made in theatre prior to surgery commencing as part of a bespoke WHO transplant surgical safety checklist.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
	For deceased liver and multivisceral transplants the process is similar to that of kidneys as described above. The offer is received by the transplant coordinator who logs onto EOS and records donor and organ information onto a donor offer form. The coordinator then discusses the offer with the implanting surgeon who then consults with the establishment's hepatologist. The implanting surgeon and hepatologist then decide on the most suitable recipient, this decision and the reasons for why a particular recipient was chosen are recorded. As with kidneys above, the implanting surgeon makes checks on the organ prior to transplant. Small bowel transplants follow the same process as for liver and multivisceral transplants however without the input of the hepatologist when deciding whether to accept or reject the organ or selection of the most appropriate recipient.	
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. In living donor retrievals the donor consent is verified before commencing the procedure as part of the establishment's WHO surgical safety checklist.	**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 Trust's Medical Devices Management Policy states that all medical devices purchased by the Trust must comply with the legislative requirements and be CE marked to confirm compliance.	**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. 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. Once discharged following the surgery kidney donors are then seen at the transplant clinic after six weeks. Following this, annual check ups are organised either at the establishment or the donor's local hospital. If seen at the donor's local hospital a letter is sent to their treating physician to detail what tests should be performed. A letter is also sent to the donor's GP which contains instructions to look for and report any contra indications which may have consequences for the organ recipient. Live liver lobe donors are seen at four weeks following discharge after surgery. Following this visit donors are seen every three months for the following year after which a program of life long follow up visits takes place. In effect, the establishment mirrors the post transplant check up cycle of the organ recipient with live liver lobe 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. 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. If a liver is split and perfused, the establishment indicated that records of perfusion fluid used would be recorded on the NHSBT split liver form (this was not reviewed 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. During NORS team retrievals, the retrieving surgeon and either the SNOD or the perfusionist agree each other's roles with regards to packing the organ prior to the retrieval commencing. It is usual for the retrieving surgeon to bag the organ which is then handed to the SNOD/perfusionist for packing in the transport container. While undertaking NORS retrievals the establishment staff follow the National Organ Retrieval Service guidelines with regards to packing of organs. There may be instances when an organ arriving at the establishment is rejected and the organ will require re-packing for being sent on to another recipient centre. In these cases the organ packing procedure which establishment staff follow is printed on the front cover of the bespoke 'Transplant organ tissue and vessels register' which has been produced by the establishment. This register is also used for recording the sending of an organ when it is taken to another recipient centre.	**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 and has been deemed suitable for the transport of kidneys. The establishment has developed an SOP covering the use of the hypothermic perfusion device for transportation of organs which includes details of how labels should be attached and accompanying paperwork managed. Livers, small bowels and multivisceral transplants 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 seals the cool boxes used for transport with tape and labels the outside of the box with the information specified in paragraph 68 of the framework document. The establishment has also been working with NHSBT and trialing new transport boxes for larger organs. Advice has been given below with regard to developing a procedure to ensure that labels on transport boxes are fully removed rather than sticking a new sticker over the previous one.	**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. Refer to criteria 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.	The HTA A form is included as part of the transportation documentation. Information regarding donor characterisation is uploaded to EOS by the SNOD at the donor establishment. The establishment has adopted NOP003 which details what information must accompany the organ during transportation. If a liver has been split and a lobe is sent onto another recipient centre then a copy of the split liver form is placed in the transport box with the organ.	**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. Schedule 5 of this agreement includes instructions and a flow chart to follow so that any adverse event occurring during transport can be recognised and reported to the establishment.	

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 an SOP, 'Organ Safety and Confirmation of Correct Identity Prior to Surgery' which contains details of who is responsible for verifying the identity of the organ and that the information in Annex A and B of the Directive is verified prior to implantation. The implanting surgeon is responsible for verifying this information. Details on the HTA A form are cross checked with the information provided by the transplant coordinator. This SOP is further strengthened by the use of a bespoke WHO transplant surgical checklist. The checklist includes a transplant specific check where the implanting surgeon signs to confirm that the donor organ arrived intact and with complete identifying paperwork. The signature confirms that the identity on the HTA A form matched the donor offer information and that the blood group is suitable.	**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. Refer to criterion I2.	**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 there is anything unexpected, which had not been originally discussed with the recipient or that the implanting surgeon perceives as a potential risk, the implanting surgeon will undertake a risk assessment to assess the risks versus the benefits. Following this risk assessment another discussion with the recipient takes place and this will be recorded in the recipient's clinical notes. An example of such a discussion was reviewed in a recipient's clinical notes during the traceability exercise undertaken during the audit.	**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 adopted NOP006 which states the requirement to return HTA A and B forms to NHSBT and the timeframe. Following implantation of an organ the implanting surgeon completes the HTA B form and passes this to the transplant coordinator who then returns the form to NHSBT. Following a NORS team retrieval, the lead retrieving surgeon completes the HTA A form which is then returned to NHSBT by the SNOD. For living donors, the living donor HTA A form is completed by the retrieving surgeon and returned to NHSBT by the transplant coordinator. Advice has been given below with regards to reflecting the process of returning living donor HTA A forms to NHSBT in NOP006. During the HTA audit it was found that in the past not all HTA A and B forms were being returned within the correct timeframe. This has been identified by the establishment during an internal, establishment led audit, following which the establishment put in place new systems including the recording of return of the forms. These new systems have increased the establishment's compliance with the required timeframe for return of HTA A and 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. The establishment has created a 'Transplant organ tissue and vessels register' which is used to record every organ that arrives at the establishment. This register is then maintained in line with the establishment's record management policy and since it pertains to transplantation will be kept 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 developed a flow chart covering the adverse event or reaction reporting procedure. This flow chart includes details of how to report adverse events or reactions to NHSBT and within what timeframe they should be reported. Also included in this process flow is reference to the establishment's internal incident reporting form and procedure which would also be completed if there were a serious adverse event or a serious adverse reaction.	**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 criterion S1.	**None**
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.	This criterion is fully met. Refer to criterion 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. Junior clinical staff work under the supervision of consultant surgeons until competent to perform procedures without supervision. Surgical staff have performance reviews as part of the Trust's performance and appraisal process. Additionally, the progress of trainee surgeons is monitored by the deanery. During the training period there is constant review and feedback on performance given by senior staff. Any incidents are also reviewed with trainees. There is a weekly forum including all of the surgeons where, amongst other items, training and training requirements are discussed. Nursing staff and coordinators are trained in the procedures which they perform and maintain a continuous professional development folder which records relevant training. Training for transplant coordinators is competency based and a competency based training program is followed. Coordinators work closely with surgical staff and each other during training. Coordinators also have annual appraisals as part of the Trust's performance and appraisal process. Evidence confirming that surgical staff and coordinators were up to date with their training and appraisals was 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. 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 staff with a consultant surgeon present at retrieval and implantation. The establishment has adopted National Operating Procedure 005 '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.	TP2	The establishment labels the large organ cool boxes with the required information using adhesive address labels attached to the outside of the box. Once a particular organ has been transported the labels are then crossed out or a new blank label attached over the top of the old label. The licence holder is advised to develop a procedure to ensure that old labels are always removed to avoid the chance of an incorrect label being left on a transport box.
2.	TC1	The establishment has adopted NOP006 which details who is responsible for returning HTA A and B forms. The licence holder is advised to amend NOP006 so that it includes details of the process for returning living donor HTA A forms.

Concluding comments

The HTA has given advice to the establishment with respect to the labelling of large organ transport boxes and amendment of one of the establishment's SOPs relating to the return of HTA A and B forms.

Several areas of good practice were observed during the audit. The establishment has been proactive in relation to developing its systems to aid compliance with the new legislative requirements. A number of bespoke forms and procedures have been developed, notably the register used for tracking organs arriving at the establishment and recording their fate and the newly developed WHO transplant surgical safety checklist. The establishment has considered its processes and procedures and amended them, not only in reaction to the legislation but also to develop and streamline them, helping to strengthen practice. This is not a static review of practice as evidence was seen that as the new systems become established, further changes and improvements have been identified by the establishment which will be implemented in the future.

Also, the establishment undertakes monthly audits of organ offer forms and adverse events/reactions. In reviewing any adverse incidents, why organs were accepted and why organ were rejected by the establishment the staff hope to identify further improvements to their practices or use the data to help confirm that the establishment's practices are operating as they should.

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

Report sent for factual accuracy: 1 November 2013

Report returned with comments: 12 November 2013

Final report issued: 4 December 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.