Site visit audit report on compliance with HTA requirements

Royal Free London NHS Foundation Trust

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

29 – 31 August 2018

Summary of Audit findings

Although the HTA found that Royal Free London NHS Foundation Trust (the establishment) had met the majority of the assessment criteria, five shortfalls were found, particularly in relation to several areas of procedural documentation. The HTA has also given advice to the establishment with respect to procedural documentation, temperature monitoring of fluids used during retrieval and transplant, document completion and document retention.

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

The HTA's regulatory requirements

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

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

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

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

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

Licensable activities carried out by the establishment – Procurement activities

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

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

Licensable activities carried out by the establishment – Transplant activities

Organ type	Kidney	Liver
Adult living	**OC, P, T, I**	**OC, P, T, I**
Adult deceased	**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 Royal Free London NHS Foundation Trust 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 and liver transplants and also participates in National Organ Retrieval Service (NORS) activity, through which it retrieves abdominal organs from deceased donors. In addition, the establishment has living donor kidney and living donor liver transplant programmes both of which are undertaken privately and within the NHS.

The establishment stores chilled perfusion fluids in a fridge within theatres with a larger stock supply, both chilled and ambient, held in the perfusion room. Although both fridge temperatures are monitored daily, the temperature reading recorded is the current temperature of the storage area, meaning that there is a risk that any temperature deviation that may have occurred out of hours would not be detected (see advice item 4). Retrieval kits used by the NORS team are also stored within the theatre department. Kits are replenished as soon as one is used, in case the NORS team has a call out immediately upon their return. Packing lists are kept with the kits to assist staff in assuring themselves that all of the required equipment has been packed.

The establishment has a procedural document relating to 'sterile services, material and equipment' however this document does not include any reference to the establishment only using equipment for retrieval and transplantation that meets the requirements of the medical devices regulations. Although verbal assurance from the Trust's procurement department was given that only compliant, CE marked equipment was purchased by the Trust, there is no documented procedure which describes how this is assured (see shortfall 1).

Documentation demonstrating that the establishment's sterile services provider meets the requirements of the assessment criteria was reviewed during the audit. 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, histocompatibility and immunogenetics (H&I) and histology laboratories have current United Kingdom Accreditation Service (UKAS) or Clinical Pathology Accreditation (CPA) accreditation. The H&I laboratory is additionally accredited by the European Federation of Immunogenetics (EFI).

Establishment staff involved in transplantation and retrieval of organs are suitably trained. Competency based training is in place for nursing, theatre and coordinator staff. New surgical staff are mentored by senior staff until they have been assessed as competent to work independently. The establishment has purchased a new mechanical perfusion device however relevant staff, including perfusionists and surgical staff, are undergoing training by the manufacturer before use of the equipment is initiated.

Cadaveric Donor Kidney Transplantation (Kidney)

Organ offers from NHSBT's Hub are received by the on-call nephrologist who uses the donor details to review detailed donor and organ characterisation information in NHSBT's electronic organ offering system (EOS). If the organ offer is suitable for the recipient to whom it has been offered, the nephrologist passes on the donor details to the implanting surgeon who also reviews the donor and characterisation information in EOS. If an organ offer is unsuitable the nephrologist can decline the offer. However, if the offer is a standard criteria organ offer, the nephrologist would seek confirmation from a surgical colleague that the offer is unsuitable before declining the offer.

If the offer is suitable, the nephrologist contacts the H&I laboratory who can advise on the type of cross match required. The laboratory may either advise that the transplant can

proceed on a virtual cross match or a prospective cross match using a pre-retrieval donor blood sample or a wet cross match using tissue that accompanies the retrieved organ. The nephrology registrar then contacts the recipient, the transplant ward and theatres to alert them about the transplant and to give estimated timings.

Upon arrival at the establishment, recipients are clerked in by a nephrology registrar or senior house officer (SHO). Additionally, the recipient is seen by the implanting surgeon. The surgeon discusses the transplant. Should there be any additional or raised risk associated with the donor or organ, risks and benefits are discussed between the recipient and surgeon and recorded in the clinical notes prior to the transplant surgery.

When the kidney arrives at the hospital, the date and time of receipt are recorded and the paperwork checked to verify that it matches the labels on the box and that it matches the details of the expected organ. The transport box is then placed into a fridge where it is stored until being taken to theatres. In theatre, the implanting surgeon inspects and prepares the organ before calling the recipient for surgery. Samples of the organ transport fluid and a biopsy of the kidney are tested by the establishment to help inform post implantation management of the recipient. Prior to implantation, the surgeon checks the paperwork including the cross match report, hard copy blood group form and donor details. Post implantation, the HTA-B forms are completed using records taken during the surgery, signed by the implanting surgeon and returned to NHSBT by an administrator.

Living Kidney Donor Transplantation

The establishment has a living kidney donor programme through which adult donors can donate a kidney to adult recipients. Potential donors contact the establishment at which time they are asked what they know about living donation, a high level medical history is taken and they are given some information verbally about living donation. If the potential donor wishes to proceed an appointment is made with a living donor coordinator. At this first appointment, the coordinator discusses the risks associated with being a live donor in addition to going through a health questionnaire with potential donors which includes medical history, lifestyle and travel history questions. At this same appointment, blood samples are taken from the donor for full blood counts, glucose testing, liver and kidney screening, blood group testing and HLA typing.

The results from the initial screening visit are discussed at a multidisciplinary meeting (MDT) and if suitable, the potential donor will be asked to attend the establishment for a ‘one stop shop’ visit where kidney function tests, imaging, electrocardiogram assessments and blood screening for transmissible infections are undertaken. Results from these screens are recorded onto a donor work up sheet and shared with the nephrologist who would then request any further assessments that may be necessary. Once all of the tests are completed, the potential donor is referred for a surgical review following which an appointment is made for an Independent Assessor (IA) interview.

Results of the IA assessment and all screening tests are discussed again at an MDT at which time, potential dates for the transplant are discussed and the procedure is arranged. Following the transplant, the donor coordinator returns the HTA-A forms and the administration team return the HTA-B forms to NHSBT. The living donor is seen by the surgeon following surgery and then at a nurse lead clinic at two weeks. The donor is again followed up by the surgeon at six weeks post surgery at which time they are discharged into the care of their General Practitioner (GP). Donors are then seen annually by the establishment for their follow up or some may choose to have follow up visits at their local GP.

The establishment also undertakes living kidney donor transplants for private patients including overseas patients. The establishment follows the same procedures as for the NHS patients with the same staff undertaking both private and NHS work. Any donor

characterisation assessments that have been undertaken overseas are repeated by the establishment once the potential donor arrives in the UK.

Cadaveric Liver Donor Transplantation

Organ offers from NHSBT's Hub are received by the transplant coordinator (TC) who uses the donor details that are passed on to them to review detailed donor and organ characterisation information in EOS. The characterisation information is discussed with the on-call surgeon and hepatologist who make an initial decision on the organ's suitability. The TC alerts theatres to the transplant and calls the intended recipient to ask them to attend the establishment. Although donor and organ characterisation information has been reviewed initially by the implanting surgeon, characterisation information is reviewed again in EOS by the surgeon when they arrive at the establishment prior to transplant.

The surgeon sees the recipient to discuss the transplant and should there be any additional or raised risk associated with the donor or organ, the risks and benefits are discussed between the recipient and surgeon and recorded in the clinical notes prior to the transplant surgery. When the organ arrives, it is received by the theatre coordinator who records the date and time that the organ was received. The organ is then transferred to theatres where the implanting surgeon checks the donor paperwork and hard copy blood group forms. The implanting surgeon inspects the organ in theatres to assess its suitability. During this inspection, the organ is weighed, its anatomy is reviewed and it is inspected for any signs of injury following its retrieval and transport. The organ is prepared for implantation and then either implanted directly from the theatre back table or, depending on the recipient, it can be re-packed and placed on ice until the recipient is ready for implantation.

Following the transplant, the implanting surgeon completes the HTA-B form which is returned to NHSBT by an administrator.

Living Liver Donor Transplant

The establishment has a living liver donor programme through which adult donors can donate a part of their liver to an adult recipient. Potential donors contact the live donor coordinator (LDC) at the establishment. The LDC arranges to obtain a medical history from the potential donor's GP, arranges to confirm the potential donor's blood group and sends the potential donor a medical questionnaire.

If the potential donor wishes to proceed, they are seen in clinic by the LDC when the medical questionnaire is revisited again with the potential donor by the LDC. The potential donor sees a hepatologist who is independent to the establishment's transplant programme and based at another hospital or, where this is not possible, a hepatologist who is not part of the transplant team. The potential donor moves through the assessment pathway with further characterisation assessments being undertaken until they are seen by the surgeon. The surgeon reviews the organ anatomy and size of the recipient to determine whether the hepatectomy will be left or right.

Following the surgical review, the donor is discussed at an MDT to make an assessment on the suitability of the donor. If it is agreed that the potential donor is suitable, final characterisation assessments including a liver biopsy and a final surgical review are arranged. A final MDT is arranged where treatment plans for the donor and recipient are discussed in addition to planning intensive care provision and dates for the transplant. During the transplant surgery the recipient's procedure is not commenced until the retrieving surgeon has visualised the donor organ. Following surgery the HTA-A and HTA-B forms are returned to NHSBT by the LDC and the team's administrator respectively.

Post surgery, the donor is seen on the ward and is discharged at ten days post surgery. The surgeon then sees the donor as an outpatient at various clinics post surgery. These can be

up to weekly for the first two months post surgery, followed by further visits at three, six and twelve months before seeing them annually for lifelong follow up.

National Organ Retrieval Scheme (NORS)

The establishment's NORS team comprises of a lead surgeon, qualified assisting surgeon, a senior clinical fellow that may be undergoing training, a perfusionist, a scrub nurse and the ambulance team. Upon notification of a potential cadaveric donor, the TC notifies theatres of a retrieval. Organ boxes, perfusion fluids, ice and equipment is collected and the team meets the perfusionist who records all of the timings for the team, such as team meeting and when the team is mobilised. While on the way to the retrieval, the surgeon is briefed on the type of donor and which organs are to be retrieved in addition to reviewing donor characterisation information.

Upon arrival at the retrieval centre the surgeon discusses the donor with the specialist nurse for organ donation (SNOD) in relation to the donor details, whether the donor is a heartbeating or circulatory death donor, the donor's age, cause of death, donor height and weight, the organs to be retrieved and details of other retrieval teams which will be present. The surgeon reviews the consent form, blood group, clinical notes and previous medical history. A pre-surgical brief is undertaken and the world health organisation safer surgical checklist performed prior to the retrieval commencing. The organs are prepared for transport according to the national NORS team operating standards. Organs are then placed into the relevant transport box with the relevant traceability paperwork and tissues for typing before being collected for transport to the transplant centres. The surgeon completes the HTA-A form, copies of which are included with the transported organs and that include details of organ anatomy and condition of the organ.

Audit of Clinical Notes

Audits of clinical notes relating to donation and transplant were reviewed during the audit as detailed below:

Living Kidney Donor (Private patients) Transplants

Two sets of living donor, and the appropriate recipient records, were reviewed. Both transplants were directed donations with the kidneys going to relatives of the donors. The review included the HTA-A forms, HTA-B forms, serological screening results, consent for the donation and transplant, donor characterisation assessments, HTA living donor approval, cross matching reports and nephrological and surgical confirmation that the donors were suitable. The review found one example where the HTA-A form number had not been transcribed onto the HTA-B form. No further anomalies were identified.

Living Kidney Donor (NHS patients) Transplants

Two sets of living donor, and the appropriate recipient records, were reviewed. One transplant was a directed donation with the kidney going to a relative of the donor. The other donor was a non-directed altruistic donor and the kidney was sent to another transplant centre for implantation. The review included the HTA-A forms, HTA-B forms (where applicable), serological screening results, consent for the donation and transplant (where applicable), donor characterisation assessments, HTA living donor approval, cross matching reports and nephrological and surgical confirmation that the donors were suitable. No anomalies were identified.

Cadaveric Kidney Donor Transplant

One set of records relating to a recipient of a cadaveric donor kidney was reviewed. The review included the HTA-A form, HTA-B form, consent for the transplant, the establishment's Donor and Recipient Details form (used to capture some donor and recipient information and which is signed by the implanting surgeon to confirm that they

have reviewed the donor characterisation information), the operating note and the donor blood group form. No anomalies were identified.

Living Liver Donor (NHS patient) Transplant

One set of records relating to a living liver lobe donor were reviewed. The transplant was a directed donation with the liver lobe going to a relative of the donor. The HTA-A form, HTA-B form, the split liver form, donor serological screening results, consent for the donation and transplant, donor characterisation assessments, the establishment's Evaluation Protocol Living Liver Donor form which is used to capture the dates of each donor characterisation assessment taking place, HTA living donor approval, hepatological and surgical confirmation that the donor was suitable. No anomalies were identified.

Cadaveric Liver Donor Transplants

Two sets of records relating to cadaveric liver donor transplants were reviewed. The review included the HTA-A forms, HTA-B forms, hard copy of the donor blood group form, consent for the transplant, the transplant checklist, characterisation information, copy of the donor's EOS printouts and the operating notes. The review found one example where the HTA-A form number had not been transcribed onto the HTA-B form. No further anomalies were identified.

Compliance with HTA assessment criteria

<table>
<tr><th>Assessment Criteria</th><th>Audit findings</th><th>Level of Shortfall</th></tr>
<tr><td colspan="3">Retrieval of Organs for transplantation</td></tr>
<tr><td>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.</td><td rowspan="3">The establishment has a procedural document relating to sterile services, material and equipment however, this document does not include any reference to the establishment only using equipment for retrieval and transplantation that meets the requirements of the medical devices regulations. Although verbal assurance from the Trust's procurement department was given that only compliant, CE marked equipment was purchased by the Trust, there is no documented procedure which describes how this is assured.</td><td rowspan="3">Minor</td></tr>
<tr><td>Organ preservation</td></tr>
<tr><td>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.</td></tr>
</table>

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.	The establishment has developed a flow chart detailing the procedure for transport, packing and labelling of organs which relates to organs being transported to other licensed premises. This flow chart however references a type of kidney transport box that is no longer in use, and does not include details of how livers would be packed. In addition, the flow chart does not include instructions on how the transport container should be packed with ice or how the container should be secured and labelled.	**Minor**
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.		

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 to proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	Although the transplant coordinator, hepatologist and surgeon all review donor characterisation information prior to the implantation of livers, there is no documented procedure which describes how and when this takes place.	**Minor**

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
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.	The establishment has created a flow chart describing the process for reporting SAEARs to NHSBT. This document however references an out of date version of an NHSBT SAEARs reporting procedure. In addition, the flow chart initially instructs the user to report the SAEAR via NHSBT's reporting portal but then later in the flow chart, instructs the user to report to the NORS team lead within 24 hours of discovery.	**Minor**

Assessment Criteria	Audit findings	Level of Shortfall
General – (*these criteria apply to all licensed activities*)		
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.	The establishment does not have any documented procedure detailing which activities are performed under the advice and guidance of a registered medical practitioner.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	Some of the wording in the establishment's documentation could be clarified so that the process is clearly defined. The establishment is advised to review all procedural documentation to find any areas which may benefit from clarification. Examples of areas that could be clarified include but are not limited to: • The renal living donor pathway document currently indicates that approval of a living donor comes from the Independent Assessor. This should be clarified so that it is clear that living donor approval comes from the HTA following its review of the Independent Assessor's report. • Additionally, in the same document it states that SAEARs 'should' be reported within 24 hours. This document should be amended so that it is clear that SAEARs 'must' be reported to NHSBT within 24 hours of discovery.
2.	CT4	In reviewing the Trust's on-line document retention policy, the inspection team were able to identify the storage retention periods of records relating to transplantation however, the table which specifies this was accessed by following multiple links within the policy. The establishment is advised to consider including a signpost to the actual document retention schedule table so that it can be found via a single link, which may help to make it more accessible to establishment staff.
3.	R4	Upon discharge of a living kidney or liver lobe donor, a letter is sent to the donor's GP. The establishment is advised to consider amending 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 so that the recipient can be reviewed and followed up as necessary. 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 the donor and the recipient.

No.	Assessment Criterion	Advice
4.	P3	Refrigerated storage temperatures of perfusion fluid is recorded by the establishment however, only the temperature of the stored fluids at the time the reading is taken is reviewed and recorded. This poses a potential risk that any temperature deviation from the expected range that may have occurred out of hours or inbetween storage temperature recording may not be detected. The establishment is advised to record the maximum and minimum temperatures that the stored fluids have been exposed to in order to help in identifying any deviation from the expected storage temperature range. Additionally, the establishment is advised to monitor the temperature of the fluids stored at ambient temperature in the same way.
5.	I2	In both kidney and liver transplant settings, the implanting surgeon verifies that the conditions of preservation during transport of an organ to the establishment have been maintained. This verification step however is not included in any procedural documents. The establishment is advised to include the verification step within their procedural documentation and/or policies.
6.	TC1	During the review of donor and recipient clinical notes in both the kidney and liver transplant settings, examples where the HTA-A form number had not been transcribed on to the HTA-B form were identified. Traceability of the organs had not been compromised as other details recorded on the forms, and in the establishment's documentation, maintained traceability details of the organs. However, the establishment is advised to develop and implement a procedure through which it can assure itself that the HTA-A form number is always added to the HTA-B form before the forms are returned to NHSBT.
7.	TC3	Some of the documentation that is required to be maintained for 30 years, for example, records of receipt of an organ in theatres, is not held within donor or recipient clinical notes and is therefore not subject to the Trust's clinical record management processes. The establishment is advised to review all such documentation and records and to develop a system to assure itself that these will be maintained for the required 30 year period. In addressing this advice, the establishment may wish to consider scanning such records onto a secure Trust server so that they are maintained.
8.	S2	In addressing the shortfall identified against assessment criteria S2, the establishment may wish to consider adopting NHSBT's current SAEARs reporting procedure and sharing this with establishment staff.
9.	GN3	In addressing the shortfall identified against assessment criteria GN3, the establishment may wish to consider adopting and adapting the national operating procedure NOP005. This may help in providing a framework for an establishment specific operating procedure that, after adaptation to reflect practice at the establishment, may be used to detail the procedures undertaken under the advice and guidance of registered medical practitioners.

Concluding comments

Areas of good practice were observed during the audit. For example, the establishment has developed clear donor work-up checklists for both living liver and kidney donors. These help

to assure the establishment that all of the donor characterisation assessments have been completed as expected.

There are a number of areas of practice that require improvement, including five minor shortfalls. The HTA has given advice to the establishment with respect to procedural documentation, temperature monitoring of fluids used during retrieval and transplant, document completion and document retention.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent for factual accuracy: 26 September 2018

Report returned with comments: 9 October 2018

Final report issued: 25 October 2018

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: 3 August 2019

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.

HTA assessment criteria

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.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
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.
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.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.

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.
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.
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.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
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.
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.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.
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.
TP2) The organ shipping container is suitable for transport of the specified organ.
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.
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.
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.
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.

I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.
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.
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.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
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.
Serious adverse events and adverse 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.
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.
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.
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.
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.
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.