Site visit audit report on compliance with HTA requirements

Cardiff and Vale University Health Board

HTA licensing number 40037

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.

5-6 December 2016

Summary of Audit findings

Cardiff and Vale University Health Board (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to documentation of procedures, living donor discharge and adverse incident reporting and recording.

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

The HTA's regulatory requirements

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

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

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

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

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

Licensable activities carried out by the establishment – Procurement activities

Organ type	Kidney	Pancreas	Liver
Adult Deceased	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**
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	Kidney	Pancreas
Adult	**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 Cardiff and Vale University Health Board (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 University Hospital Wales where the establishment undertakes cadaveric donor kidney and pancreas transplants in addition to living donor kidney transplants. The establishment also participates in National Organ Retrieval Service (NORS) activity through which it retrieves kidneys, pancreases and livers from deceased donors.

The establishment stores organ transport boxes, surgical retrieval kits and perfusion fluids in the 'retrieval room' which is a dedicated secure room on the renal ward. This room is also used for the storage of cadaveric organs received by the establishment prior to their transfer to theatres for implantation. Perfusion fluid, delivered by the hospital's pharmacy department, is stored in a dedicated fridge within the retrieval room.

Staff undertake regular checks of the temperature of the fridge to ensure it has been operating at the expected temperature. Staff also check the temperature when removing fluid from the fridge. During the audit, in response to advice given by the audit team, the establishment created a temperature log and intends to record the fridge temperature daily so that an auditable record of historical fridge temperatures is available to staff if needed.

During the audit the accreditation certificates for the laboratories and other services were reviewed. Clinical Pathology Accreditation certification was reviewed for the Histocompatibility and Immunogenetics (H&I) and microbiology laboratories. The pathology laboratory is accredited by the United Kingdom Accreditation Service and the appropriate accreditation confirmation was reviewed. Relevant certification relating to the sterilisation service used by the hospital's sterilisation and decontamination unit (HSDU) was reviewed and found to be appropriate. The HSDU also has systems in place to track equipment through the decontamination and sterilisation process. The Trust's Medical Devices policy mandates that all equipment purchased by the Trust must be CE marked which indicates that it complies with the requirements of the Medical Devices Regulations 2002.

Nursing and Medical staff at the establishment undergo induction upon joining the establishment and also receive regular mandatory training such as manual handling and fire training. Training relating to their role within the transplant unit is undertaken and recorded. The establishment has developed a new system of competency assessments; the newly appointed Divisional Development Lead is in the process of reviewing the competencies and checking that they remain appropriate. Nursing and Medical staff also receive annual appraisals as part of their on-going development. The surgical transplant lead observes new members of the surgical team when they undertake organ retrievals. The new team members are assessed and receive a certificate once they are assessed as competent.

Deceased Organ Transplants

The initial organ offer from the NHSBT Duty Office is received by the on-call recipient coordinator. The recipient coordinator logs onto NHSBT's Electronic Offering System (EOS) and records key organ and donor characterisation information on an Organ Offer form. This information is reviewed by the implanting surgeon who can make an initial decision to accept the organ. The Organ Offer form continues to be used to record further information relating to the offer in addition to recording interactions between the recipient coordinator and other staff or organisations, for example, NHSBT Duty Office. If the organ offer is initially accepted by the surgeon, the recipient coordinator liaises with the testing laboratory, NHSBT Duty Office and the potential recipient.

At the time of joining the waiting list, the surgeon and clinical nurse specialist discuss extended criteria organs with potential recipients to explain the various risks and benefits involved in receiving such an organ. The recipient is able to state what type of extended criteria organ they would be willing to accept and this is recorded in their clinical notes and reviewed when an organ offer is received. The recipient's choices regarding extended criteria organ offers are reviewed annually at one of their regular clinic appointments. The establishment has also developed an internal protocol when deciding whether or not to accept organs which are assessed to represent an increased risk of transmission of donor disease. If a surgeon decides that the donor or organ characterisation information indicates that an offered organ may pose an increased risk of transmission of donor disease, they consult a second clinician for another opinion on the suitability of the organ, for transplantation into the recipient.

Recipients on the waiting list for an organ are tissue typed by an H&I laboratory every three months. In many cases, this enables an implanting surgeon to accept the offer of an organ based on a virtual cross match using the previous typing results. Potential recipients are asked about any sensitising events they may have experienced, such as blood transfusions, at the time they are contacted regarding the organ offer. The H&I laboratory advises the surgeon on whether a recipient is suitable for virtual cross matching or whether a wet cross match is needed, in addition to advising on the level of match/mismatch between the donor organ and the recipient at the time of the organ offer.

The implanting surgeon logs onto EOS to review the donor and organ characterisation information and signs and dates the establishment's 'Kidney/Pancreas Received for Transplantation' form (Transplant form) to record that they have reviewed EOS. This form accompanies the organ from the time the organ arrives at the hospital until the organ is implanted. The form is used to record various time points and information relating to the transplant.

Upon the organ's arrival at the establishment, the recipient coordinator greets the transport driver and records the driver's details and time of arrival in a diary located within the retrieval room on the transplant ward. In addition, the recipient coordinator checks the condition of the transport box, ice level, paperwork accompanying the organ and records the time of arrival, organ type, intended recipient name and hospital number. These checks, including checks on the ice level, is recorded on the Transplant form. If the transport box does not have sufficient ice, the recipient coordinator tops up the ice level of the box and records this on the transplant form. The transplant form is also used to record two hourly checks on the ice level, which take place before the organ goes into theatres. This includes whether any additional ice has been added, and by whom. In the case of kidney transplants, the implanting surgeon may place the organ onto a hypothermic perfusion device until it is ready for transplant, however the establishment reported that use of this device has decreased in recent years and in most cases, the kidney remains in the transport box.

If a wet cross match is required prior to transplant, the donor organ will be routed via the nearby H&I laboratory so that the cross match material can be removed and the typing process started. If this is the case, the H&I laboratory staff record the security tag number on the transport box before they open it and also the number of the new security tag which is placed onto the box prior to it continuing on its journey to the establishment. During the opening of the transport box, the transport driver accompanies the organ and observes the removal of the tissue typing material, maintaining a chain of custody of the organ. Where a wet cross match is not required prior to transplant, the organ arrives at the establishment and the tissue typing material is removed by the recipient coordinator and given to the driver who takes it to the H&I laboratory. Whether the organ travels via the H&I laboratory or comes directly to the establishment, details of the tissue typing material and whether it was removed at the laboratory or at the establishment are recorded on the Transplant form.

Should any of the required donor or organ characterisation information be unavailable at the time of the transplant, the implanting surgeon would undertake a risk benefit analysis and discuss this with the recipient prior to surgery. Such discussions are recorded within the recipient's clinical notes.

Prior to implantation, a surgical registrar will collect the organ from the transplant ward and take it to theatre where the organ is prepared for implantation and re-perfused. The implanting surgeon is present in theatre and verifies the conditions of preservation as the organ is removed from the transport box. Details of who collected the organ from the ward including the time it is collected and time it arrives in theatre are recorded on the Transplant form. Additionally, details of the surgeon who prepares the organ for transplant is also recorded along with details of the perfusion fluid used. During the preparation of the organ, if the surgeon finds anything suspicious, for example a nodule on a kidney, a biopsy is taken and sent for histological analysis. Should any significant organ damage that may have occurred during retrieval be found, the implanting surgeon will liaise directly with the retrieving surgeon once the NHSBT Duty Office has been informed.

The establishment's Clinical Nurse Specialist (CNS) for transplant uses the information from the Transplant form to complete the HTA-B form which is checked and signed by the implanting surgeon prior to being returned electronically via secure email to NHSBT. Copies of the HTA-A, HTA-B, organ offer record form and Transplant form are filed within a dedicated donor file which is held securely within the CNS' office.

Living Kidney Transplants

Potential living kidney donors are given an initial general health questionnaire which also includes consent for the establishment to contact their General Practitioner (GP) for further medical information. The GP is then sent a medical history questionnaire for the potential living donor which they return to the establishment.

Potential donors are seen by the Living Donor Coordinator in clinic where further discussions around becoming a living donor take place and the potential donor is asked if they wish to proceed with the work up. If so, tests to establish their blood group and tissue type are undertaken. Should the potential donor be suitable, they are seen again by the Living Donor Coordinator at a further clinic.

At this further clinic, donor and organ characterisation tests are recorded in a bespoke Living Kidney Donor Pathway document. Records include laboratory test results in addition to medical and social history questions which are in accordance with the mandatory donor characterisation information requirements under the Regulations. Donor and organ characterisation tests are reviewed by a nephrologist and surgeon. The pathway document has a dedicated section which is used to record that these reviews have been undertaken. The pathway document also captures the nephrologist's and surgeon's decision about donor suitability. Once the characterisation assessments have been reviewed, the donor is discussed at an MDT meeting with a clinical nurse specialist, nephrologist, surgeon and, if required, a psychologist. The MDT is where the final decision about the suitability of the donor is made and the results of this meeting are also recorded in the pathway document. Living donors are seen again at a clinic around thirteen days prior to surgery when further typing samples, virology testing samples and routine bloods are taken. Donors are admitted to hospital the night before surgery which is when consent for the donation is sought and recorded in a hospital 'consent for treatment and examination' form. In addition, the donor's wishes relating to the fate of the organ if for some reason, it cannot be implanted into the intended recipient are sought; options include implanting the organ back into the donor, giving the organ to an alternative recipient, sending the organ for research or disposal. The

establishment uses a World Health Organisation Surgical Safety Checklist prior to start of surgery during which the donor consent and donor identity is re-confirmed.

Following the retrieval surgery the HTA-A form is completed by the living donor coordinator, signed by the surgeon and sent electronically to NHSBT. Following their surgery the donor is seen on the ward by the ward consultant. The donor is seen by the surgeon ten to fourteen days after surgery and then by a nephrologist three months post surgery before starting annual post donation reviews. Post transplant, the establishment contacts living donors by letter and telephone in order to invite them back for their annual review.

Deceased Organ Retrieval

The establishment's National Organ Retrieval Service (NORS) team operate within their region one week in three with the other weeks covered by a NORS team linked to another HTA licensed establishment. Since the previous audit, the NORS team now operates as a stand alone team with the establishment providing surgical retrieval kits, transport boxes, scrub and surgical personnel. The establishment does not have its own contract with the transport provider which is instead provided by NHSBT who are also responsible for arranging onward transport for retrieved organs to the relevant transplant centre.

When mobilised to a retrieval, the scrub nurse completes a donor form which is a bespoke document used at the establishment to record the donor number and other relevant donor details. The lead surgeon uses the donor number to review donor details in EOS such as age, date of death, medical history. The donor form is signed by the retrieving surgeon to record that they have reviewed EOS. Details of donor consent are also reviewed prior to retrieval and are provided by the Specialist Nurse for Organ Donation (SNOD) who attends the retrieval.

Following the retrieval, the organ specific forms are completed by the lead surgeon and returned to NHSBT by the SNOD. Organs are packed by the surgical and scrub team and are placed into the transport boxes by the SNOD who also labels the boxes with the required details. The establishment may also remove samples from the donor and retrieved organs for a national research project providing that this activity has been consented to. The SNOD provides the retrieval team with copies of the research consent. The lead surgeon has received training relating to the removal of samples for the project with their competency being recorded in their log book. The NORS team work to the national organ retrieval protocol and national research sample protocol.

Document review

The establishment has adopted a range of the National Operating Procedures (NOPs) which describe how licensable activities are undertaken. The establishment has not customised each of the NOPs to match local procedures. However, the NOPs are supported by a range of bespoke documents created by staff at the establishment. These supporting documents include 'How to' flow diagrams setting out the establishment's processes and bespoke record keeping forms such as the 'Kidney/Pancreas received for Transplant' form, the 'Living Kidney Donor Pathway' document, the 'Organ Offer' record document and the 'Donor Details' form. Additional internal documentation at the establishment such as the Medical Devices Policy also support the licensable activity. The establishment also uses documentation that has been issued by NHSBT and which describe national procedures such as organ retrieval and adverse event or reaction reporting.

Audit

A review of two sets of living kidney donor notes were undertaken during the audit. Both contained copies of the Living Kidney Donor Pathway document which recorded the mandatory virology and other donor/organ characterisation tests in addition to the MDT discussions relating to the donors. No anomalies were found during the audit.

A review of three sets of clinical notes and the associated donor files from deceased organ recipients was also undertaken. Records of consent to being registered on the transplant list, copies of the HTA-A and HTA-B forms, details of perfusion fluids used, consent to transplant, copies of EOS information, the in-house offer form and the Kidney/Pancreas Received for Transplant form were reviewed and were present as appropriate in all three cases.

In all three cases, records of a risk benefit conversations relating to tissue type mismatches or risks of malignancy transmission were present within the notes evidencing that the implanting surgeon had held the relevant discussions with the recipients prior to implantation.

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.	CT4	Although the establishment has adopted NOP006, which includes the requirement to maintain transplant related records for 30 years, the establishment also follows an internal policy. The internal records management policy refers to the Records Management Code of Practice 2006 which although not formally adopted in Wales, is used as guidance. The transplant service lead confirmed that national guidance is followed and all transplant related records are maintained for 30 years. The establishment is advised to develop a bespoke policy for the transplant unit or amend an existing procedure to reference Annex D1: Health Records Retention Schedule which stipulates that all transplant related documents are maintained for 30 years.
2.	R4	The establishment follows up living donors at three months post surgery, 12 months and then annually. Upon discharge of a living donor, a letter is sent to the donor's GP. The establishment is advised to amend the content of this discharge letter to include a reminder to the GP that should the living donor present with any medical conditions which may have an impact for an organ recipient, that the establishment should be contacted immediately so that the recipient can be reviewed. This is important as the GP will potentially see the donor more frequently than the establishment, facilitating earlier detection of such medical conditions. 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. The feedback to the establishment

No.	Assessment Criterion	Advice
		regarding relevant medical conditions about which the recipient would have no awareness, is important so that the recipient can be appropriately followed up.
3.	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). The reason being that the two teams, donor and recipient, each complete and return their relevant forms separately to NHSBT. The establishment is advised to develop and document 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.
4.	TC3	The establishment is advised to amend the in-house procedural document 'TC1, 2 & 3 Traceability' so that it includes details of the 'Kidney/Pancreas Received for Transplant' form and states that this form will be retained, along with other transplant related documentation for 30 years.
5.	S1	Adverse events and reactions are reported to NHSBT by the person associated to the event, who then receives follow-up and details of corrective actions directly once the investigation has been completed. It is not always straight forward to find details of the incident, reaction or follow-up/corrective actions if the person searching for these is not the reporter of the incident. The establishment is advised that the Clinical Nurse Specialist for transplant maintains a record of all events or reactions that are reported to NHSBT and copies of any follow-up/corrective actions following the conclusion of the investigation. These copies could then be filed in the transplant office and be available for review by establishment staff which could form a valuable learning tool for establishment staff not involved in the incident.
6.	S3	The establishment works closely with all of the laboratories which undertake donor and organ characterisation tests. The HTA team was informed that the laboratories would notify the establishment of any adverse events relating to testing, should they occur. The establishment is advised to confirm in writing with the leads in the relevant laboratories that the establishment must be notified of any adverse events relating to samples from the transplant unit.
7.	N/A	The establishment has started to produce a number of in-house procedural documents and record forms to support the transplant process. The establishment is advised to continue with the development of its bespoke procedural documentation while ensuring that all mandatory aspects of the NOPs are included within the new documents. These in house documents describe the establishment's own procedures and detail the people carrying them out, helping to augment the use of bespoke record keeping forms used throughout the transplant unit.

Concluding comments

There were a number of good practices observed during the audit. Examples of these include:-

- The in-house designed Organ for Transplant form which is used to record critical

information relating to the organ such as its arrival time at the establishment, perfusion fluid used and the monitoring of ice levels.

- The donor files where copies of EOS information, donor offer form, copies of HTA-A and HTA-B form and other transplant associated documentation is stored have a standardised filing format meaning that the documents are always filed in the same order within each donor file. This facilitates quick access to the relevant document should a clinician be required to review any of the information.

The HTA has given advice to the establishment with respect to procedural documentation, living donor discharge and adverse incident reporting and recording.

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

Report sent for factual accuracy: 3 January 2017

Report returned with comments: 16 January 2017

Final report issued: 7 February 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.

Compliance with HTA assessment criteria

Donor Characterisation and Organ Characterisation
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.
CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.

Retrieval of Organs for transplantation
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.
Organ preservation
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.
Making arrangements to transport an organ
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP2) The organ shipping container is suitable for transport of the specified organ.
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.
Implantation
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.

I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.
Traceability – (*these criteria apply to all licensed activities*)
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.
Serious adverse events and adverse reactions (SAEARs) – (*these criteria apply to all licensed activities*)
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.
General – (*these criteria apply to all licensed activities*)
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.
GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.