Site visit audit report on compliance with HTA requirements

North Bristol NHS Trust

HTA licensing number 40048

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

24 – 25 September 2013

Summary of Audit findings

North Bristol NHS Trust (the establishment) was found to have met all assessment criteria.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

Organ type	
Adult living kidney	**DC, OC, P, T and 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	
Adult living and deceased kidney	**OC, P, T and 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 is a renal and transplant directorate responsible for the retrieval and implantation of living adult kidneys and implantation of deceased donor kidneys. Approximately 120 kidneys are implanted a year. Of those, around 40 are from living donors. In 2012, 12 kidneys were implanted in paediatric patients at the Bristol Royal Hospital for Children, which operates organ transplantation activities under a separate HTA licence (40049). Of these, six were from deceased donors and six from living donors. The inspection team audited the paediatric transplant centre on the second day of this two day audit. Further information about this establishment can be found in the audit report for HTA licence number 40049.

For offers of kidneys from deceased donors, transplant coordinators are contacted by a specialist nurse for organ donation (SN-OD), from NHS Blood and Transplant (NHSBT). The transplant coordinator generally acts as a central point of contact between the consultant nephrologist and consultant surgeon, to determine whether the donor is suitable for a particular recipient. Consultants may also discuss offers directly with each other.

Multidisciplinary team meetings are held on a regular basis. During these meetings, the transplant team discuss cases including assessment of living donors and recipients. Recipients are flagged with a red-amber-green alert system to indicate what type of donor type would be suitable for a particular recipient. If a recipient is at a red level for a particular donor, then the transplant coordinator can decline an offer without further discussion, to allow rapid reoffer of the organ by NHSBT.

All kidneys from deceased donors are accepted onto the renal and transplant ward by trained staff. The kidney is taken into a clinical preparation area and the ward staff complete a kidney checklist to ensure all the necessary people are alerted to facilitate the transplant. This includes contacting the transplant coordinator and laboratory staff, at the on-site, clinical pathology accredited (CPA) histocompatibility and immunogenetics laboratory to take the lymph nodes and spleen for tissue typing. The surgeon checks the quality of the organ soon after its arrival at the establishment. At the time of arrival a kidney inspection time is also booked in theatre along with a surgical timeslot.

Living kidney referrals are generally received through a consultant nephrologist. Patients are seen initially as a pair, or in a group if there are several potential donors by the living donor coordinators. Blood grouping is completed and there is some general education given about the donation process. Once a suitable donor is accepted, the living donor coordinators arrange a second appointment with the donor to complete a living kidney donor assessment and consent form. Patients are given a pack containing pamphlets and a DVD about various aspects of kidney donation. If the donor proceeds to transplant then there are subsequent appointments with a consultant nephrologist and consultant surgeon. Approximately two weeks before the transplant date the donor will meet with an HTA independent assessor. Living donors are followed up at several points directly after the transplant and subsequently annually.

Organs may be repackaged at the establishment for a variety of reasons, including reoffer, transport to the paediatric transplant centre, or transport between theatres for a living kidney donation. If organs are repackaged, they are all labelled and packaged according to the National Organ Retrieval Service (NORS) Guidelines and in line with the establishment's own documented procedures. Any transport to and from the centre is generally organised under the NHSBT's licence. On rare occasions, organs may go with a local transport provider to the paediatric centre, but organs are usually accompanied by a consultant surgeon. The local transport provider has been vetted by the establishment and is suitable.

This was a routine, first site-based audit of the establishment. The audit encompassed, round-table discussions with staff, a review of patient notes and documents and a tour of the premises. This included viewing the area where kidneys are received into the establishment, a secure storage area, theatre suite and a storage area for organ transport boxes. The establishment had an action plan in place prior to the audit. The actions taken to address the action plan are suitable. The action plan will be closed.

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 a SN-OD under NHSBT's licence.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. The establishment has adapted national operating procedure (NOP)001 as standard operating procedure *(SOP)001*, *Donor and organ characterisation, assessment and allocation in deceased and living kidney donation and transplantation.* This has been clearly adapted for local procedures. The SOP specifically states that the establishment uses absolute contraindications from the NORS and British Transplant Society and Renal Association UK Guidelines for living donor kidney transplantation. It also uses the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidance on the use of organs from donors with infections or malignancy. All mandatory information from Part A of the Annex for living donors is captured using the South West and South Wales Alliance 'Living kidney donor assessment and consent form'. The establishment refers to NHSBT's electronic offer system (EOS) to ensure that all mandatory information is collected before implantation for kidneys from deceased donors. In addition to printing EOS information, transplant coordinators also use a 'Donor details form' to record key information. Advice is provided below.	**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. Refer to CT2.	**None**

CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adapted NOP001 as *SOP001*, *Donor and organ characterisation, assessment and allocation in deceased and living kidney donation and transplantation.* The establishment has also adapted NOP006 as *SOP006*, *Transfer and storage of donor and organ characterisation information and storage of traceability data.* The establishment has also put *SOP006(2), Storage of donor and organ characterisation information and storage of traceability data* in place. This SOP refers specifically to the use of stickers on transplant patient notes, to ensure retention for 30 years. Donor and organ characterisation information is held in the transplant coordinators' office. Packs specifically contain a transport handover form, kidney checklist, donor blood group information and an HTA A form. The Trust *Information governance policy* does not state a specific retention period, but does not contradict the minimum 30 year period specified in SOP006. The transplant surgeon confirmed that discussions had been held at board level to ensure documents were retained for the minimum 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 establishment uses its own clinical pathology accredited (CPA) laboratories. CPA status was confirmed using the CPA (UK) Ltd website.	**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 adapted NOP001 as SOP001. This assigns responsibility to the transplant medical team to inform the implanting surgeon immediately of any relevant information. A consultant surgeon confirmed that all implanting surgeons are involved in discussions about organ and donor characterisation prior to transplant. The surgeon reads the EOS printout and 'Donor details form'. The transplant coordinator completes an 'Offer form', to document all conversations held throughout the offer process. This is also reviewed by the surgeon prior to implant.	**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. Consent is sought by the living donor coordinators, consultant nephrologists and consultant surgeons in a staged manner, over an extended period of time. A final interview with an HTA independent assessor is scheduled two weeks before the operation. *TH001*, *Pre op safety checklist* also specifically refers to checking of consent prior to retrieval.	**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. NOP004 has been adapted as *SOP004, Management of procurement material and equipment in deceased and living kidney donation and transplantation.* The Trust *Medical Equipment Policy* requires the procurement and use of CE marked equipment.	**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. All reusable instruments are sterilised by the in-house Central Sterilisation Services Department (CSSD). The establishment produced the British Standards Institute / UK Accreditation Service Certificate of registration for quality management system, ISO13485:2003 for North Bristol NHS Trust, Sterile Services Department as evidence that the CSSD holds certificate number MD78786, for the provision of a sterilisation and disinfection service for Southmead Hospital, other NHS trusts, general practitioner's (GP) surgeries, community staff and primary care trust.	**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. Living donor coordinators would be contacted by living donors or GPs about potentially relevant events and would liaise with a surgeon about whether or not to see a donor. The establishment includes a reference in its discharge letters to reporting any relevant medical information.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Refer to R2. Preservation fluid is kept in a refrigerator in theatres. Theatre staff ensure stock control.	**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. NOP004 has been adapted as SOP004. Evidence was seen of perfusion fluid recorded correctly on HTA A and B forms. One anomaly was found on an HTA A form, during review of patient notes. This did not affect traceability, as the details could be found in the patient's operation notes. Advice is provided below.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Making arrangements to transport an organ		
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adapted NOP001 as SOP001. This refers specifically to the need for the implanting surgeon and transplant medical team to take responsibility for checking the integrity and suitability of the organ. The establishment has adapted NOP003 as *SOP003, Packaging, labelling and transport of organs in deceased and living donation and transplantation*. This includes a requirement to audit the return of the 'Kidney checklist' and completion of data. Organs are received on the ward. All packaging protocols are kept in a folder in the secure clinical preparation room, where the kidney is stored prior to implantation. A 'Kidney checklist' is completed by trained ward staff. The *Kidney transplant import protocol (adults)* refers to the need to keep a copy of the 'Handover transport form' and the 'Kidney checklist'. The 'Kidney checklist' is reviewed regularly to ensure its relevance. Advice is provided below.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses the NHSBT approved boxes for kidney transport.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adapted NOP003 as SOP003.	**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. Refer to TP3.	**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. Transport of organs from deceased donors and from living donors for paired / pooled donations is arranged under NHSBT's licence. On rare occasions, the establishment may use a separate provider to transport kidneys from deceased donors to the paediatric transplant centre (HTA licence number 40049). This is a sub-contractor of the NHSBT provider and is suitable. There is an understanding this provider would report incidents, however the establishment has not received specific written confirmation that this is the case. Advice 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 adapted NOP002 as *SOP002, Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living kidney donation and transplantation.* The establishment uses a modified World Health Organization (WHO) surgical checklist to confirm donor details prior to implant. Advice is provided below.	**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 TP1. Trained ward staff complete initial checks and book a kidney inspection slot in theatres at the same time as securing an operation time. The surgeon ensures the conditions of preservation and transport are complied with prior to implantation.	**None**

I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.	This criterion is fully met. Establishment staff confirmed that if information is not available, then the establishment will seek the extra information and document this. The establishment records all risk-benefit analyses in patient notes. In addition, all discussions throughout the offer process are tracked using the 'Offer 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. NOP006 has been adapted as SOP006 and SOP006(2). The establishment also operates a 'red-box' system to ensure forms are returned on time. This is specifically referred to in the *Kidney transplant import protocol.*	**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. The establishment uses hospital ID numbers, names and dates of birth to confirm the identity of donors, recipients and organs.	**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 CT4.	**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 adapted *SOP3888/1, Reporting and* (sic) *organ donation or transplantation incident to NHSBT*. This clearly identifies responsibility for reporting of incidents at the establishment and has been adapted in line with local roles and procedures.	**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 uses its own CPA accredited laboratories. These would report incidents using the Trust electronic incident management system. Refer to TP5. Advice is provided below.	**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. All staff are competent and suitably qualified. Staff receive annual appraisals and the Trust requires registration with appropriate registered bodies. Transplant coordinators complete competency packs. New coordinators need to be signed-off for particular competencies. Training includes a minimum of one month of shadowing an experienced transplant coordinator. Senior transplant coordinators are always available to advise. Medical staff are subject to revalidation by the General Medical Council. Medical staff are also subject to audits of transplant outcomes. All staff are required to acknowledge receipt of emails about new transplant processes, such as introduction of the 'red box' system for returning all transplant-related paperwork.	**None**
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	This criterion is fully met. Transplant coordinators provide regular training sessions to all staff involved in the transplant process, such as ward staff involved in receiving kidneys. The inspection team viewed the *Reicing, kidney checklist and transport form* training presentation and associated signed, training records, as evidence of this.	**None**

GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	This criterion is fully met. The establishment has adapted NOP005 as *SOP005, Activities to be performed under the guidance of a registered medical practitioner in deceased and living kidney donation and transplantation.* Additionally all SOPs clearly define roles and responsibilities of staff invoved in organ donation and transplantation activities.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	In addition to printing EOS, transplant coordinators use a 'Donor details form' to record key information. It may be helpful to ensure a field to record intravenous drug history status is also included on this form. This may improve the utility of the form as an additional tool to confirm and verify all mandatory information has been collected.
2.	P3	An anomaly was found relating to proper recording of perfusion fluid on an HTA A form. This did not affect traceability, as the details could be found in the patient's operation notes. SOPs refer to 'snap audits' to ensure staff are using forms correctly. The HTA supports that approach and introduction of any other measures to ensure forms are completed correctly, such as further training and reminders to staff.
3.	TP1	The establishment uses a 'Kidney checklist' to track the receipt procedure. When the form is next reviewed, the establishment may wish to consider including a driver ID tick box to confirm that the ID check has taken place.
4.	TP5, S3	There are very rare occasions when the establishment engages a local transport provider to transport kidneys from deceased donors to the paediatric transplant centre (HTA licence number 40049). The establishment has determined the provider to be suitable, as a sub-contractor of NHSBT's provider. The establishment is advised to obtain written confirmation from its local provider that it will report any serious adverse events immediately.
5.	I1	The establishment uses a modified WHO checklist prior to implantation. The establishment may wish to consider modifying this further to ensure confirmation of all mandatory information from Annex A has taken place.

Concluding comments

There were several areas of good practice observed during the audit. Discussions with staff demonstrated a strong awareness of requirements and procedures, at the establishment and the interaction with the paediatric transplant centre (HTA licence number 40049). The establishment's SOPs provide an exemplary example of adaptation of NOPs to suit local practices. All SOPs clearly identify roles and responsibilities of the team and individual positions in relation to all transplant-related activities. SOPs also require 'snapshot audits' to ensure processes are followed.

The establishment uses several customised forms to ensure traceability, including the 'Kidney checklist' and 'Offer form'. The 'Offer form' in particular, allows clear documentation of the decisions made throughout the offer process. The living donor coordinators use the South West and South Wales Alliance 'Living kidney donor assessment and consent form' to ensure all mandatory information is collected. This form collects extensive information on travel and social history.

The establishment has a red-amber-green alert system to assess its recipient and ensure waiting list details are up to date. This allows for rapid assessment of unsuitable offers by transplant coordinators. This process seems to be compatible with the aims of the National Allocation Scheme to make sure that each kidney is given to the person who needs it most. The establishment's streamlined decision-making process may assist with NHSBT's ability to reoffer organs to the right recipient quickly.

The establishment has a good training system in place to ensure all staff involved in transplant are aware of requirements. Measures are also in place to ensure staff comply. In particular, the transplant coordinators have set up a 'red box' system at the establishment. This red box is placed in a prominent place in the surgical break-out area. A sign indicates that all HTA forms are to be deposited by surgeons in the box, so transplant coordinators can return them to NHSBT within the required seven days. This simple process, is easily complied with and allows for forms to be returned within time.

The HTA has given advice to the establishment with respect to ongoing review of forms used to capture relevant data, monitoring compliance with new processes and forms and formally confirming external transport providers are aware of the need to report relevant incidents.

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

Report sent for factual accuracy: 14 October 2013

Report returned with comments: 8 November 2013

Final report issued: 11 November 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.