Site visit audit report on compliance with HTA requirements

Royal Free London NHS Foundation

HTA licensing number 40025

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

26 - 27 June 2013

Summary of Audit findings

The HTA found that Royal Free London NHS Foundation (the establishment) had met the majority of the HTA assessment criteria.

One shortfall was found, in relation to identifying, managing and reporting serious adverse events and reactions. The HTA have provided advice in relation to a number of other standards.

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

Adult (living donor)	**Kidney**
	DC, OC, P, T, R
	Liver
	DC, 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

Adult Recipients	**Kidney (living and deceased)**
	OC, P, T, I
	Liver (living and deceased)
	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 inspection activities undertaken

The Royal Free London NHS Foundation (the establishment) HTA licence (40025) covers organ procurement and transplantation activities carried out at the Royal Free Hospital. The hospital receives deceased donor livers and kidneys for transplant and also supports renal and hepatic living donor.

Living kidney and Liver donors are characterised at the establishment under the care of the respective teams living donor coordinator, consultant nephrologist and renal transplant surgeon. Tests required for donor / organ characterisation are carried out by Royal Free Hospital Laboratories. Histocompatibility and Immunogenetics (H & I) testing is provided by Anthony Nolan laboratories who are based on the Royal Free Hospital site. All laboratories that conduct donor and organ characterisation testing are accredited by Clinical Pathology Accreditation (UK) Ltd (CPA).

The Royal Free Hospital also provides a National Organ Retrieval Service (NORS) abdominal organ team. This team shares an on-call rota with the oxford abdominal NORS team in a week on / week off basis. The team includes a dedicated perfusionist. During the 2011/2012 business year the team were mobilised 92 times.

Living donor nephrectomies are carried out from related and unrelated directed donors who have been characterised locally. Transplants of living donor kidneys make take place on site, at the Royal Free Hospital, or kidneys may be transported to another hospital for transplant (e.g. paediatric centre). The establishment provides transport in these instances and uses a recognised UK provider and the surgeon will perfuse and package the organ. The

establishment has also carried out nephrectomies on living altruistic donors and as part of the paired pooled exchange scheme.

The establishment has also successfully transplanted a liver lobe from a living donor into a related recipient. Living liver donations take place less frequently. Donors are characterised at the establishment using

In 2011/12 the unit carried out 111 kidney transplants: 68 cadaveric organs; 43 live donor transplants and three donor nephrectomies where kidneys were transplanted at another centre. In the same period, the liver team carried out 63 cadaveric donor transplants and one live donor transplant.

The establishment has adopted all the relevant National Operating Procedures (NOPs) and have produced their own flow process maps to reflect local practice.

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.	Deceased donor organs are received at the establishment for transplant, but information for this assessment criterion is obtained and transmitted under NHS Blood and Transplant's (NHSBT) 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 assessment criterion is fully met. This criterion is applicable for living donors and organs and any subsequent tests conducted under this licence for deceased donor organs. All mandatory and complementary donor tests are carried out as part of living donor work up to assess the suitability of living kidney and liver lobe donors. The establishment has a 'donor work up sheet' that captures all mandatory information required to meet this standard for living kidney donors. Mandatory donor and organ characterisation for living liver donors is captured on the form 'evaluation protocol living liver donor'; there is also an accompanying flowchart that explains the steps in donor work up.	**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 assessment criterion is fully met. Reference is made to CT2 above.	**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 assessment criterion is fully met. The establishment provided a copy of Records Management Policy which stated that the Trust adheres to the minimum mandatory retention periods. Records that are required to be retained are visibly identified with a sticker when archived.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This assessment criterion is fully met. Donor and organ characterisation tests are carried out by the Trust's laboratories. The establishment confirmed that the microbiology / virology / biochemistry and histopathology laboratories used for donor and organ characterisation of living donors are all CPA accredited. This has also been verified on the CPA website. H & I testing is carried out at Anthony Nolan laboratories that are on site at the Royal Free Hospital. This laboratory is also CPA accredited.	**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 assessment criterion is fully met. The Living Donor Coordinators are responsible for collecting information on donor and organ characterisation for living kidney and liver donors. This would be discussed with the nephrologist / hepatologist in the first instance, and then with the implanting surgeon. Any relevant test results and risk factors for living donors would be discussed at the respective multidisciplinary team (MDT) meetings. The renal team also have flow process maps for altruistic kidney donation and altruistic kidney offers providing an overview of the communication process. For deceased organ donation the recipient point of contact (usually the recipient co-ordinator) will receive the initial organ offer from NHSBT and will access the donor and organ characterisation information via the electronic offering system (EOS). The recipient coordinator will then discuss the information with the responsible surgeon who will cross check EOS information. The establishment has adopted the NOP 002 – Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living donation and transplantation, and also have an accompanying flow process maps; Implantation: Verification of Donor ID Information; and, Communication: Organ Offering - Accepting, to reflect local practice.	**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 assessment criterion is fully met. Living donors are consented by the consultant surgeon who will conduct the explant of the kidney or liver lobe. Evidence of consent for living donors of kidneys or livers was seen in medical notes available during the site visit audit. The establishment also uses the World Health Organization (WHO) Surgical checklist to confirm consent prior to administering anaesthesia. When organs are retrieved by the NORS teams, consent will be the responsibility of specialist nurse – organ donation (SNOD) employed by NHSBT. The lead NORS surgeon will check the appropriate consent is in place prior to commencement of 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 assessment criterion is fully met. This assessment criterion is applicable material & equipment used in living donations of kidney and liver. It is also applicable for deceased retrievals carried out by staff of the abdominal NORS team. The establishment have a Medical Equipment Management Policy, which covers procurement, service & maintenance of materials and equipment and covers all surgical areas for solid organs, ensuring that materials and equipment meet the requirements of the medical Devices Regulations 2002. The establishment also have a documented process map (Sterile Services: Material and Equipment) to accompany NOP 004.	**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 assessment criterion is fully met. All sterilisation of reusable medical equipment is carried out by The Royal Free Hospital Sterile Services Department. The audit team were provided with current Quality Assurance certificates for the Sterilisation and Disinfection unit. The establishment have a documented flow chart (Sterile Services: Material and Equipment) to accompany NOP 004.	**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 assessment criterion is fully met. Living donors are extensively followed up and offered this service for life. Follow up will be frequent in the first twelve months and in accordance with the national guidelines. Follow up reports are submitted to NHSBT between one and ten years post donation. When donors are discharged to primary care they are accompanied with a thorough discharge letter. The establishment have a 'Post Donor Nephrectomy Pathway' that outlines follow up requirements for living kidney donors. The HTA have provided advice in relation to this criterion.	**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 assessment criterion is fully met. Reference is made 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 assessment criterion is fully met. Reference is made to R3.	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This assessment criterion is fully met. There have been no live liver donations since the requirement to record the batch number of perfusion fluid. Evidence was provided to the audit team that the establishment record the batch numbers and expiry dates of perfusion fluids are recorded on HTA A and B forms for living kidney donations. The audit team were advised that HTA A forms would be completed to include the perfusion fluid batch number and expiry date in accordance with NORS team guidelines.	**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 assessment criterion is fully met. For kidneys obtained from living donors that were intended for transplant at another centre, Royal Free Hospital staff would be responsible for packing of the kidney. The establishment have produced a flow chart to outline packaging, labelling and transport for organs deceased and living donation to accompany NOP003 – Packaging, labelling and transport of organs in deceased and living donation and transplantation. The HTA has provided advice against this criterion.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This assessment criterion is fully met. The Royal Free Hospital uses kidney boxes provided by NHSBT. These boxes are suitable for the transport of kidneys. Livers are currently transported in proprietary cool boxes. The establishment will use NHSBT-approved transport boxes for these organs, when such boxes become available nationally.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labeled with the information specified in paragraph 8(b) (i) to (iv) of the SI, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This assessment criterion is fully met. Labels for the kidney boxes are supplied by NHSBT and would be completed in accordance with the regulatory requirements. NHSBT are currently in the process of commissioning new large organ boxes, the labels for which will meet the regulatory requirements. In the meantime advice is provided against this assessment criterion. The establishment have adapted NOP 003 – Packaging, labelling and transport of organs in deceased and living donation and transplantation.	**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 assessment criterion is fully met. Donor and organ characterisation information for deceased donor organs is the responsibility of NHSBT. When living donor kidneys are transported for implant at another transplant centre all donor and organ characterisation information will have been shared and discussed with the implanting transplant team. The establishment have adapted NOP 003 – Packaging, labelling and transport of organs in deceased and living donation and transplantation	**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 assessment criterion is fully met. The Royal Free Hospital transport organs using a national transport provider. This provider has been advised of the requirements to report any serious adverse events related to organ transport.	**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 assessment criterion is fully met. The establishment uses the WHO surgical checklist and will verify the donor identity and all relevant information in advance of anaesthetising the living donor or recipient. The establishment has developed a flow chart 'implantation: verification of donor ID information to accompany their adapted version of the NOP 002 – Verification of donor ID, consent and donor characterisation. Advice is given against this assessment criterion.	**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 assessment criterion is fully met. Deceased donor organs received at the establishment are checked by the responsible medical team to ensure integrity has been maintained during transport. If there are any anomalies that may impact on the quality of the organ these are documented in the recipient's medical notes. Advice is provided in relation to the consideration of a check list where any anomalies could be recorded.	**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 assessment criterion is fully met. The audit team were advised that in situations where a risk benefit analysis was required, evidence of this would be documented in the patients' medical 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 assessment criterion is fully met. The establishment return the forms to NHSBT within 5 working days. The establishment has adapted the NOP 006 – Transfer and storage of donor and organ characterisation information and traceability data, to reflect their own local practice.	**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 assessment criterion is fully met. All donors and recipients are identified using unique identifiers, including NHS numbers.	**None**

TC3) A record (date and time) of the transportation of organs arriving at/or leaving the establishment is kept for 30 years as part of the traceability information.	This assessment criterion is fully met. Deceased donor livers and kidneys are received at the theatre reception, which is always manned. Kidney boxes are placed in the locked NORS fridge while livers taken straight to theatres. All organ arrivals (kidney and liver) are booked into the 'Donor organ transplant recipient traceability' logbook. When kidneys from living donors leave the establishment a record of the time / date the organ has left the premises is logged on the 'live donor organ release form'. When living donor kidneys are received for transplant the establishment have the altruistic kidney offer and altruistic kidney donation forms to record receipt.	**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.	There is a minor shortfall against assessment criteria S1 and S2. The establishment has a process map; Serious adverse events and reactions (SAEARs): managing and reporting. This process map however, appears to relate only to serious adverse events associated with retrieval damage and specifies that the NORS team will report to NHBST. There is no reference in this process map to identify and manage other potential serious adverse events or reactions, such as transmissible diseases or living donor reactions. Although some staff are familiar with the online reporting system for SAEARs and have reported incidents, not all staff working under the licence appeared to be familiar with what would constitute a serious adverse event and reaction or when and how these should be reported to NHSBT. This constitutes a minor shortfall against this assessment criterion. The establishment did provide a copy of SOP 3888/1 – Reporting an organ donation or transplantation incident to NHSBT, produced by NHSBT.	**Minor**

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.	Not all the establishment's staff involved in the audit were aware of the requirement to report any adverse incidents via the NHSBT portal and some were not familiar with the SAEARs Guidance document. The establishment will benefit from raising staff awareness in relation to identifying and reporting serious adverse events and reactions (SAEARs) and the mandatory time frames associated with reporting.	
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 assessment criterion is fully met. The establishment uses a third party provider of laboratory services which are based on site at the Royal Free Hospital. The establishment have a process map titled Notification of Testing Problems in the laboratory: managing and reporting. Advice is provided against this assessment criterion.	**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 assessment criterion is fully met. The competence of all staff is assessed by the appraisal process. Staff involved in donation and transplantation keep electronic personal professional development portfolios.	**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 assessment criterion is fully met. Staff are provided with training required to perform their tasks. Nursing staff involved in transplantation are required to complete renal transplant training, evidence of which was seen during the audit.	**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 assessment criterion is fully met. The establishment provides a consultant-led service for transplantation where all relevant medical activities are performed under the guidance of the consultant surgeon or physician. The trust has adopted NOP 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.	R4	The HTA advises that the discharge letter should emphasise that in the event that the donor develops any transmissible disease that was unknown at time of donation and may have the potential to affect the recipient, then this should be reported to the transplant team.
2.	TP1	The flow chart describes only NORS team activity and references responsibilities of the specialist nurses – organ donation (SNOD). The flow chart should consider including responsible roles when living donor organs are packaged and transported.
3.	TP3	The establishment are advised to consider adopting a system of labelling the larger organ boxes in accordance with The Framework document, paragraph 68. Whilst on site the establishment did have some boxes in use that had been received from another centre and these boxes contained a laminated label tagged to the handle. A similar system could be adopted for the kidney life ports when the establishment begins using life ports on a regular basis.
4.	I1	The establishment may wish to consider updating the flow chart to include the mandatory data set of information in Annex A of the Framework document. The establishment may also consider implementing a checklist of the information in annex A so that the details can be verified before implantation.
5.	I2	The establishment is advised to consider implementing a checklist to be completed upon receipt of organs. Such a system would allow for any anomalies, for example; missing paperwork, low levels of melting water ice etc, to be documented.
6.	S2	The HTA advises the establishment to provide staff with training in relation to identification and management of serious adverse events and reactions. The HTA also advises that laboratory staff are included in the training sessions

		or provided with information to allow them to identify potential serious adverse events that may occur in relation to donor and organ characterisation tests. The establishment may find the following document useful when providing this training: 'Serious adverse event and reaction reporting for organs intended for transplantation – guidance for licence holders'.
7.	S3	The establishment are advised to emphasise to the testing laboratories, that form part of the Trust (i.e. not third party testing facilities), the requirement to identify and report any serious adverse events associated with living donor and organ characterisation tests and the time frames within which these should be reported.

Concluding comments

The audit team would like to thank the staff at The Royal Free Hospital for their engagement with the audit process, both during the preparation and on site. All staff actively participated in discussions and provided the audit team with a detailed overview of activities carried out under the licence.

The audit team also noted a number of examples of good practice.

There was evidence of good governance in place and staff had produced flow process maps to accompany the national operating procedures and reflect local practice.

The renal team conducts bacteriological testing on the perfusion fluid used to transport the kidney, as an indicator of any potential contaminants.

Finally, the audit team wanted to acknowledge the electronic recipient and donor databases. These electronic databases were developed for audit purposes but contained extensive traceability information that could be readily searched.

The HTA requires that the establishment addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the audit and subject to completion of the existing action plan.

Report sent for factual accuracy: 29 July 2013

Report returned with comments: 19 August 2013

Final report issued: 27 August 2013

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the organisation has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Audit Report.

Date: 23 June 2014

Appendix: Classification of the level of shortfall (HA)

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 recipient patient or to a living donor,
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 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 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 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 inspection.
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 inspection 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 inspection 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.