Site visit audit report on compliance with HTA requirements

Royal Liverpool and Broadgreen University Hospitals NHS Trust

HTA licensing number 40031

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

13 December 2018

Summary of Audit findings

Although the HTA found that Royal Liverpool and Broadgreen University Hospitals NHS Trust (the establishment) had met the majority of the assessment criteria, shortfalls were found, particularly in relation to procedural documentation and laboratory accreditation. Following the audit and prior to the draft report being issued, the establishment has put in place the majority of procedural documents that are required. However the shortfalls identified during the audit are recorded in this report and marked as now being met. The HTA has also given advice to the establishment with respect to procedural documentation, donor characterisation, temperature monitoring, live donor follow up and serious adverse event and reaction reporting.

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
Adult living	**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	
Adult living	**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

Royal Liverpool and Broadgreen University Hospitals NHS 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, which is based at the Royal Liverpool University Hospital, undertakes adult kidney transplants from cadaveric donors. In addition, the establishment has a living donor kidney transplant programme.

During the establishment's previous audit in 2013, it was found that the establishment had adopted the national operating procedure (NOP) documentation which, in combination with other Trust documents, outlined the procedures used at the establishment. However, since the previous audit, the establishment had not maintained the NOPs in its governance systems meaning that they had not been updated to reflect the changes made to the national documents in 2016 and establishment staff were not aware of them. Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The NOPs are now in place meaning that shortfalls identified during the 2018 audit relating to them are now considered to be met, however advice has been given as the establishment should adapt the NOPs to more closely reflect its own practice. In addition, the establishment's own patient pathway documents, checklists and proformas should be appended to the relevant NOPs. Advice has been given below with regards to this. As a result of the NOPS having been put in place following the 2018 audit visit and prior to the issue of the draft inspection report, shortfalls identified during the audit relating to procedural documentation have been marked in this report as being met.

The establishment stores perfusion fluids in the theatre department's store room. Fluids are stored at ambient temperature and are placed into chilled storage prior to being needed such as when the establishment receives a cadaveric donor organ offer or is undertaking a live donor transplant. The room where the perfusion fluids are stored at ambient temperature is not currently temperature monitored (see advice item 6).

Documentation demonstrating that the establishment's sterile services provider met the requirements of the assessment criteria following last year's validation visit was provided and reviewed following the audit. In addition, the establishment has adopted National Operating Procedure 004 (NOP004) which stipulates that all equipment must meet the requirements of the medical devices regulations. Although reviewed during the 2013 audit, Trust documentation specifying that only medical devices that meet the requirements of the medical devices regulations are used at the Trust were not provided (see advice item 5).

A review of the laboratory accreditation was undertaken for the laboratories used by the establishment. The Histocompatibility and Immunogenetics (H&I) laboratory has current United Kingdom Accreditation Service (UKAS) accreditation. The department of virology's laboratory which undertakes serological testing of living donors and the clinical biochemistry laboratory which undertakes biochemical analysis of living donors also both have current UKAS accreditation. The majority of histological analysis of tissues is undertaken during cadaveric organ retrieval, however, the establishment may send tissue samples from organs for analysis locally upon receipt of an organ. The Trust's histopathology laboratory was accredited under the Clinical Pathology Accreditation system which ceased in September 2018. The laboratory is transitioning to UKAS ISO:15189 accreditation however, it currently does not have UKAS accreditation.

Transplant and live donor coordinators all undergo a corporate induction and an induction to the transplant unit upon starting work at the establishment. New coordinators shadow existing team members and gain experience of each aspect of the role. Once familiar with the role, new staff start undertaking various tasks with the support of other colleagues. Once

competent, coordinator staff start to work independently however are still able to contact other colleagues if needed. Coordinators also undertake external coordinator training. The establishment has a programme through which interesting cases can be discussed internally to help facilitate learning.

Surgical staff also receive a corporate and transplant unit induction upon starting work at the establishment. Surgical staff shadow consultant surgeons and train on the various surgical transplant procedures until being determined to be able to work independently.

Staff are subject to professional revalidation and have annual appraisals through which they can identify development needs and appropriate continuous professional development. Staff are also able to attend external transplant sector conferences.

Cadaveric Donor Kidney Transplantation

Cadaveric donor organ offers are received from NHSBT's Hub Operations by the transplant coordinator (the coordinator). During out of hours periods, the transplant unit's registrar will receive the organ offers and liaise with the other establishment staff as described below in place of the coordinator. The registrar will then hand over to the coordinator at the start of the next working day. The coordinator uses the donor identification details obtained from Hub Operations to log into the Electronic Offering System (EOS) and reviews the donor and organ information. The Coordinator saves an electronic copy of EOS and prints a hard copy. The coordinator then contacts the consultant implanting surgeon who then also reviews the organ offer, organ and donor details either electronically via EOS or from the printed copy produced by the coordinator. If the establishment is alerted to any new information being available, a new version of EOS is saved and printed and the coordinator would update the surgeon.

If the offer is accepted the coordinator alerts Hub Operations and enquires about anticipated timings. The coordinator then calls the recipient and asks about any recent sensitising events that they may have experenced. The coordinator organises the patient to attend the establishment and books a theatre time slot before calling the establishment's H&I laboratory to find out if the donor is suitable for a virtual cross match or if a formal wet cross match is needed. If transplant proceeds on a virtual cross match, a wet cross match is still undertaken post implantation.

The recipient is clerked onto the ward and is met by the coordinator who goes through what to expect. The recipient is also seen and assessed by the implanting surgeon and anaesthetist. If there are any potential risks associated with the organ or donor, these are discussed between the surgeon and recipient and recorded in the recipient's clinical notes.

Prior to the organ arriving at the transplant ward, the coordinator completes a Transplant Information form which has been created by the establishment and records some recipient details and some details of the organ such as the estimated time of arrival, left or right kidney. In addition, the form is used by the nurse receiving the organ to record time of arrival, the shipping box condition, checks that the paperwork is present and that the ice levels are sufficient. The organ is kept in a locked room opposite the transplant ward's nursing station until it is collected and taken to theatres.

The organ is collected by a registrar who takes the organ to the establishment's theatres. The surgeon checks the paperwork including the donor details, HTA-A form, and the hard copy of the donor's blood group. A sample of the transport fluid is taken and sent for microbiological testing. The implanting surgeon then examines the organ and prepares it for implantation. Depending on when the surgery will take place, the organ may be re-packed and kept in theatres prior to surgery. Once the organ has been implanted the surgeon completes operation notes including details of timings and perfusion fluids used. This information is used by the coordinator to complete the HTA-B form which is then reviewed and signed by the implanting surgeon before being returned to NHSBT by the coordinator. The coordinators

also use a Transplant Recipient Information form, created by the establishment, to record details of the recipient and key details of the transplant for example, recipient details, pre and post transplant urinalysis and transplant timings among other data. This form also includes a check list for coordinators to verify that various actions have been completed such as getting the HTA-B form reviewed, signed and returned.

Living Kidney Donor Transplantation

Potential live donors come forward to the unit either altruistically or while their family members are undergoing renal treatment which may include planning for a kidney transplant in the future. Once notified, the live donor coordinator (LDC) asks the potential donor to attend the establishment for an appointment. During this first appointment, in addition to talking through what is involved in being a live donor, less invasive characterisation assessments are started for example, blood group, urinalysis, blood pressure, tissue typing. In addition, the LDC takes a medical history of the potential donor and goes through a Live Donor Assessment medical questionnaire which includes behavioural and social history questions.

A recipient may have had several potential donors come forward at this stage. The results of the early stage characterisation assessments are reviewed by a consultant surgeon to identify the most appropriate potential donor. Once identified, a suitable potential donor is contacted with the results of the characterisation assessments and asked to consider if they still wish to proceed with being a donor.

If the potential donor wishes to proceed with donation they attend a further appointment for x-ray, echocardiogram, kidney function tests and virology screening. If the kidney function tests are satisfactory, the potential donor will be booked for computerised tomography (CT) assessment. Results of the donor and organ characterisation assessments are reviewed at a monthly multi disciplinary team (MDT) meeting and if deemed suitable to donate, the potential donor is booked for an appointment with a nephrologist. The nephrologist reviews the characterisation assessments and assesses the potential donor's fitness for surgery and for living with a single kidney post donation. The nephrologist confirms a donor's suitability by letter.

The potential donor is then seen by a surgeon who discusses the potential risks of being a donor and reviews all of the characterisation assessment data again. The surgeon then sees the donor and recipient together and goes through the procedure again with them both. If still wishing to proceed, the donor is booked for an interview with an Independent Assessor. Donors have a pre-surgical assessment with a LDC and within two weeks prior to surgery, routine bloods are taken and virology screening, apart from HIV, is repeated (see advice item 2).

Donor nephrectomy and transplant procedures occur back to back. Following the organ retrieval and implantation, the LDC completes the HTA-A form and the recipient coordinator completes the HTA-B form, once reviewed and signed by the relevant surgeon, these forms are returned to NHSBT by the relevant coordinator.

Post donation, donors are seen by the retrieving surgeon immediately post surgery and then by the LDC one to two days post surgery. A further post donation surgical review occurs four to six weeks after the procedure followed by annual follow up at the establishment or if the donor prefers, by their local GP. Donors from overseas are given information about ongoing follow up and monitoring so that this can be shared with their local medical team.

Audit of Transplant Records

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

- Three sets of records from recipients of cadaveric donor kidneys
- Two sets of records from live donors

In all of these cases, where applicable, the following records were reviewed: donor consent, recipient consent, operation note, living donor characterisation assessments and questionnaires, copy of EOS information, hard copy of donor blood group sent with the cadaveric donor kidney, donor virology, repeat virology for living donors, cross match data, surgical and nephrology living donor sign offs, HTA-A and HTA-B forms, records of perfusion fluids used, records of receipt, recipient checklist forms, fate of kidney if not transplanted form, independent assessment letters and HTA live donor approvals. No anomalies were identified.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
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 had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

Assessment Criteria	Audit findings	Level of Shortfall
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	Although the majority of histological analysis of tissues is undertaken during cadaveric organ retrieval, the establishment may send tissue samples from organs for histological analysis locally upon receipt of an organ. The Trust's histopathology laboratory was accredited under the Clinical Pathology Accreditation system which ceased in September 2018. The histopathology laboratory that is potentially used for donor and/or organ characterisation does not have current 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**
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.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

Assessment Criteria	Audit findings	Level of Shortfall
Retrieval of Organs for transplantation		
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.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

Assessment Criteria	Audit findings	Level of Shortfall
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

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 had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***
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.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

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.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

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.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

Assessment Criteria	Audit findings	Level of Shortfall
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	The establishment had used the national operating procedures (NOPs) as a documented procedure demonstrating how this assessment criteria's requirements are met. The NOPs however are not maintained within the establishment's governance system and had not been updated to reflect the national changes made to the NOPs. *Since the audit visit in 2018, the establishment has now put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as necessary. The HTA now considers this assessment criteria as being met.*	**Minor** ***Fully Met***

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 an out of date copy of the SAEARs reporting SOP (SOP3888/1) within its procedural documents. (see also advice item 9)	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	General	Since the previous audit, the establishment had not maintained the NOPs in its governance systems meaning that they had not been updated to reflect the changes made to the national documents in 2016 and establishment staff were not aware of them. Since the audit visit in 2018, the establishment has put in place the latest versions of the NOPs and incorporated them into its governance systems so that they will be reviewed on a two yearly basis and updated as

No.	Assessment Criterion	Advice
		necessary. The establishment is advised that the newly implemented NOPs should now be adapted to more closely reflect the practice at the establishment. In addition, the establishment's own patient pathway documents, checklists and proformas should be appended to the relevant NOPs so that any establishment staff reviewing the procedural document will be made aware of the establishment's own documentation that is used.
2.	CT2	The establishment is advised to ensure that living donor characterisation is undertaken in accordance with British Transplantation Society or The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidelines as currently, the unit does not ensure that a blood sample is tested for HIV at a maximum of 30 days prior to organ donation. This test could be performed when the establishment retests for other infectious markers at two weeks prior to donation.
3.	CT2	Potential live donors are asked about previous history of IV drug use early in the donor assessment process via the 'Live Donor Assessment Medical Questionnaire'. Data from the paper copies of these documents is transferred and entered into the establishment's electronic patient clinical records system. The electronic patient records system has data fields for the responses to the questionnaire but not from the response regarding previous IV drug use. The establishment is advised to amend the electronic patient record system so that the response to the questions regarding previous IV drug use can be formally and electronically recorded with the other characterisation data.
4.	CT4	The establishment is advised to append the relevant section of the Trust's record retention policy (which was reviewed during the 2013 audit and provided following the audit in 2018) to the NOP006. This may help to support the documented procedure by clearly demonstrating that in addition to NOP006, the Trust's policy with regards to record retention is to retain transplant related information for 30 years from the date of the organ retrieval.
5.	R2 & P1	The establishment is advised to append the relevant section of the Trust's operational policy: Clinical Governance and Quality Department: introduction of a new technique or medical device (which was reviewed during the 2013 audit and provided following the audit in 2018) to the NOP004. This may help to support the documented procedure by clearly demonstrating that in addition to NOP004, the Trust's policy with regards to medical devices is that only medical devices that meet the requirements of the medical devices regulations should be used at the Trust and therefore, the establishment.
6.	P3	The establishment is advised to review the temperature monitoring arrangements for the perfusion fluids stored at ambient temperature before being chilled and used to develop a procedure though which any excursions from the expected temperature ranges during storage can be identified. In reviewing the temperature monitoring procedures, the establishment may wish to consider the use of maximum and minimum temperature logging devices. Temperatures may then be checked regularly and upon removal of fluids from storage to verify that they have been stored at the correct temperature.

No.	Assessment Criterion	Advice
7.	R4	The establishment follows up living donors immediately post surgery and at four to six weeks post surgery before they are discharged into the care of their GP. The establishment is advised to inform the donor's 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 a donor and the recipient.
8.	I2	The nurse receiving a cadaveric donor organ on the transplant ward performs various checks on the shipping container and paperwork including the box's ice level. The establishment's Transplant Information form currently only has space to record a single check of the ice level. The establishment may wish to consider adding a more fields to record subsequent ice level checks should the organ be stored on the ward for longer than expected prior to being taken to theatre for implantation.
9.	S2	In addressing the shortfall identified against assessment criteria S2, the establishment is advised to obtain the NHSBT's latest copy of the SAEARs reporting SOP (SOP3888/2) and incorporate this into its suite of procedural documentation and governance systems.

Concluding comments

There are a number of areas of practice that require improvement, including twelve minor shortfalls, ten of which are now considered to have been met. The HTA has given advice to the establishment with respect to procedural documentation, donor characterisation, temperature monitoring, live donor follow up and serious adverse event and reaction reporting.

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: 15 January 2019

Report returned with comments: 18 and 28 January 2019

Final report issued: 18 February 2019

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: 19 December 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.