**Site visit audit report on compliance with HTA requirements**

**Newcastle upon Tyne Hospitals NHS Foundation Trust**

**HTA licensing number 40045**

**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 Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.**

**12-14 September 2017**

**Summary of Audit findings**

Newcastle upon Tyne Hospitals NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to documentation, record keeping, procedures and the follow up of living donors.

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

**The HTA's regulatory requirements**

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

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

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

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

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

**Licensable activities carried out by the establishment – Procurement activities**

| Organ type | Liver | Kidney | Pancreas | Heart | Lung |
|---|---|---|---|---|---|
| **Adult living** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **-** | **-** | **-** |
| **Adult deceased** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **DC, OC, P, T, R** |
| **Paediatric deceased** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **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**

| Organ type | Liver | Kidney | Pancreas | Heart | Lung |
|---|---|---|---|---|---|
| **Adult** | **OC, P, T, I** | **OC, P, T, I** | **OC, P, T, I** | **OC, P, T, I** | **OC, P, T, I** |
| **Paediatric** | **-** | **DC, OC, P, T, R** | **-** | **OC, P, T, I** | **OC, P, T, I** |

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)

## Background to the establishment and description of audit activities undertaken

The Newcastle upon Tyne Hospitals NHS Foundation Trust (the establishment) has been licensed by the HTA since December 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. The establishment undertakes kidney, pancreas, combined kidney/pancreas, liver, heart, lung and combined heart and lung transplants and also participates in National Organ Retrieval Service (NORS) activity through which it retrieves all of the above organs from deceased donors. In addition, the establishment has living donor kidney and living donor liver transplant programs.

The establishment operates at both the Freeman Hospital and the Royal Victoria Infirmary (RVI). The Freeman Hospital is where the Institute of Transplantation (IoT) is located and where adult kidney, pancreas, liver, heart and lung recipients are treated. Paediatric heart and lung transplantation is also carried out at the Freeman Hospital and paediatric kidney transplants take place at the RVI. Transplants at the IoT, Freeman Hospital, take place in two separate theatre areas; operating theatres where abdominal organs are transplanted and the cardiothoracic theatres where hearts and lungs are transplanted. In both of these areas, stocks of organ relevant perfusion fluids and equipment are stored along with equipment and perfusion fluids used by the establishment's NORS teams during deceased donor organ retrievals. NORS kits include a list of components which helps staff to refill and pack kits following a retrieval.

The fridges where perfusion fluids are stored are monitored. The perfusion fluid storage fridge for abdominal organs is alarmed and the alarm is linked to a dedicated portable phone held by a member of the theatre staff. The alarm is triggered if the temperature of the fridge deviates from the expected range. The temperature of the storage fridge holding cardiothoracic perfusion fluids is monitored daily by staff and will also alarm if the temperature deviates from the expected range. The cardiothoracic fridge's alarm is a local alarm and would be detected by theatre staff who work in the theatres 24 hours per day, seven days per week. Advice has been given to the establishment regarding testing both storage fridge/freezer alarms to assure the establishment that they continue to operate as expected (see advice item 4).

Paediatric kidney transplants are undertaken in the paediatric theatres at the RVI. The establishment predominantly transplants live donor kidneys which are retrieved at the IoT for transplantation into paediatric recipients; however, cadaveric organs are also transplanted. Perfusion fluids and theatre equipment used during transplant surgery at the RVI site are transported to the RVI as they are needed for a transplant case and are not stored on site.

Documentation demonstrating that the establishment's sterile services provider met the requirements of the assessment criteria was reviewed during the audit. In addition, discussions were held with cardiothoracic theatre staff regarding the decontamination and sterilisation procedures relating to reusable equipment used during heart and lung retrievals. Transoesophageal echocardiography (TOE) probes are cleaned following use at the retrieval site and brought back to cardio thoracic theatres for ultra violet sterilisation and storage in a specialist storage cupboard. The establishment has a reusable bronchoscope which again is cleaned following use at the retrieval site before being brought back to the establishment for reprocessing. In addition to reusable bronchoscopes, the establishment also uses disposable bronchoscopes.

The establishment has adopted National Operating Procedure 004 (NOP004) which mandates that all equipment used in retrieval and transplantation by the establishment must meet the requirements of the medical devices regulations. During the audit a member of the Trust's Purchasing Specialist team assured the audit team that all equipment purchased at

the Trust met the requirements of the applicable medical devices regulations. Establishment staff wishing to purchase new equipment must first ask the equipment's vendor to complete a pre-purchase questionnaire which includes details of the equipment's compliance with the medical devices regulations.

The establishment is involved in various clinical trials involving mechanical perfusion of organs immediately after retrieval and following receipt at the establishment. Equipment used for normothermic and hypothermic perfusion of organs is CE marked indicating that it meets the requirements of the medical devices regulations. In addition, the equipment's manufacturer is aware of the purposes for which the equipment is being used and is satisfied that the equipment is suitable for these purposes.

Both the internal and external testing laboratories undertaking donor and organ characterisation assessments are appropriately accredited by a relevant body. The audit team verified that the virology, microbiology and histology laboratories have current United Kingdom Accreditation Service (UKAS) accreditation. The histocompatibility and immunogenetics laboratory is additionally accredited by the European Federation of Immunogenetics (EFI).

Establishment staff involved in transplantation and retrievals are suitably trained. Transplant coordinators undergo competency based training with final sign off by a senior member of the team. Theatre staff undertaking NORS activities undergo national competency based training. Theatre staff involved in transplantation also have competency based training, with a final sign off once competent, by a senior member of the theatre staff. Both coordinator and theatre staff have team meetings to discuss areas around transplantation and retrievals.

Surgical staff undertake specific transplant and retrieval training in addition to being supervised by a senior member of the surgical team during their training. All staff at the establishment receive annual appraisals.

## Cadaveric Donor Organ Transplantation

Coordinators discuss the risks and benefits of transplantation with potential recipients before they are listed on the transplant waiting list. Should an organ offer be received which poses a potential greater risk to the recipient than those already discussed, the implanting surgeon will have a discussion with the recipient prior to surgery and outline the additional risks. Details of this conversation are recorded in the recipient's clinical notes.

Transplantation of all organ types at the establishment broadly follows a similar pathway. There are some differences in timings due to the differing cold ischaemic time limitations and cross matching requirements of the different organ types; however, a high level outline of the transplant pathway is described below.

Organ offers from NHSBT, the national organisation responsible for organ allocation, are received by a transplant coordinator (the coordinator). The coordinator takes three points of identification relating to the donor and uses these to access and review the Electronic Offering System (EOS) to gather further key donor and organ characterisation information. The key donor and organ characterisation information is recorded by the coordinator onto a donor offer form created specifically for this purpose by the establishment. Different donor offer forms are used depending upon whether the organ offer is for a kidney/pancreas, liver or heart/lung.

The donor offer form is shared with the implanting surgeon who reviews the information on the form and liaises with the relevant medical colleague such as nephrologist, hepatologist or cardiothoracic specialist. The surgeon may request further donor or organ characterisation information via the coordinator from the specialist nurse for organ donation (SNOD) at the

donor hospital or, if sufficient information to make a decision is available, decide to accept or reject the offer of the organ.

If the organ offer is accepted, the coordinator liaises with the SNOD at the donor hospital and the duty office at NHSBT to accept the organ and arrange transport to the establishment. The coordinator maintains a record of all conversations held including both internal discussions with theatres, intensive care, the recipient, implanting surgeon and others involved in the transplant in addition to external conversations with the duty office and SNOD. These records of conversations are made on the organ offer form.

The implanting surgeon reviews all of the available donor and organ characterisation information via EOS. The establishment has developed processes through which the implanting surgeon records that they have reviewed the information in EOS and the donor/recipient blood groups. For abdominal organs, this is recorded on the operation note and for cardiothoracic organs; the implanting surgeon signs a printed copy of EOS. During the reviews of donor and recipient clinical files (see below) it was noted that the implanting surgeons do not always sign the relevant document to indicate that they have reviewed the blood groups and characterisation information in EOS. The audit team was assured that these reviews always take place, often in conjunction with the coordinator; advice has been given to the establishment to re-evaluate the procedures for recording these reviews in order to increase compliance with the establishment's requirement to record them (see advice item 7).

The coordinator also liaises with the tissue typing laboratory, apart from liver transplants which are matched on blood group, in order to assess whether the transplant can proceed using a virtual cross match followed by a post transplant wet cross match or if a wet cross match is needed prior to implantation. The tissue typing laboratory analyses each recipient's antibody status every three months while on the waiting list so that a transplant may proceed on a virtual cross match provided that the recipient has not been recently exposed to any potential sensitising events.

Receipt of organs at the establishment is recorded using an organ receipt form. The receipt form for kidneys/pancreases includes a space to record that the transport box was opened to check the ice levels. Kidneys are normally taken to the transplant ward where they are stored in a secure area until being collected and taken to theatre by a member of the surgical team. Pancreases, livers, hearts and lungs are received by the coordinators or theatre team and are taken directly to theatres.

The implanting surgeon checks the accompanying paperwork and inspects the organ in theatres when removing the organ from the transport box. If the organ is perfused prior to implantation, details of the perfusion fluid used are recorded on the HTA-B form which is signed by the implanting surgeon following surgery and returned to NHSBT by the department's administrative staff.

## Living Kidney Donor Transplantation

The establishment has a living kidney donor program through which adult donors can donate a kidney to both adult and paediatric recipients.

The establishment is normally approached by a potential donor via the coordinator who gives information about living donation and a health screening questionnaire. The questionnaire covers past medical and social history.

If the donor still wishes to proceed, they have an appointment with the coordinator during which living donation and what is involved is discussed again in addition to seeking consent for virology testing and contacting the potential donor's general practitioner (GP) to request

their medical history. The coordinator also goes through similar questions to the health/social questionnaire during this initial meeting so that there is an opportunity to clarify any responses on the initial form.

Potential donors are referred to a nephrologist who undertakes a similar medical clerking of the donor in addition to requesting any further characterisation tests as a result of the initial medical information such as cardiac assessment. If the potential donor is suitable, the nephrologist will request further characterisation assessments such as kidney function and nuclear medicine imaging. If these further characterisation assessments indicate that the donor is suitable to donate, the donor is referred for a surgical assessment with a urology surgeon who is trained to undertake kidney retrieval surgery. The urological surgeon reviews the imaging and the assessments undertaken by the nephrologist in addition undertaking further assessment of the donor with a focus on surgical aspects, for example, previous surgical procedures. The urological surgeon informs the donor about the risks involved in donating a kidney both on their own and in conjunction with a coordinator where other aspects of post donation care are covered such as recuperation and post operative care/risks.

If the donor still wishes to proceed, they are referred for an anaesthetic review and an HTA Independent Assessor appointment, before starting to plan the surgery. Virology testing and cross matching assessments are repeated two weeks prior to surgery. Retrieval from the donor and implantation into the recipient occur in parallel which helps to reduce the cold ischaemic time of the kidney. Details of the surgery timings and perfusion fluids used are recorded on the HTA-A and HTA-B forms which are sent to NHSBT.

Immediately following surgery the surgeon sees the donor and sees them again at six weeks post surgery. Donors may then be discharged to their local GP for annual post donation follow up. Advice has been given to the establishment to remind the GP that should the donor present with any condition which may have an impact for the organ recipient, such as a malignancy, then GP should also alert the transplant centre or recipient (see advice item 3).

## Living Liver Donor Transplantation

The process for living liver donor characterisation is broadly the same as for living kidney donors. Potential donors that come forward receive preliminary information about living liver donation and a medical/social history questionnaire. The establishment waits for the potential donor to get back in touch and return their questionnaire which indicates that having reviewed the initial information, they still wish to proceed with donation.

Potential donors are then seen by a hepatologist for clinical evaluation which includes a review of the donor's medical history supplied by their GP, blood tests and imaging including computerised tomography and magnetic resonance imaging. Donor and organ characterisation assessments are reviewed in a multidisciplinary team meeting. If the donor is suitable, imaging data is used to create a three dimensional model of the donor organ by an external organisation and which is reviewed during the establishment's weekly x-ray meeting. Reviewing the model in this way helps the team to decide on the suitability of the donor, the organ and to discuss and finalise potential surgical approaches.

The establishment has reviewed several potential donors but has not as yet retrieved liver from a living donor. Thus far, donors have either been found to be unsuitable or the recipients of the potential living liver donation have received a cadaveric organ instead. If living donor liver retrieval proceeds past this stage of the assessments, an Independent Assessor interview would be arranged and possibly psychiatric and social work evaluations. Should the establishment identify a suitable living liver donor in the future, the establishment's surgical team undertaking the retrieval would be joined by an experienced living donor

retrieval surgeon from another licensed establishment to oversee the surgery. This proctorship would continue until the establishment's surgical team had undertaken multiple procedures and been deemed to be competent to perform the procedure independently.

## Deceased Donor Organ Retrieval

The establishment's coordinators (both cardiothoracic and abdominal teams) are alerted to a potential donor and mobilise the NORS team members. Retrieval kits, one for the cardiothoracic team and one for the abdominal team, are collected from the IoT and the two teams travel to the donor hospital. The teams travel separately to allow time for additional characterisation assessments which will be undertaken by the cardiothoracic team upon arrival.

The retrieval teams review characterisation data relating to the donor via EOS during the journey to the donor hospital. Upon arrival at the donor hospital, both teams meet with the SNOD and review the latest donor and organ characterisation information, the donor consent information and the donor's clinical notes. The retrieval teams may also liaise with implanting surgeons at transplant centres if requested to do so.

Both surgical teams pack the organ according to the national NORS standards. Organs are then placed into the relevant transport box with the relevant traceability paperwork and tissues for typing before being collected for transportation to the transplant centres.

The establishment's cardiothoracic NORS team are taking part in a clinical trial which involves normothermic perfusion of hearts following retrieval and during transport. If normothermic perfusion is being used, additional team members who have been trained in the use and monitoring of the equipment join the NORS team.

## Audit of Clinical Notes

During the establishment's audit, a review of recipient clinical notes and associated donor files was undertaken by the audit team as described below:-

- Three sets of notes relating to living kidney donors and respective recipients. In one case, a paediatric recipient, the living donor was from another establishment and therefore the donor notes were not reviewed
- Three sets of notes relating to deceased donor kidney transplants (adult)
- Three sets of notes relating to deceased donor kidney and pancreas transplants (adult)
- One set of notes relating to deceased donor kidney transplants (paediatric)
- Two sets of notes relating to heart transplantation, one adult recipient and one paediatric recipient
- Two sets of notes relating to deceased donor lung transplants (adult)
- Three sets of notes relating to deceased donor liver transplants (adult).

In all of these cases, where applicable, the following records were reviewed: donor consent, recipient consent, operation note, organ offer form, copy of EOS information, donor virology, cross match data, HTA-A form and HTA-B form, records of perfusion fluids used and records of receipt and records indicating that the implanting surgeon had reviewed donor and organ characterisation data in accordance with the establishment's procedures. In some cases, the implanting surgeon had not signed the relevant paperwork to indicate that they had reviewed the donor and organ characterisation information in EOS however; all staff spoken with during

the audit confirmed that the implanting surgeons always review characterisation data prior to implantation. No other anomalies were found during the review of the clinical notes.

### Advice

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

| No. | Assessment Criterion | Advice |
|---|---|---|
| 1. | CT3 | Some living organ donor's characterisation assessments are carried out by referring centres prior to the donor attending the establishment for review of this data and donation. Some referring centres use their own forms during the collection of some characterisation information.<br><br>The establishment is advised to review all documentation used by referring centres to ensure that all relevant questions are included in the medical/social history questionnaire sent to potential living donors, for example, travel history and previous history of IV drug use. |
| 2. | CT4 | The establishment has created an in-house (SOP) to supplement national operating procedure (NOP) 006 which details the storage requirements for organ and donor characterisation assessments.<br><br>The establishment is advised to amend this SOP so that it includes details on how data from mechanical perfusion devices, including devices used during Clinical Trials are stored for the required 30 year period. |
| 3. | R4 | The establishment follows up living donors immediately post surgery and at six weeks post surgery before they are discharged into the care of their GP.<br><br>Upon discharge of a living donor, a letter is sent to the donor's GP. The establishment is advised to amend the content of this discharge letter to include a reminder to the GP that should the living donor present with any medical conditions which may have an impact for the organ recipient, that the establishment should be contacted immediately so that the recipient can be reviewed and followed up as necessary.<br><br>This is important as it may facilitate earlier detection of medical conditions that could impact an organ recipient. This is of particular importance in cases of paired/pooled donations or non-directed altruistic living donations where there is no link between a donor and the recipient. |
| 4. | P3 | The cardiothoracic team's fridge and freezer, used to store saline and perfusion fluids, have alarms which sound locally should their temperature deviate from the expected range. The establishment is advised to test the alarm system to assure itself that the alarm sounds as expected and that theatre staff who work in theatres 7 days a week, 24 hours a day, respond to the alarm appropriately and alert the transplant team to the alarm.<br><br>In addition, the establishment is advised that abdominal team's storage fridge/freezer should also be tested so that the establishment can assure itself that the automatic dial out alert is triggered and responded to as expected. |
| 5. | TP4 | The establishment has developed an in-house SOP, "Exporting Live Kidney" covering instances where living donor kidneys are sent to other transplant centres for implantation. The establishment is advised to amend this SOP to include details of how and by whom the centre to centre communication should |

| No. | Assessment Criterion | Advice |
|---|---|---|
| | | take place when transferring organs. This should include, but is not limited to, the coordinator to coordinator discussions about transport details, transport timings and transfer of characterisation information. |
| 6. | TP5 | The establishment has a contract with a transport provider which is sometimes used for the transportation of organs to and from the establishment. The contract stipulates that the transport provider must be aware of all relevant statutory requirements, acts of parliament and relevant guidance. This would include an awareness that adverse events must be reported to the establishment.<br><br>The establishment is advised to update this contract during its next review to include an explicit statement covering adverse events during transportation of organs and mandating that they are reported immediately to the establishment. |
| 7. | I1 | The establishment has created systems to record the implanting surgeon's review of EOS information. In abdominal organ transplants, the surgeon signs a dedicated area of the operation note and in cardiothoracic transplants, signs a hard copy of the EOS information. All staff spoken with during the audit confirmed that implanting surgeons always review characterisation data prior to implantation; however, from the audits undertaken on recipient clinical notes, compliance with the establishment's procedures for recording these reviews was inconsistent.<br><br>The establishment is advised to review its procedures for recording that the implanting surgeon has reviewed the donor and organ characterisation data to see if changing the way that these reviews are recorded, or the time point at which they are recorded, may help to increase compliance with the establishment's procedures regarding documenting the reviews. Possible changes discussed during the audit included recording the reviews prior to implantation surgery or including a record that the surgeon has reviewed the information within the pre-surgical world health organisation (WHO) surgical safety checklist. |
| 8. | I2 | The establishment has developed an organ receipt form which is used to record receipt of organs at the establishment. The form also has space to record that staff receiving the organ have opened the box to check that there is sufficient ice to maintain the quality and safety of the organ during its storage prior to surgery. A review of the organ receipt forms highlighted examples where the section recording ice level checks had not been completed. The establishment reported that the new transport boxes being used for kidneys and pancreases are more thermally efficient and the need to replenish ice has reduced.<br><br>The establishment is advised to review its procedures relating to the checking of ice levels and remind staff of the procedure to ensure that ice levels are checked appropriately and that when transport boxes are opened to check ice levels it is appropriately recorded. |
| 9. | TC3 | The establishment stores the organ receipt forms at the point where the organ is received, for example, at the transplant ward or in theatres. The establishment is advised to consider periodically collecting these forms from the wards and theatres and storing them centrally for the required 30 year timeframe. |

| No. | Assessment Criterion | Advice |
|---|---|---|
| 10. | S3 | The establishment works closely with the laboratories which undertake donor and organ characterisation tests on its behalf. These include laboratories that are part of the establishment's Trust and external laboratories. The audit team was informed that the laboratories would notify the establishment of any adverse events relating to testing, should they occur.<br><br>The establishment is advised to contact the lead contact in the relevant laboratories that the establishment uses and remind them of the importance of notifying the establishment of any adverse events relating to samples from the establishment. |

**Concluding comments**

Areas of good practice were observed during the audit, some examples of these are included below.

- When involved in organ retrieval, the establishment's cardiothoracic team takes additional consumable items as part of their retrieval kits. This helps to assure the team that should they be needed, additional consumables are available to them where such items may not necessarily be available at the donor hospital.

- The cardiothoracic team has developed a series of coloured labels which are used to label the bags which are used to package organs after they are retrieved. Different coloured labels help to differentiate between hearts, heart/lung and lungs.

- The establishment routinely screens a sample of donor blood for disease markers upon receipt of organs with an accompanying blood sample. The establishment has recently implemented a new procedure where upon receipt of the virology results from the establishment's internal laboratory, the laboratory staff check the internal results against the original results from EOS and alert establishment staff and NHSBT to any discrepancies between the two sets of results.

- The living donor kidney team has developed a patient friendly information leaflet which provides donors with useful information about being a living kidney donor and details about some of the clinical staff that they may meet during the process, including their photographs.

- The establishment has adopted the NOPs which describe many of the procedures taking place. Since the last audit, the establishment has also produced a number of stand alone SOPs which supplement the content of the NOPs and describe in more detail how each procedure is undertaken at the establishment.

The HTA has given advice to the establishment with respect to documentation, record keeping, procedures and the follow up of living donors.

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

**Report sent for factual accuracy: 12 October 2017**

**Report returned with comments: 17 October 2017**

**Final report issued: 14 November 2017**

## 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.