Site visit audit report on compliance with HTA requirements

Oxford University Hospitals NHS Trust

HTA licensing number 40038

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.

1 – 3 February 2017

Summary of Audit findings

Oxford University Hospitals NHS Trust (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to temperature monitoring, procedural documentation and traceability systems.

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

The HTA's regulatory requirements

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

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

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

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

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

Licensable activities currently carried out by the establishment – Procurement activities

Organ type	Kidney	Pancreas	Liver	Adrenal gland	Small bowel and modified multivisceral	Composite-abdominal wall	Sentinel skin flaps
Adult living	DC, OC, P, T, R						
Adult deceased	OC, P, T, R	OC, P, T, R	OC, P, T, R	OC, P, T, R	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 currently carried out by the establishment – Transplant activities

Organ type	Kidney	Pancreas	Adrenal gland	Small bowel and modified multivisceral	Composite-abdominal wall	Sentinel skin flaps
Adult living	OC, P, T, I					
Adult deceased	OC, P, T, I	OC, P, T, I	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

The Oxford University Hospitals NHS Trust (the establishment) has been licensed by the HTA since December 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. Licensable activities are undertaken at the Churchill Hospital, Oxford where the establishment undertakes cadaveric donor kidney transplants, pancreas transplants, adrenal gland transplants, abdominal wall, sentinel skin flaps, living donor kidney transplants and intestinal transplants, including small bowel and modified multivisceral transplants. The establishment also participates in National Organ Retrieval Service (NORS) activity through which it retrieves kidneys, pancreases, livers, adrenal glands, abdominal wall, sentinel skin flaps and intestinal organs from deceased donors.

The establishment stores organ transport boxes, hypothermic perfusion devices, surgical retrieval kits, normothermic regional perfusion equipment and perfusion fluids in a dedicated storage room within the transplant centre's premises. There is an additional fridge within the establishment's theatres, which holds a smaller stock of perfusion fluids. The perfusion fluid fridge in theatres has its temperature monitored daily by the theatre staff as part of the daily critical equipment checks. However, the fridge used to store perfusion fluid in the storage room has its temperature monitored weekly by the Medical Technical Officers (MTOs) leading to a risk that, should the storage temperature deviate from the expected range, it may not be discovered immediately. Advice has been offered below regarding temperature monitoring of the perfusion fluid storage fridge (see advice item 1).

During the audit, a letter from the Director of Procurement was reviewed which confirmed that the Trust routinely purchases equipment that is CE marked which indicates that the equipment meets the requirements of the Medical Devices Regulations 2002. Where CE marked equipment is not available, appropriate waiver procedures are in place to assess these rare exceptions.

A review of accreditation certificates from the laboratories performing donor and organ characterisation assessments was also undertaken during the audit. All of the laboratories used by the establishment for organ and donor characterisation are accredited by the United Kingdom Accreditation Service (UKAS) and the appropriate accreditation confirmation for each laboratory was reviewed; these laboratories are Transplant Immunology and Immunogenetics, Department of Microbiology at John Radcliffe Hospital, Oxford Medical Genetics laboratory, Department of Haematology, and Oxford Histopathology and Cellular Pathology at the John Radcliffe Hospital. The audit team visited both the immunology and immunogenetics laboratory and the microbiology laboratory at John Radcliffe Hospital during the audit to review sample tracking and results reporting procedures. UKAS certification relating to the establishment's disinfection, assembly, packing, hydrogen peroxide and moist heat sterilisation of theatre trays, theatre packs and supplementary equipment was also reviewed. The sterilisation service was appropriately accredited to ISO9001, ISO13485:2003 and ISO13485:2012.

The establishment's staff are suitably qualified to undertake their roles. Records of staff appraisals showed that staff appraisals for staff working under the licence are within date with no reviews being overdue; appraisals help to monitor staff performance and to identify any training and development needs. Where appropriate, professional registration details are recorded and training records for the NORS team and recipient transplant coordinators were reviewed. All surgeons working within the NORS team must have completed on line learning and attended retrieval master class training. In addition, the establishment has developed a tabular list showing the various key activities undertaken as part of its transplant activity; the table includes the role title of the person authorised to undertake each of the various activities within the transplant unit and references under whose supervision they act.

Deceased Organ Transplants – Kidney, pancreas and adrenal gland

The adrenal gland has been added as an organ type to the licence and it is anticipated that it will follow the same cadaveric organ pathway as kidney/pancreas transplants however, at the time of the audit, no adrenal gland transplants had taken place. It is envisaged that adrenal gland transplants would happen simultaneously with a kidney/pancreas transplant.

At the time of being added to the recipient waiting list for kidney or pancreas transplant, potential recipients are seen by the specialist nurse and transplant surgeon. Discussions held with both clinicians cover the type of donor such as brain death (DBD) or circulatory death (DCD) and from which type of donor a potential recipient is willing to accept organs. Recently, during this meeting, the specialist nurses have started to discuss other donor factors and extended criteria organs with potential recipients who again, can detail which types of donors and what level of risk they would be willing to accept. The specialist nurses will review these decisions annually to determine if the potential recipient's wishes have changed. Should any donor or organ risk factors be identified at the time of an organ offer being received, the implanting surgeon will discuss these with the recipient prior to surgery and record their consent or objection within their clinical notes. The establishment reported that most patients wish to be considered for all organs at the time of listing and do not limit the type of organ that they would consider receiving.

When a donor organ for one of the establishment's potential recipients becomes available, the transplant recipient coordinator (TRC) receives a notification from the NHS Blood and transplant's (NHSBT) duty office. The notification can come via a direct telephone call, text or a telephone call via a dedicated number at the establishment's switchboard. The TRC then logs into the electronic offering system (EOS) and reviews the donor and organ characterisation information which they record using an organ offer form. The TRC contacts the implanting surgeon and relays the key characterisation information to the implanting surgeon, which is sufficient for the surgeon to make an initial decision regarding the suitability of the organ. Following their initial assessment, the implanting surgeon also logs onto to EOS to review the full donor and organ characterisation in more detail. The establishment stated that it would be unlikely for them to proceed without all of the required characterisation information being available.However, if there was an urgent clinical need, a risk benefit analysis would be undertaken, discussed with the recipient and recorded in the recipient's clinical notes.

Once the organ is accepted, the TRC liaises with the duty office and transplant teams at the establishment which includes the immunology lab. In most cases, a donor blood is requested prior to the organ's arrival so that a wet cross match can be performed. In cases where timings or logistics do not allow this to happen, the immunology laboratory advises the implanting surgeon on whether the intended recipient requires a wet cross match or if the team can proceed on a virtual cross match. The laboratory screens all potential recipients on the waiting list at three monthly intervals meaning that up to date recipient information is available at the time of an offer, should a virtual cross match be carried out. As potential recipients are called to inform them about an organ offer, they are asked about possible sensitising events. Even if a transplant proceeds on the basis of a virtual cross match, a wet cross match is performed following the transplant using organ donor tissue samples that accompany the donor organ.

The TRC maintains contact with the specialist nurse for organ donation (SNOD) at the donor hospital and receives updates regarding the donor organ such as anatomical details and estimated retrieval and arrival times. If there are any particular donor or organ issues such as an unusual donor anatomy, the TRC records the retrieving surgeon's contact details so that retrieving and implanting surgeon can discuss the organ and its characteristics in more detail.

Arrival of the donor organ (kidney, pancreas or adrenal gland) at the establishment is recorded in a log book, which includes arrival time, date, details of the courier and details of the person receiving the organ. The unopened organ box is placed into a locked fridge for secure storage until it is required in theatres. As the organ is collected and taken to theatres prior to implantation, the time and details of the person collecting the organ are recorded in the log book. In theatre, the implanting surgeon verifies that the organ box is intact, the paperwork with the organ matches the details of the organ that they are expecting and that the organ was suitably packaged to maintain the required storage conditions throughout its transport. Samples of the transport fluid surrounding the organ are also taken and sent for microbiological analysis the results of which may be used to attenuate the treatment of the recipient post transplant, depending on the findings. Should any contaminants be found in the transport fluid that affect the recipient's treatment, the implanting surgeon notifies the NHSBT duty office so that any other centres receiving organs from the same donor are aware of the findings. The implanting surgeon prepares the organ for implantation and can re-pack the organ and return it to the fridge for storage if there is an unexpected delay before the implantation commences. During the preparation of the organ, any unusual findings not noted during retrieval such as lesions on a kidney are investigated. The implanting surgeon takes a biopsy and sends it for histopathological analysis.

Prior to implanting the organ, the surgeon reviews the paperwork with the organ, the donor's HLA typing results and blood group along with the relevant recipient's identity and clinical details. Once satisfied that the organ is suitable for transplant, HLA types and blood groups for donor and recipient match and all identification details are correct, the implanting surgeon signs a dedicated form. The dedicated forms signed by the surgeons, 'surgeons copy of the donor HLA Typing and cross match report', are held within donor files maintained by the establishment.

With pancreas and simultaneous pancreas and kidney transplants the establishment, if retrieving the organ via their own NORS team, also retrieves a section of skin from the donors forearm if consent for this retrieval is in place. This skin is packed and transported in the same way as the organ and is transplanted onto the recipient's forearm during the implantation surgery. The full thickness skin graft is vascularised and used to alert the transplant team to early signs of organ rejection. This information is used to monitor the recipient's immunological reaction to the donor tissue and possibly to adjust the recipient's immunological suppression therapy to help prevent rejection of the graft. Consent for the transplant of these sentinel skin flaps is recorded in the recipient's clinical notes.

The establishment has amended its world health organisation (WHO) surgical safety checklist to include prompts for the surgical team to complete the required paperwork following implantation surgery. Theatre nurses add details of the perfusion fluid used prior to implantation of the organ on the HTA-B forms which are then completed and signed by the implanting surgeon. The TRC returns copies of the completed and signed HTA-B forms to NHSBT following the transplant surgery.

Deceased Organ Transplants – Intestinal and modified multivisceral

Potential recipients are referred to the establishment for intestinal organ transplants and if appropriate are added to the organ waiting list. The intestinal organ pathway is similar to that of kidney, pancreas and adrenal gland; organ offers are initially received by the TRC who logs into EOS and reviews the donor and organ characterisation information which is recorded onto an organ offer form. The TRC contacts the implanting surgeon and relays the key characterisation information to the implanting surgeon who makes an initial decision regarding the suitability of the organ/organs. If accepted, the TRC will liaise with the NHSBT duty office and the establishment's immunology laboratory to get a list of suitable recipients.

Potential recipients on the waiting list are screened by the immunology laboratory monthly however, a sample of donor blood is requested by the laboratory so that a wet cross match can be performed prior to transplant.

A retrieval team trained in retrieval of intestinal and modified multivisceral organs attends the donor hospital. The retrieving surgeon is in contact with the implanting surgeon during retrieval and once the donor organs have been examined by the retrieving surgeon, a retrieval to implanting surgeon discussion of their suitability takes place. The donor organ anatomy and any other information required by the implanting surgeon in order to ascertain the organ's suitability are relayed between the two surgeons. Should the organs be suitable, the recipient will be prepared for surgery which will commence prior to the organ's arrival at the establishment.

Since there is no organ specific HTA-A form for intestinal and modified multivisceral organ retrievals, the retrieving team record details of perfusion fluid used on a liver HTA-A form. Unlike kidneys and pancreases, intestinal and modified multivisceral organs are taken back to the establishment by the retrieval team using a dedicated intestinal organ transport box. The organs are taken directly to the theatre where the recipient surgery is being undertaken. Receipt of organs at the establishment is recorded in the organ register so that a record of arrival date and time is maintained. Through regular communication between the retrieval and implanting teams, the organs usually arrive at the time when they are needed for implantation.

During implantation, to facilitate closure of the surgical opening in the recipient, abdominal wall retrieved from the same donor as the intestinal/modified multivisceral organs is used during the implantation surgery. As with kidney/pancreas and pancreas transplants, a sentinel skin flap (described above) may also be grafted on to the recipient to act as an early indicator of rejection. Both the abdominal wall and sentinel skin flaps are full thickness and vascularised and consent is sought to both retrieve these and transplant them. HTA-B forms are completed for all organs implanted during the recipient surgery and are returned to NHSBT by the TRC.

Living Donor Kidney Transplants

Living donors may come forward to the establishment staff either as independent referrals or via family members attending nephrology clinics with renal patients. People asking about becoming a living donor are given living donor packs which include information abut being a living donor and a general health questionnaire.

Potential donors still wishing to become living donors after reviewing the information attend a clinic, clinic one, with the potential recipient to discuss living donation and transplant in more detail. The potential living donor is also seen independently of the recipient and a detailed medical history is taken along with general biochemistry bloods, bloods for cross matching and urine samples. During this individual consultation, paired and pooled donation is also discussed should the potential donor not be a match for the recipient. Finally, consent is sought to contact the potential donor's GP for a medical history. At the same time, potential donors are informed that that the results of tissue typing and blood group assessments may reveal the absence of a presumed genetic relationship. Potential donors are asked if they wish to be made aware of such findings or not. All interactions and characterisation assessments are recorded within a single chronologically organised 'Living Donor Pathway' document which is used by all clinicians during donor work up.

The results of the cross matching investigations are sent to the potential living donor(s). If the living donor is a suitable match for the recipient and if they wish to proceed, the living donors contact the establishment and are asked to attend clinic two. At clinic two, more bloods are

taken to confirm the tissue typing data and living donor's blood group. Additionally, ultrasound, x-ray and echo cardiogram assessments are undertaken. Living donors also go through a more detailed questionnaire with the living donor coordinators (LDCs). This questionnaire includes questions about the donor's behavioural and social history, including previous history of using intravenous drugs. Consent for donor serological screening for disease markers including human immunodeficiency virus (HIV), hepatitis B, hepatitis C and syphilis is also sought. During clinic two, the living donor also meets with the retrieval surgeon and nephrologist. The surgeon discusses the procedures related to being a living kidney donor and the risks associated with these. The nephrologist takes a full medical history including mental health history. The nephrologist may refer living donors to a psychologist for further evaluation if deemed necessary. Non-directed altruistic donors are always referred to a psychiatrist for evaluation prior to proceeding along the living donor work up pathway. The living donor is also informed about living with one kidney, once they have donated a kidney. Following clinic two, and if the nephrologist assess living donors as potentially suitable candidates, living donors are booked in for a computed tomography (CT) scan and glomerular filtration rate (GFR) assessments.

Results of living donor characterisation assessments are reviewed at multidisciplinary team (MDT) meetings where the living donor cases are presented. The MDT meeting includes a radiologist, nephrologist, surgeon and living donor coordinator. During the MDT the characterisation data is reviewed and any contraindications to donation looked for. If following the MDT all participants agree, the donor is signed off as a suitable donor and the decision is recorded within the living donor pathway document. The surgeon will determine if the donor's right or left kidney is most suitable for transplant.

If suitable to be a donor, the transplant is planned. Two weeks prior to the transplant surgery donors attend clinic three, a pre-assessment visit where the donor will see the surgeon, anaesthetist, pharmacist and the Independent Assessor. A final cross match is also undertaken to verify that the donor and recipient are still compatible. If a prolonged delay occurs in between the clinic three visit and the transplant, clinicians decide if a second pre-assessment visit is required prior to transplant.

Overseas living donors receive the living donor information pack and undergo some assessments such as BMI measurements, blood pressure, serology tests, tissue type analysis and ultrasound investigations in their home country. The tissue type analysis is sent to the establishment's immunology laboratory so that a virtual cross match can be performed against the intended recipient. If suitable and wishing to proceed, overseas living donors attend the establishment where all living donor characterisation assessments within the living donor pathway are undertaken prior to surgery.

Following surgery, donors are seen in recovery and again at six weeks post surgery by the retrieving surgeon. The LDC sees the donors on the ward shortly after surgery. Following the six week surgical consultation, living donors are scheduled for annual follow up assessments. The establishment maintains a database of living donors to help track them and record changes of address so that they can be contacted for their annual follow up. Overseas donors may return to the establishment or have follow up assessments in their home country; the establishment reported that often, if follow up assessments take place overseas, results are sent back to the establishment for review.

National Organ Retrieval Service (NORS) team

The establishment's National Organ Retrieval Service (NORS) team operate on a one week on/one week off duty rota in conjunction with a NORS team linked to another HTA licensed establishment. Following a mobilisation phone call from the NHSBT duty office received by pager or via a dedicated telephone number linked to the establishment's switchboard, the on-

call retrieval surgeon finds out the details of the retrieval location. The surgeon calls the SNOD at the donor centre to discuss the type of retrieval and what time the retrieval team should arrive. The establishment's medical technical officers (MTOs) organise the rest of the team. MTOs pack the necessary equipment using a checklist to help ensure that all necessary equipment is included. MTOs liaise with the SNODs at the donor centres and arrange the transport. Sterile kits are checked by scrub nurses who are part of the retrieval team.

Upon arrival at the recipient centre, retrieving surgeons meet with SNODs to handover the cases. During the handover, surgeons review the donor consent and donor characterisation information. A standardised NHSBT checklist is used for the team introduction and recording who is present at retrievals. In addition, the retrieval teams perform the WHO surgical safety checklist of the donor hospital prior to starting retrievals.

The establishment's NORS team has, in the last six months, started to undertake normothermic regional perfusion (NRP) of DCD donors prior to retrieval. There are various criteria to be met before NRP is undertaken, including time available within the donor centre's theatres and location of the donor hospital relative to the establishment. If NRP is to be undertaken, the retrieval team is expanded to include three surgeons, two MTOs and a scrub nurse. Equipment and preservation fluids are taken with the retrieval team and matched blood supplied by the donor hospital.

Following retrieval, the retrieval surgeons pack the organs in accordance with the national standards. SNODs label the transport boxes and ensure that the correct paperwork is present and that tissue samples have been included. HTA-A forms are completed by the retrieving surgeons and given to the SNODs for packing with the organs. For its own record, the establishment retains copies of all HTA-A forms completed by their retrieval team. On occasion, when the retrieval surgeon is continuing with the retrieval of organs and remains 'scrubbed in' but some organs with shorter ischaemic times are ready for transporting to their respective recipient centres, the HTA-A form is completed and signed on behalf of the surgeon by an MTO. On such occasions where a member of the retrieval team, other than the retrieving surgeon, completes and signs the form, all information contained within the form has been reviewed by the retrieving surgeon prior to the form being signed and leaving the theatre. Additionally, the procedure describing the completion and signing of the form by the MTO and review of the form's contents by the retrieving surgeon has been included within the establishment's operating procedures.

Other Organ types

During the audit, discussions with the establishment took place to consider the new organ types recently added to the licence. Activity with these new organ types has not yet started and is not planned to commence until later in 2017 or 2018. Although some preliminary documentation was reviewed during the audit, procedures are at an early stage and have not yet been modified to reflect the proposed practices to be undertaken at the establishment. As a result, the audit team advised the establishment that prior to any activity commencing with these new organ types, another visit from the HTA would be necessary so that up to date documents could be reviewed and further discussions around the transplants and the various pathways can be undertaken.

Document review

The establishment has adopted a range of the National Operating Procedures (NOPs) which describe how licensable activities are undertaken. The NOPs have been adapted so that the establishment's specific procedures and staff responsible for carrying these out are detailed within the procedures. In addition to the NOPs, the establishment has stand alone documented procedures for some activities, for example, the retrieval and packing of sentinel skin flaps.

During the audit, several reviews of recipient and associated donor records were conducted as detailed below:

Three sets of clinical notes for intestinal organ recipients were reviewed. In all three cases records of donor characterisation, copies of the HTA-B forms, recipient consent forms and traceability from donor to recipient were seen.

Three sets of living kidney donor clinical notes were reviewed with one donor being a direct living donor transplant, the second donor being part of a paired transplant and the third being a non-directed altruistic donor. In all three cases, the donor behavioural questionnaire, consent to donation, consent to the surgery, details of perfusion fluids used and raw data relating to donor characterisation such as serology test results, urinalysis and ECG traces were present. Additionally, records of the sign off as being a suitable living donor at the MDT were present. For the direct living donation, the reciprocal recipient notes were also seen and cross checked for surgery dates and times. No recipient results were seen for the paired and altruistic donors as these organs were sent outside of the establishment for implantation at other HTA licensed establishments.

Finally, five sets of deceased kidney recipient clinical notes, and the reciprocal donor information maintained by the establishment separately to the recipient's notes were reviewed. In each case, HTA-A and HTA-B forms were present and included details of perfusion fluid used. Donor and recipient blood groups and HLA types were also present. During the audit it was found that there was an inconsistent approach to the use of the 'surgeons copy of the Donor HLA Typing and cross match report' form used to record that blood groups, HLA types, donor characterisation and recipient identification have been verified by the surgeon. Advice has been offered below (see advice item 3).

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

Advice

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

No.	Assessment Criterion	Advice
1.	P1	The fridge used to store perfusion fluid in the establishment's storage room has its temperature monitored weekly by the Medical Technical Officers (MTOs). Should the storage temperature deviate from the expected range, it may not be discovered immediately if the deviation occurs out of hours or in between temperature measurements.

No.	Assessment Criterion	Advice
		The establishment is advised to consider using a maximum/minimum thermometer to record the storage fridge's temperature which could be reviewed daily and prior to any perfusion fluid being removed from storage. This would allow any temperature deviations to be detected, even if the operating temperature of the fridge has returned to normal following a deviation out of hours.
2.	TP1	The establishment has amended NOP003 to describe the process for packing kidneys, pancreases, livers and hearts for valve retrieval. Separate procedures relating to abdominal wall and sentinel skin flaps include instructions for appropriate packing. Although always surgically lead, the packing of intestinal or modified multivisceral organs is not described in either a stand alone procedure or NOP003. The establishment is advised to document the packing procedure for intestinal or modified multivisceral organs either within NOP003 or a stand alone procedure relating to their retrieval.
3.	I1	Prior to implanting the organ, the surgeon reviews the paperwork with the organ, the donor's HLA typing results and blood group along with the relevant recipient's identity and clinical details. Once satisfied that the organ is suitable for implantation, HLA types and blood groups for donor and recipient match and all identification details are correct, the implanting surgeon signs a dedicated form, 'surgeons copy of the donor HLA Typing and cross match report' to record that blood groups, HLA types, donor characterisation and recipient identification have been verified. During the audit, five sets of donor and recipient files relating to deceased kidney donor transplants were reviewed.The review included the 'surgeons copy of the donor HLA Typing and cross match report' form. One instance of the form was correctly completed, three had not been fully completed and a fifth was left blank. The establishment is advised to re-evaluate the use of this form to record that these verification steps have been undertaken as there is an inconsistent approach to its completion. The establishment may wish to liaise with the surgical team to discuss the use of this form and the best way to use it in the future. Additionally, the establishment may wish to consider incorporating some elements of the form, such as verifying the surgeon has reviewed the relevant donor characterisation information into the establishment's modified WHO surgical safety checklist.
4.	TC1	During the audit it was found that in living kidney donations, the HTA-A form number (donor details form) is not being added to the HTA-B form (recipient details form). This was due to the living donor team being separate from the recipient team and each team returning their respective forms to NHSBT independently. The establishment is advised to develop a new procedure through which the HTA-A form number can be passed on to the recipient team and recorded on the respective HTA-B form. Once developed, this new procedure should be documented within the establishment's suite of procedural documents.
5.	TC3	The establishment records the time of arrival for kidneys and pancreases using an organ log book located near to the fridge where the organ is stored

No.	Assessment Criterion	Advice
		prior to transfer to theatres for implantation. Following a change to the HTA-B form, time of receipt for an organ is now recorded on this form. The establishment is advised to consider whether, following the change to the HTA-B form, the current process whereby a member of staff must return to the organ storage fridge on the renal ward to review the log book and find the arrival time remains appropriate. The establishment may wish to consider developing an organ receipt record which could be transferred to theatres with the organ and post transplant, filed with other donor related paperwork in the establishment's donor files.
6.	General	During the audit, transplantation of new organ types was discussed although activity with these has not yet started and is not planned to commence until later in 2017 or 2018. Related procedural documentation is at an early stage and has not yet been finalised to reflect the proposed practices to be undertaken and who will be undertaking them at the establishment. The establishment is advised that prior to any activity commencing with new organ types, the HTA will need to re-visit the establishment so that the finalised procedural documentation can be reviewed and further discussions around the new transplants and the various organ pathways can be undertaken. The establishment should alert the HTA once the procedural documentation is completed and it is envisaged that these transplant may begin in the near future.

Concluding comments

Good practice was also observed during the audit, examples of which include:

Following the previous audit in 2013, the establishment has redesigned the living kidney donor pathway documentation. All living donor characterisation assessments and raw data such as ECGs, urinalysis, routine bloods and virology serological screens are transcribed into a single donor pathway document. In addition, the establishment has adopted standardised system of filing within the live donor records meaning that the pathway document and hard copies of accompanying raw data should be filled in the same order within all donor files. In doing this, the establishment has given consideration to which data various clinicians and medics often seek; the standardised filing format allows clinical and medical staff to be able to quickly locate relevant information that they are seeking within the donor file. Finally, the living donor pathway document includes checklists at the end of each major milestone of the donor work up. These checklists help the living donor coordinators to verify that all necessary assessments or reviews by clinicians have been carried out.

The establishment's documentation continues to develop. Procedural documents have been updated to reflect how procedures are undertaken at the establishment and who undertakes them. Where a national operating procedure does not cover a specific activity, for example, retrieval and transport of sentinel skin flaps, stand alone documentation has been put in place.

The HTA has given advice to the establishment with respect to temperature monitoring, procedural documentation and traceability systems.

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

Report sent for factual accuracy: 3 March 2017

Report returned with comments: 10 March 2017

Final report issued: 5 April 2017

Appendix: Classification of the level of shortfall

Where the HTA determines that an assessment criterion is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an assessment criterion, it works on the premise that a lack of evidence indicates a shortfall.
The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.
Or
A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.
A shortfall in the carrying out of licensable activities which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient
or
A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;
or
A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;
or
A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final audit report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next audit.
In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final audit report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final audit report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.
Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit audit.

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