Site visit audit report on compliance with HTA requirements

University Hospitals Birmingham NHS Foundation Trust

HTA licensing number 40042

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.

20-22 June 2017

Summary of Audit findings

Although the HTA found that University Hospitals Birmingham (the establishment) had met the majority of the assessment criteria, three shortfalls were found. These were in relation to recording IV drug use in the donor assessment form for living donors, lack of a documented procedure for keeping information on donor and organ characterisation for 30 years and the use of a histopathology laboratory which is not currently accredited by CPA or UKAS without risk assessing the potential impact on the quality and safety of the organ as a result of this change to the accreditation status of the laboratory.

During the last financial year the establishment undertook 191 liver transplants, 113 kidney transplants, 26 heart transplants and 11 lung transplants from deceased donors. In addition, there were directed donations from living donors - 56 kidneys and five liver lobes along with five non-directed altruistic donations of kidneys from living donors.

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

Donor	Kidney	Pancreas	Liver	Small bowel	Heart	Lung
Adult - deceased	**OC, R, P, T**	**OC, R, P, T**	**OC, R, P, T**	**OC, R, P, T**	**OC, R, P, T**	**OC, R, P, T**
Adult – living	**DC, OC, R, P, T**		**DC, OC, R, P, T**			

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

Recipient	Kidney	Liver	Heart	Lung
Adult	**OC, P, T, I**	**OC, P, T, I**	**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

University Hospitals Birmingham NHS Foundation Trust has been licensed by the HTA since August 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. Licensable activities are undertaken at the Queen Elizabeth Hospital, Birmingham (QEH).

Serology and molecular biology testing services are provided by laboratories based at the QEH. These laboratories were not inspected during the audit. The laboratories undertake serology, molecular biology, biochemistry and microbiological examination activities for the purposes of clinical diagnosis and are accredited by United Kingdom Accreditation Service (UKAS - Medical Laboratory No 8910 and No 8760). The audit team were informed that the Clinical Pathology Accreditation for Histopathology services was revoked pending a review of the services; UKAS will undertake an assessment visit within the next six months to assess compliance against ISO 15189:2012.

The HTA team understands that staff at the histopathology laboratory provide after-hours services to the transplant team even though these services are not part of their routine contractual obligations. The service includes examination of biopsies of organs, as well as samples from deceased donors to assess any suspected malignancy and determine the suitability of donors and whether or not the donated organs are suitable for transplantation.

Retrieval of Cardiothoracic and Abdominal Organs from Deceased donors

Surgeons and theatre staff based at QEH are commissioned by NHSBT as part of the National Organ Retrieval Service (NORS) to retrieve cardiothoracic and abdominal organs from deceased adult donors. Each team is made up of a lead surgeon, assistant surgeon, scrub nurse and an Operating Department Practitioner (ODP). The abdominal team is one of seven in the country and shares on-call responsibilities (two weeks out of three) with another NORS team. The cardiothoracic team is one of three in the UK. Each year the abdominal team and the cardiothoracic team attend around 200 and 100 retrievals respectively.

Abdominal and cardiothoracic NORS teams prepare and store retrieval kits and organ boxes in a dedicated NORS room within the secure theatre area of the hospital. Scrub nurses prepare the 'scrub suitcases' containing all equipment required for retrieval and a list of components of each kit is placed in the room for staff to follow and check. Perfusion fluids are packed and ice is placed in boxes when the team is mobilised. The teams do not take mechanical perfusion devices to the donor hospital. The NORS teams use the new kidney boxes supplied by NHSBT; all other organs are packed in large insulated boxes. NHSBT Duty Office mobilises the NORS team which has to start its journey towards the donor hospital within 60 minutes of being mobilised.

Perfusion fluids and saline are stored in freezers, fridges or at room temperature in the NORS room or near individual theatres, depending on storage requirements for each fluid. Fridges are set at 4^0C, but the temperature of these fridges are not monitored (see advice item 2). Staff check stock levels and discard any fluids which are out of date.

The NORS teams meet the Specialist Nurse-Organ Donation (SNOD) at the donor hospital and check the identity of the donor, death certificate, consent for donation and permission from the Coroner (if required). The audit team was informed that delays do occur at donor hospitals, due to availability of theatres, staff or equipment.

Cardiothoracic organs are retrieved before abdominal organs as the acceptable cold ischaemic times are much shorter. Retrieval begins as soon as the retrieval surgeon receives confirmation that the transplant centre is ready to implant the heart/lungs when they arrive at

the hospital. Retrieval teams inform NHSBT Duty Office and implanting surgeons if they have any concerns about the donor or the quality of the organs retrieved.

The retrieval surgeon completes an HTA A form and records observations about the organ such as any unusual anatomy, damage during retrieval, type and batch number of perfusion fluids used to perfuse the organ. The organs are triple bagged and packed under the supervision of the retrieval surgeon, in accordance with the National Standards for Organ Retrieval from Deceased Donors (MPD1043/7 published by NHSBT). Staff use the coloured tags provided by NHSBT to label boxes – left kidney (yellow), right kidney (red), pancreas (blue). NHSBT is responsible for transporting organs from the donor hospital to transplant centres and between QEH and Birmingham Children's Hospital as needed.

If consent is in place, the NORS teams remove kidney and liver biopsies and collect samples such as blood, urine, spleen and ureter if the donor hospital holds an HTA Human Tissue Act 2004 licence for removal of tissues from the deceased. These samples are sent to an HTA licensed establishment for ethically approved research as part of the Quality in Organ Donation project. This project aims to improve transplant outcomes by analysing biological markers, which could help to predict transplant outcomes thus potentially increasing the pool of available organs including transplants of marginal organs.

Staff attend the National Retrieval Group meeting held twice each year to discuss any issues relating to retrieval. They also attend NORS certification courses run by NHSBT which covers training of personnel involved in retrievals.

Deceased Organ Transplants

Transplants take place in the theatres at QEH. The on-call recipient transplant co-ordinator (RTC) receives the offer of an abdominal or cardiothoracic organ from NHSBT Duty Office. The RTC reviews the NHSBT Electronic Offering System (EOS), mobile version, which links to Donor Path and the Patient Assessment Form. The RTC records key information on a pro-forma and alerts the on-call surgeon who decides on the suitability of the donor and organ.

Before potential recipients are listed for a transplant they are informed that well matched donors could include extended-criteria donors and high risk donors. When such organs are offered by NHSBT Duty Office, the surgeon discusses the risks relating to each organ with potential recipients and confirms their consent before the transplant takes place. Potential recipients on the kidney waiting list are Human Leukocyte Antigen typed every three months, as they may have been exposed to sensitising events.

RTCs who receive offers of organs from NHSBT Duty Office enter details of the offer using an on-call pro-forma (kidneys) or Donor Alert Form (livers). The forms prompt RTCs to record relevant information such as donor testing results, pending results, details relating to the potential recipient, possible back up recipients, key theatre contacts etc. The form helps to facilitate the transplant pathway so that transplants can take place within the appropriate timeframe. Once the surgeon accepts the offered organ and the RTC informs NHSBT Duty Office, the retrieved organ is transported to QEH. The RTC is responsible for liaising with theatres and making arrangements with the potential recipient to travel to QEH.

When organs arrive at QEH, staff open the transport box, check the level of ice in the box and remove the spleen, lymph nodes and donor blood samples which are sent for cross matching. Cross matching is undertaken to confirm the donor/recipient match, and informs the anti-rejection medication provided to the recipients after the transplantation. In the case of abdominal organs, the implanting surgeon samples around 20ml of the transport fluid which is sent for testing for microbial contamination.

Abdominal organs arrive in the main reception of the secure theatre suite and are immediately transferred to dedicated rooms adjoining the theatres. Kidneys are checked by a surgeon and perfused if appropriate before the potential recipient is transferred into theatre. The establishment has temporarily stopped using a machine to perfuse kidneys whilst it awaits the arrival of two new machine perfusion devices (see advice item 2). Receipt of kidneys, perfusion, and transplantation of kidneys are recorded in the Kidney Transplant Record Book (see shortfall under assessment criterion CT4). Livers received are kept in a room adjoining theatre 3 and recorded in the 'Organ Received Record'. The unit rarely splits livers for transplantation. If splitting is required, it takes place at Birmingham Children's Hospital before the liver lobes intended for adult recipients are transported to QEH. On occasion, splitting takes place at QEH, especially, if the paediatric graft is not for implantation at Birmingham Children's Hospital.

Staff complete an Organ Transfer Record when abdominal organs are sent away to other transplant centres. The form has details including the ODT number of the donor, time and destination of the organ and the name of the courier who collected the organ.

The liver transplant team participates in a clinical trial - Viability Testing and Transplantation of Marginal Livers (VITTAL), which involves ex-vivo normothermic machine preservation of whole livers which have been rejected as unsuitable for transplantation by all other transplant centres. Potential recipients are provided with patient information leaflets; clinicians discuss associated risks and seek consent before enrolling them into the trial. The liver is perfused at 37^0C with perfusion fluid consisting of colloids, bile salts, insulin, prostacyclin and heparin which is added to oxygenated blood which is matched to the recipient. The production of bile, blood gas analysis and biochemical tests undertaken on the circulating perfusion fluid are monitored in order to assess the viability/metabolic status of the perfused liver.

The audit team were informed that the liver is flushed with cold perfusion fluid and transplanted into the recipient if the assessment meets the relevant assessment criteria for the trial. To date, the unit in Birmingham has transplanted over 200 livers which have been subjected to normothermic machine perfusion. During the audit the HTA audit team were not provided with patient files or donor information relating to the VITTAL trial. The HTA understands that an external review is due to look at clinical practice relating to perfusing and transplanting livers.

Cardiothoracic organs are received by the RTC at the entrance to the hospital. In order to ensure the shortest possible cold ischaemic time, the surgical team and recipient would be in theatre ready to receive the heart/lungs. The cardiothoracic organs are immediately transferred to theatres where they are checked before being transplanted into the recipient.

In all cases, the surgeon either reviews the most up to date version of EOS or is informed of any recent updates by the RTC before he/she proceeds with the transplant. A surgical pause is observed and the World Health Organisation (WHO) checklist is followed before any incision is made. Details about the condition of the received organ, perfusion fluids used, whether the organ was machine perfused and other details are recorded on the HTA B form. Completed HTA B forms are scanned and sent to the NHSBT Duty Office.

The transplant service undertakes a declined organ review meeting where all organs, which have been declined, are discussed by the team to ensure that the clinical team agree with the decision in each case.

Living Donation

The establishment retrieves kidneys and liver lobes for adult and paediatric recipients. Potential kidney donors are assessed at QEH and in regional hospitals. The living kidney donor team provide regular information sessions at QEH for potential donors where they

describe living donation, the pathway for assessing the suitability of living donors, the risks attached to donation and support provided to donors. Living liver donors and non-directed altruistic donors are always assessed at QEH.

Potential living donors are matched against the recipients before further interviews and tests are undertaken. Matched donors are provided with an initial medical questionnaire covering travel history and high risk behaviours which they take away to complete. Once the potential donor completes the form, the co-ordinator meets the donor, takes samples for donor testing, collects a detailed family and personal medical history and refers them for psychiatric and psychological evaluation. Referral to the HTA Independent Assessor then takes place.

Formal consent is sought once a detailed medical evaluation takes place and HTA approval is obtained. All medical tests are repeated if donors come from overseas to donate an organ. The donor's wishes regarding the fate of kidneys or liver lobes, if it is not possible to implant it into the named recipient, is recorded. Multidisciplinary team (MDT) meetings attended by transplant co-ordinators, surgeons and the rest of the clinical team review and agree on the suitability of each donor before living donors can proceed to surgery.

Mandatory tests are repeated if living donation is postponed for any reason. The date of surgery is scheduled, and donors and recipients are admitted into the hospital. Donors are re-consented and checks carried out on the identity of the donor before the kidney or liver lobe is retrieved. Liver lobe donation can be associated with significant blood loss so in the case of living liver donors, two units of autologous blood is pre-donated four weeks and two weeks before surgery so that the donor's own blood can be re-transfused into the donor if required during surgery. If the liver lobe is to be transferred to Birmingham Children's hospital, it is triple bagged with perfusion fluid surrounding the organ and transported using the contracted courier.

Discharge letters are sent to the donor's General Practitioner or in the case of donors from overseas, to the referral centre overseas, when the donor is discharged (see advice item 1). Regular annual follow up of donors takes place. In the case of overseas donors they are advised to attend an annual follow up in their home country.

NHSBT is responsible for transporting the kidneys which are donated under the paired/pooled programme to the relevant transplant centres.

Incident reporting

Staff report incidents directly to NHSBT electronically and also report incidents within the Trust. These incidents usually relate to organ damage during retrieval and issues such as transport delays, delays at donor hospitals, communication issues and recipient reactions following transplantation. NHSBT provides feedback directly to the person who has reported the incident (see advice item 4).

Document Review

A document review was carried out during the audit. Two operational policy documents which cover liver transplants and adult renal transplants (issued in 2016) were reviewed (see advice item 6). Training records relating to core competencies for transplant co-ordinators, the scrub nurse, recipient co-ordinators, ODPs for the cardiothoracic teams and abdominal teams were reviewed. Clinical notes relating to two deceased donor kidney transplants, one living donor kidney transplant and transplant packs relating to two heart transplants were reviewed. Records of consent, mandatory test results, HTA A and HTA B forms, type and batch numbers of perfusion fluids used, printout of EOS, donor alert records, donor assessments, WHO type checklists detailing checks undertaken before operations and operation notes, as

applicable, were reviewed. There were a few minor anomalies noted in the HTA A and HTA B forms relating to recording of times when organs were received and implanted. Electronic records relating to liver transplants which included referral letters, donor assessment and donor testing were also reviewed.

Procedural documents such as relevant flow charts and procedures for incident reporting were also reviewed.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	The Donor assessment form which is completed in order to assess living kidney donors, records the use of 'illegal drugs' but does not specifically record past or present history of IV drug abuse as noted in Part A (minimum data set) of the Annex to the Directive, paragraphs 32 and 79 of the HTA Framework document – Quality and Safety of Organs intended for Transplantation updated November 2016. The HTA audit team was informed that staff are trained to ask follow up questions which cover IV drug use, should a potential donor state that they use or have used illegal drugs. Donor assessment is undertaken at several regional centres and there is the risk that new members of staff at other centres may not be fully aware of the need to ask this question.	**Minor**

Assessment Criteria	Audit findings	Level of Shortfall
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.	The establishment uses machine perfusion to preserve some livers before they are transplanted. Current practice in the case of clinical trials relating to normothermic liver perfusion of livers from extended criteria donors, is that all data is kept for 15 years as part of the clinical trial data. Traceability information such as the machine used, relevant data stored within the machine, identification of the batch of consumables used during machine perfusion, unique blood ID and results from analysis of the blood gases and other metabolic tests must be stored for 30 years as noted in paragraph 86 in the HTA Framework document – Quality and Safety of Organs intended for Transplantation updated November 2016. These requirements also apply to data relating to machine perfusion of kidneys. Traceability data must be kept in a manner so that it can easily be traced to each transplanted organ and recipient.	**Minor**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	The histopathology laboratory frequently used for donor and/or organ characterisation does not have current CPA or UKAS accreditation. The use of this laboratory has not been formally justified nor has the accreditation status been reviewed on a regular basis as noted in paragraphs 40-42 in the HTA Framework document – Quality and Safety of Organs intended for Transplantation updated November 2016.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	R4	The establishment is advised to include a statement in the discharge letter for living donors which states that the GP or other referral centres, including those outside the UK, should inform QEH if, post donation, the donor develops a condition such as a malignancy, which may have implications for the wellbeing of the recipient.

No.	Assessment Criterion	Advice
		Due to the existing relationship, recipients of organs from directed donors would usually be aware if their donor develops a health condition which could have consequences. However in cases of non-directed altruistic or paired and pooled donations, the absence of a direct relationship between the living donor and the recipient means that the recipient may not be aware of any change to the health status of the donor.
2.	P1 and P2	The storage temperature of perfusion fluids and saline stored in freezers, fridges or at room temperature as required, is not routinely monitored. The establishment is advised to implement a system of monitoring of storage areas to ensure that the temperature does not deviate from the manufacturer's recommended storage temperature. The establishment could consider using minimum/maximum thermometers to monitor the temperature of the storage areas. The establishment is advised to update the following document - *Management of Procurement Material and Equipment in Deceased and Living Donation and Transplantation (no:CG022)* to include a reference to Guidance issued by the Medicines and Healthcare Products Regulatory Agency in April 2015 on Managing Medical Devices which covers procurement, training, maintenance and repair of medical devices. The establishment sometimes uses machine perfusion to preserve livers and intends to recommence the use of machines to perfuse kidneys. The establishment is advised to formalise the procedures for cleaning and regular maintenance of these machines.
3.	TC1	The establishment is advised to include a review/check step before completed HTA A forms and HTA B forms are sent to NHSBT. During a review of HTA A forms and HTA B forms it was noted that there were a few minor anomalies which could have been identified and corrected if a check step was included.
4.	S1	The establishment is advised to ensure that all staff working under the licence strictly adhere to the requirement to report all reportable incidents irrespective of whether they are minor or major incidents to NHSBT within 24 hours. The HTA is aware of one serious adverse reaction which should have been reported and was not reported within appropriate timeframes. The establishment is advised to consider implementing a system of shared learning from incidents across the transplant teams. NHSBT follows up reported incidents with the individual member of staff who reported the incident. This means that other staff in the transplant team may not become aware of the incident or share in the learning from that incident. The establishment could consider collating incidents which have been reported to NHSBT by staff who work under the licence or, if considered appropriate, report these incidents within the Trust's internal incident management system so that they are easily accessible by other professionals in the transplant teams.
5.	S2	The establishment is advised to liaise with the testing laboratory to ensure that they are aware of the need to inform the transplant teams if there have been any issues with kits or equipment which are likely to have affected, or will affect test results.

No.	Assessment Criterion	Advice
6.	N/A	The establishment is advised to include the following when Trust documents are next reviewed and updated. • Refer to the latest version of the HTA Quality and Safety of Organs Intended for Transplantation: a documentary framework which was updated in November 2016 • include information on on-going clinical trials as appropriate • include reference to non- directed altruistic kidney and liver lobe donors • include the use of machine perfusion of kidneys and livers.

Concluding comments

The establishment has a large range of documents and process flow charts which cover kidney and liver transplants. The 'Adult Renal Transplantation Operational Policy 2016' and the 'Operational Policy for Liver transplants' are detailed documents which cover live donor work up procedure, living donor retrievals and implantation of kidneys from deceased donors into recipients and associated governance arrangements including MDTs. The Trust publication 'Liver transplantation: what does it mean to me and my family' includes comprehensive information to donors, recipients and their families and covers living donor assessment, deceased donors, surgery, post-transplant care and support provided to donors and recipients.

Flow charts and notices are displayed in the Perfusion Room and the NORS Room to help remind staff of procedures which should be followed. New transplant Clinical Nurse Specialists including recipient and living donor co-ordinators are mentored and follow a formal induction programme and competency assessments before they are signed off as competent. The training includes meeting members of the cardiothoracic and abdominal teams to promote collaborative working. Trainees also meet with the SNOD, attend transplant clinics, MDT and observe transplant surgery.

There are a number of areas of practice that require improvement, including three minor shortfalls relating to recording IV drug use in the donor assessment form for living donors, keeping information on donor and organs characterisation for 30 years and the use of a histopathology laboratory which is not accredited by CPA or UKAS. The HTA has given advice to the establishment with respect to reviewing discharge letters for living donors, updating operational policy documents, monitoring storage temperature of perfusion fluids, formalising the maintenance of perfusion machines, timely reporting of incidents and shared learning from incidents.

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.

Report sent for factual accuracy: 21 August 2017

Report returned with comments: 4 September 2017

Final report issued:18 September 2017

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: 28 September 2018

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.

Compliance with HTA assessment criteria

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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.