Site visit audit report on compliance with HTA requirements

Birmingham Children's Hospital NHS Foundation Trust

HTA licensing number 40051

Licensed for

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

11-12 September 2013

Summary of Audit findings

Birmingham Children's Hospital NHS Foundation Trust (the establishment) was found to have met all assessment criteria

Particular examples of strengths 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 – Transplant activities

Organ type	Kidney	Liver	Small Bowel
Paediatric	**OC, P, I**	**OC, P, I**	**OC, P, 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, liver and small bowel transplants in paediatric patients. The small bowel program includes multi-visceral and modified multi-visceral transplants. Live donor kidney and liver transplants are performed at the establishment. However, live donor work up and organ retrieval surgery takes place at another HTA licensed establishment and is not the responsibility of the Birmingham Children's 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 is not responsible for transporting organs which is undertaken by couriers working under a contract with other HTA licensed establishments.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	This criterion is not applicable. The establishment is not responsible for 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 not applicable. The establishment is not responsible for the collection of information specified in Part A of the Annex to the Directive. For deceased donor organs, characterisation is carried out at the retrieval centres. For living donors, donor and organ characterisation is carried out by another licensed establishment which undertakes living donor work up and organ retrieval.	**N/A**
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 SN-OD under NHSBT's licence. These tests are performed at the retrieval centre. If necessary however, extra tests, most commonly histopatological analysis, may be undertaken at the establishment upon receipt of the organ. In liver transplants, an additional Epstein-Barr Virus (EBV) serology test is performed by the establishment on a donor blood sample upon arrival of the organ and blood sample at the establishment. For living donor cases, if additional tests are required, these will be carried out at another licensed establishment where the donor work up and retrieval takes place.	**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's Records Management Policy (Records Management Policy 2.0.3) refers to the Department of Health's Record Management: NHS Code of Practice (2nd edition). The audit team was informed that records relating to transplantation are to be maintained for 30 years in accordance with the policy and code of practice.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. During the audit the current CPA accreditation certificates were reviewed for the establishment's microbiology, histology and virology laboratories which may undertake donor and organ characterisation tests, if additional tests are required. Additionally, evidence that the external laboratory where tissue typing analysis is undertaken holds current CPA accreditation was also reviewed during the audit.	**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. The establishment has adopted NOP002 and NOP006 and has started to adapt them to reflect local practice more accurately. Additionally, the establishment uses a variety of supporting documents and flowcharts to record information and document its procedures, including the 'BCH Organ Transplant Surgical Checklist'. Although all of the necessary information is recorded, and additional documents such as procedural flow charts and checklists describe most aspects of the establishment's procedures advice is given below so that the establishment may further strengthen its documented procedures. Live donor work up, donor and organ characterisation, organ retrieval and donor follow up all take place at another HTA licensed establishment. For deceased donors there are differing organ pathways depending on the organ type being transplanted. **Kidney:** The renal recipient coordinator, who is based at another licensed establishment, receives notification from NHSBT relating to a potential organ offer. 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. Information from EOS is discussed with a local transplant surgeon at the other licensed establishment, who accepts or rejects the organ. If accepted, the establishment's transplant surgeon and consultant nephrologist are contacted. They assess the suitability of recipients who are on the waiting list for the organ. The establishment's transplant surgeon then logs onto EOS to download and review donor and organ characterisation information. In many cases a virtual cross match between the deceased donor and recipient may be performed. A wet cross match is also performed on donor tissue by an external tissue typing laboratory.	**None**

	The establishment has developed a new procedure for the receipt of kidneys out of hours when a recipient coordinator may not be on duty. See criterion TC3 for further details. The transplant surgeon performs checks on the identity and donor and organ characterisation prior to preparing the organ for implant. **Liver/small bowel:** The process is as described for Kidneys above however the recipient coordinator is based at the establishment two days per week. With these organ types, the recipient coordinator who is the first point of contact, records organ and donor characterisation information downloaded from EOS, on a 'Donor Alert Form' when they are alerted of a potential donor. Information in the Donor Alert Form is then provided to the implanting surgeon. Once the surgeon accepts the organ, the organ transplant pathway is the same as the kidney pathway described above including identity checks and checks between the Donor Alert form and the information gathered from EOS regarding donor and organ characterisation. Additionally in liver transplants, a donor blood sample is sent for EBV testing at the establishment's laboratory. The implanting surgeon will asses livers upon arrival at the establishment to determine if they are suitable for splitting. If split by the implanting surgeon, one liver lobe is transplanted into a paediatric patient and the remainder of the organ is sent off to another recipient centre. The surgeon completes a split liver form, a copy of which accompanies the organ to the other recipient centre. Transport of the split liver is arranged by NHSBT using their contracted courier service.	

Assessment Criteria	Audit findings	Level of Shortfall
Retrieval of Organs for transplantation		
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.	This criterion is not applicable. The establishment does not retrieve organs. On occasion, the establishment's surgical staff may join a National Organ Retrieval Service (NORS) team and attend an organ retrieval in order to assess the suitability of the organs for use in paediatric recipients. However, the retrieval activity undertaken by the NORS team is overseen by by another HTA licensed establishment, and is not the responsibility of the Birmingham Children's Hospital.	**N/A**
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is not applicable. Refer to R1.	**N/A**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is not applicable. Refer to R1.	**N/A**
R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.	This criterion is not applicable. Live donor work up, donor and organ characterisation, organ retrieval and donor follow up all take place at another HTA licensed establishment.	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment does not preserve organs following retrieval as it is not involved in organ retrieval activity. Some organs are perfused at the establishment upon arrival and prior to transplant. The establishment also undertakes the splitting of livers and prepares the split liver for transport to other recipient centres. The preparation of the split liver may include perfusion prior to packing the split liver. In these instances, records of perfusion fluid used will be made on the split liver form. The Trust's Medical Devices Policy outlines the process and assessments that must be undertaken before medical devices can be purchased and used at the establishment. The assessments undertaken include checks on CE marking and are used to ensure that the medical device meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618). Additionally the establishment provided has a second policy which covers the review and purchase of single use equipment to ensure that the equipment meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618).	**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. Reusable instruments are sent to an externally contracted sterilisation service. BSI production quality assurance certificates relating to the sterilisation service were reviewed during the audit.	**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 a review of patient notes, evidence was seen that HTA B forms contained details of the perfusion fluids and their batch numbers used during implantation. Where the establishment had split livers, details of the perfusion fluid used during the splitting were recorded on the NHSBT split liver form. Copies of HTA A forms were reviewed during the audit. HTA A forms contained details of the perfusion fluid used during organ retrieval by other licensed establishments.	**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 would be responsible for packing liver lobes following the splitting of whole livers at the establishment. The establishment has adopted NOP003 which provides an overview of the packing process. As detailed in NOP003 the packing of a split liver is a medical activity and is carried out by the surgeon who has split the liver. Although NOP003 gives an overview of the packing process advice has been given to further develop and adapt NOP003 to reflect the exact procedure used for packing organs. For example this could include the number of bags into which organs are placed and which fluids are used during the packing process.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is not applicable. The establishment is not responsible for the transport of organs. Where the establishment splits a liver and part of the split liver is sent on to another licensed establishment for transplant, the split liver is transported in the shipping container used to transport the original whole organ. Transport is arranged by NHSBT or the recipient centre which will receive the split liver.	**N/A**

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 not applicable. Refer to TC3.	**N/A**
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment does not transport organs under its own licence however it does send split livers to other licensed establishments. When sending split livers to other recipient centres a copy of the split liver form is placed with the transported 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 not applicable. The establishment is not responsible for arranging the transport of organs. Living donor organs which have been retrieved are transported to the Birmingham Children's Hospital using the courier contracted by the HTA licensed establishment where retrieval has took place. Where split livers are being sent to other establishments for transplant, transport is arranged by NHSBT or the recipient centre which will receive the split liver.	**N/A**

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 implanting surgeon verifies the identity of the donor and the information in Annex A and B of the Directive prior to implantation. The establishment has developed a transplant specific WHO surgical safety checklist relating to transplant surgery and a separate pre-implantation checklist, 'BCH Organ Transplant Surgical Checklist', which includes details of the checks to be performed prior to implant. The safety checklists help to ensure that the required characterisation information is reviewed prior to implant. The surgeon signs against each of the critical donor/organ characterisation items contained within Annex A demonstrating that the information has been reviewed. The establishment's adapted version of NOP002 does not however reflect the use of these checklists. Advice has been offered below with regards to reflecting the use of all relevant documents within the establishment's documented procedures.	**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 is responsible for verifying that the organ has been transported appropriately so as to maintain the quality and safety of the organ. Additionally, the cold ischaemic time is reviewed by the implanting surgeon to ensure that it is acceptable.	**None**
I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.	This criterion is fully met. The implanting surgeons confirmed that the transplant would not take place in the absence of any core donor or organ information. However, if there was any risks identified with the transplant a mini multi disciplinary team (MDT) meeting would be called prior to surgery commencing. During this mini MDT meeting any risks would be discussed with regards to potential benefits to the recipient. A summary of the content and the outcome of these meetings would be recorded 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 HTA B forms are completed by the implanting surgeon following the surgical procedure. Completed forms are then returned to NHSBT by the liver recipient coordinator or the renal sister. In both instances, forms are sent by recorded delivery and records of dates when forms are returned are maintained. When livers have been split, the surgeon undertaking the splitting will complete an NHSBT Split Liver Form. Copies of this form are returned to NHSBT and also accompany the organ to the recipient centre. Advice on including more detail of these procedures in the establishment's adapted NOP006 has been given below.	**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 recently updated the procedure for receiving kidneys outside of normal working hours. Previously, kidneys would be received and stored in a secure room on the renal ward until transfer to the theatres. This procedure has now changed and kidneys will arrive at the main reception. If a theatre coordinator is available, they will accept the organ and take it to theatres. If a theatre coordinator is not available, the on-call clinical coordinator is contacted who then takes the kidney for storage in the secure heart valve bank at the establishment. The time of arrival of the kidney at the heart valve bank is recorded in a log which is maintained in the bank. Kidneys are then collected and taken to theatres when theatre staff attend the hospital. Advice about reflecting this new procedure in the establishment's documents has been given below in addition to advice about recording the time when the kidneys are collected and taken to theatres. Due to the critical limits on cold ischaemic times, livers are always transferred to theatres upon arrival where transplant coordinators and surgical staff are ready to receive the organ.	**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 on-line incident reporting system to record any adverse events or reactions. Adverse events within the Trust go though the clinical governance team who are aware of the requirement to report adverse events and reactions to NHSBT within 24 hours of discovery. The central clinical governance team have developed a procedure for reporting incidents to external bodies and this procedure contains details of what would constitute a serious adverse event or reaction and how to report it. Additionally the establishment has 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. The establishment is not responsible for transport of organs. Internal testing laboratories at the establishment would report any adverse events via the Trust's adverse event reporting system and alert the consultant clinical staff. External laboratories are aware of requirement to alert the establishment to any adverse events occurring.	**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. Consultant clinical staff have performance reviews as part of the Trust's performance and appraisal process. Nursing staff and coordinators are trained in the procedures which they perform and maintain a continuous professional development folder which records relevant training. Nursing staff also have annual appraisals as part of the Trust's performance and appraisal process.	**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	**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.	CT6 I1	The establishment has introduced a number of bespoke documents to support its processes such as transplant specific WHO surgical checklists, pre-implantation checklists, donor alert forms, flow charts which outline the clinical aspects of the kidney transplant pathway and documentation regarding serious adverse events and reactions. These bespoke documents and checklists combined with the adopted NOP procedures meet the HTA's assessment criteria. However, the use of several of these supporting documents is not reflected within the national operating procedures (NOPs) adopted by the establishment.

		The licence holder is advised to review the NOPs that are in place with a view to including reference to the documentation which has been developed to support licensable activities undertaken at the establishment.
2.	TP1	When livers are split at the establishment and the remaining lobes are sent on to other recipient centres. Packing liver lobes into the primary packing is a clinical procedure carried out by the surgeon who has split the liver in the sterile field. Although NOP003 contains high level detail on how to pack organs into ice boxes it does not reflect the exact details of how the surgeon packs the liver lobes within the primary packaging. The licence holder is advised to augment NOP003 by detailing the packaging of livers by the surgeon.
3.	TC1	The establishment reported that HTA B and split liver forms are returned to NHSBT within the required timeframes. The establishment has adopted NOP006 which details this process. The establishment has also developed specific processes around the return of HTA B and split liver forms such as sending them by recorded delivery and logging when specific forms are returned. The licence holder is advised to include details of these establishment specific processes within NOP006.
4.	TC3	There is a system to record the time of receipt of kidneys which are stored in the heart valve bank until they are transferred to the theatres. The licence holder is advised to record the time when the organ is picked up from the heart valve bank and transferred to theatres. Recording of this information will provide staff with accurate information on cold ischaemic time before implantation, and provide assurance that the newly implemented kidney receipt procedure is operating as expected.
5.	S2	Adverse events and reactions are reported to the central clinical governance team who are responsible for onward reporting of them to NHSBT. The establishment has developed an SOP detailing which external bodies require events to be reported to them which includes transplant related events and NHSBT. The licence holder is advised to amend this document to include the NHSBT online event reporting portal address to facilitate rapid reporting of events.
6.	GN1 GN2	The establishment has recently implemented a new receipt procedure for kidneys that arrive outside of normal working hours. This process includes the recording of details of where the organ has been sent from, details of the courier and the time when the organ arrives. The licence holder is advised to document this procedure to provide guidance for staff who receive kidneys out of hours.

Concluding comments

During the audit it was evident that the small and dedicated transplant team work closely together and communicate effectively with the external HTA licensed establishment which undertakes living donor work up and retrieval of organs from living donors.

Although the establishment's documented procedures will benefit from further refinement and addition of detail, the establishment has taken a pro-active approach and developed new procedures and processes to aid compliance with the legislative requirements.

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

Report sent for factual accuracy: 15 October 2013

Report returned with comments: 29 October 2013

Final report issued: 13 Novemebr 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.