Site visit audit report on compliance with HTA requirements

Barts Health NHS Trust

HTA licensing number 40052

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

26 July 2017

Summary of Audit findings

Although the HTA found that Barts Heath NHS Trust (the establishment) had met the most of the assessment criteria, seven shortfalls were found. The shortfalls related to several documented procedures, formal training of locum on-call surgical transplant registrars who receive offers of kidneys, checks carried out on the integrity of the kidney box, and levels of ice within the box, and collecting information from living donors to allow assessment of the risk of transmissible infections.

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

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs

Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

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

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

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

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

Licensable activities carried out by the establishment – Procurement activities

Donor	Organ type	Activity
Adult – living	**Kidney**	**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

Recipient	Organ type	Activity
Adult	**Kidney**	**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

Barts Health NHS Trust has been licensed by the HTA since August 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. Licensable activities are undertaken at Royal London Hospital (RLH) which provides transplant services to an ethnically diverse population in East London.

The establishment undertakes transplants of kidneys from living and deceased donors. In 2016, the establishment transplanted 148 kidneys – 33 from living donors and 117 from deceased donors. The Transplant and ACcess (TRAC) team consisting of consultant transplant surgeons, physicians and nephrologists are responsible for the care of all transplant patients.

Donor testing is undertaken by the Virology/Microbiology laboratory which has Clinical Pathology Accreditation (CPA) and provides serology and molecular biology testing services. The Clinical transplantation laboratory is responsible for donor and recipient tissue typing, antibody screening services and cross matching. The laboratory has CPA and European Federation for Immunogenetics accreditation. The laboratory recently implemented the use of lymphocytes purified from the peripheral blood of deceased donors for pre-transplant cross matching. This new procedure reduces the time required to confirm the suitability of the offered kidney and helps to minimise the cold ischaemic time. Both laboratories are based at the RLH site.

Staff use a system of electronic records to store patient information which includes medical history, results from investigations, outcomes of multidisciplinary team meetings (MDT) and letters sent to patients, donors and their GPs. The Trust's computer network was severely disrupted during the cyber attack which targeted several NHS Trusts on 12 May 2017. Clinicians had to rely on paper records as they were unable to access electronic records. The HTA team was informed that staff were in the process of converting paper records made during this period into electronic records.

Deceased Kidney Transplants

The on-call surgical registrar receives the offer of a kidney from NHSBT Duty Office. The Registrar reviews the NHSBT Electronic Offering System (EOS) mobile version and contacts the on call surgeon to discuss the suitability of the donor, the donated kidney and the recipient. NHSBT Duty Office updates the surgical registrar about amendments to EOS, transport arrangements, test results, or pending test results, and any information which could have an impact on the suitability of the donor. There is no system in place to record key information in relation to kidney offers (see shortfall below).

Once the surgeon accepts the offer, the surgical registrar informs the tissue typing laboratory to let them know when to expect peripheral blood samples for tissue typing. The surgical registrar also contacts the renal registrar on the ward and theatre staff to ensure that they make arrangements for the transplant. Handover meetings take place at 8.30am each morning, when the on-call surgical registrar transfers information to the rest of the team. Core Donor Data is printed off from EOS and taken to this meeting.

The team holds regular MDT meetings before potential recipients can be listed for a transplant. Potential recipients are informed that well matched donors could include extended-criteria donors and high risk donors when they are listed for transplant. A waiting list co-ordinator was recently appointed and is responsible for bringing cases to the meeting. Patients on the kidney waiting list are Human Leukocyte Antigen (HLA) typed every three months, as they could have been exposed to recent sensitising events. The laboratory archives plasma samples which are stored on-site.

The nephrologist holds discussions with the recipient and if possible with the recipient's family if there are any concerns around the function of the offered kidney which include donor factors such as travel to countries with high infection risk, co-morbid pathologies, mismatch in the donor-recipient ages and high immunological risk. Discussions may also be held with the on-call microbiologist. All discussions are documented in the patients notes.

Perfusion fluid is stored in a dedicated fridge next to the transplant theatres on level 4 of the hospital. The HTA audit team did not enter the theatre suite, but was assured by the establishment that a senior nurse is responsible for checking the storage temperature and monitoring the stock levels (see advice item 3).

The NHSBT contracted courier brings the kidney boxes containing kidneys to the reception at 'Nursing station 9F'. The Nurse in charge receives the box, signs to acknowledge receipt and places it in the secure Drug Prep Room. The nurse informs the surgical registrar on the ward who is responsible for checking the ice level within the box. The surgical registrar removes the spleen, lymph nodes and donor blood samples and places them in a fridge located in the room and makes arrangements to send them away for cross matching. The establishment has implemented a 'Deceased Donor Kidney Pathway' form which should be used to record the time of arrival of the kidney, the level of ice and movement of the kidney from receipt at the hospital until transplantation. The HTA team noted that staff do not always complete the form (see shortfall below). The Deceased Donor Kidney Pathway form is used to record traceability of any organs which are sent away to other centres such as time and destination of the organ and the name of the courier who collected the organ.

The kidney box is moved to the ante-room of the transplant theatres in Level 4 where backbenching by surgeons takes place before the transplant. The implanting surgeon samples around 20ml of the transport fluid and sends it away to the laboratory for testing for microbial contamination. The establishment discontinued machine perfusion of kidneys from deceased donors in 2016. Surgeons intend to re-commence this practice in a few months after the perfusion devices have been serviced (see advice item 1).

The World Health Organisation (WHO) checklist is followed and the surgeon reviews the most up to date version of EOS before he/she proceeds with the transplant. Details about the condition of the received organ, perfusion fluids used, if the organ was machine perfused and other details are recorded on the HTA B form. Completed HTA B forms are scanned and sent to the NHSBT Duty Office (see shortfall below).

Living Donation

The establishment retrieves kidneys from living donors for adult and paediatric recipients. Around 30% of donors come from outside the UK. All clinical tests are repeated once they arrive in the UK. NHSBT is responsible for transporting the kidneys which are donated under the paired/pooled programme to the relevant transplant centres.

Potential kidney donors are provided with a booklet/DVD which explains kidney donation. The establishment tries to ensure that donor work-up can take place at a hospital located close to where the donor lives. The establishment's 'Living Donor Work up pathway' leaflet provides details which cover appointments with the nephrologist and the surgeon. In all cases the final stages of donor work up take place at RLH. The living kidney donor MDT is held every week and is attended by surgeons, nephrologists and staff from the Clinical Transplant Laboratory. Decisions made at the meetings are documented in the electronic patient records.

Donors are not asked to provide information about recent travel to countries where they could have been exposed to high risk of infection, either during the early stages of donor evaluation or closer to the time of donation (see shortfall below). Formal consent for the removal of a kidney is sought from the donor once a detailed medical evaluation takes place and HTA approval is obtained.

Mandatory virology tests are repeated two weeks before donation. The date of surgery is scheduled, and donors and recipients are admitted into the hospital. Donors are re-consented and checks carried out on the identity of the donor before the kidney is retrieved.

Once donation has taken place, discharge letters are sent to the donor's General Practitioner or in the case of donors from overseas, to the referral centre overseas, (see Advice item 2). Regular annual follow up of donors takes place. In the case of overseas donors they are advised to attend an annual follow up in their home country.

Incident reporting

Senior staff are aware of the requirement to report incidents directly to NHSBT electronically and the Trust. There is no formal operating procedure for reporting incidents (see shortfall below). The HTA team was informed that incidents such as organ damage are only reported if the kidney cannot be transplanted (see advice item 4). Any contamination detected in organ transport media is reported to NHSBT.

Document Review

A document review was carried out during the audit. Training records and recent core competencies assessments for nursing staff were reviewed.

Several trust documents including 'TRAC (TR and ACcess) team working', 'Living donor work up pathway', 'Live donor MDT decision proforma for communicating with this and other units', 'Pre-assessment and listing', 'Patient information and 1st Consent', 'Information and risks', 'Organ acceptance and consent to kidney transplant', 'Transplant discharge clinic', 'Reporting of complications, M&M, annual & for cause audit, NHSBT reporting' & 'Peer review in the Renal transplant service' were reviewed. The majority of these documents were issued in October 2015 and all were within the respective review dates.

Electronic notes, and paper notes relating to two deceased donor kidney transplants and two living donor/recipient kidney transplants were reviewed. Records of consent, mandatory test results, donor assessments, and WHO checklists detailing checks undertaken before operations and operation notes, as applicable, were reviewed. In many cases HTA A and HTA B forms, could not be located. The 'Deceased Donor Kidney Pathway' form could not be located or was incompletely filled (see shortfall below). Test certificates relating to washer disinfectors and sterilisers used by the Sterile Services Department at RLH to disinfect and sterilise surgical instruments were reviewed.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive. **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.	The establishment does not seek information from living donors about recent travel history to areas of high infection risk, in order to assess the possible risk of transmitting infections to the recipient. This information will inform the need to test for infectious diseases in addition to mandatory testing for HIV, HBV and HCV. Information on current and past IV drug use is not recorded. These requirements are stated in Part A (minimum data set) of the Annex to the Directive, paragraphs 32 and 79 of the HTA Framework document – Quality and Safety of Organs intended for Transplantation updated November 2016.	**Minor**
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.	Barts Health NHS Trust Corporate Policy Records Retention and Disposal states that donor records (blood and tissue) will be kept for 30 years post transplant (page 40). However the Policy states that records relating to donor and recipient sera will only be kept for 11 years post transplant (page 47) (see advice item 5) This policy was approved in November 2012 with a three year review date. It is not clear if this document has been reviewed since its approval in 2012.	**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.	There is no operating procedure or proforma in place to ensure that the on-call surgical registrar provides all relevant information relating to the organ and the deceased donor to the surgeon and other key members of the team. A proforma will help to remind the surgical registrar to contact key staff within RLH, record tests for which results are pending and ensure that accurate and complete information is transferred to the surgeon and other key members of the team.	**Minor**

Assessment Criteria	Audit findings	Level of Shortfall
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.	Kidneys from living donors including paired/ pooled and non-directed altruistic donors, and kidneys from deceased donors are occasionally sent to other centres. There is no formal procedure which fully describes how to pack organs which are sent to other recipient centres for implantation. In the absence of a formal procedure, there is a risk that transplants at other centres can be delayed if kidneys from deceased donors are not packed in accordance with the latest guidance issued by NHSBT, and all material required for cross matching such as blood samples and/or spleen are not placed in the kidney box (see advice item 5).	**Minor**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	Staff do not routinely complete the 'Deceased Donor Kidney Pathway' form and so it is not possible to verify the conditions of preservation and transport of the kidneys. There can be a delay between the arrival of the kidney box and checks carried out on the integrity of the box, including the level of ice surrounding the packed kidney. In addition, staff have not been instructed to top up the level of ice in the box in order to ensure that the organ is fully covered, as set out in section 8 and section 9 of National Operating Procedures (NOP) NOP002 and NOP003 respectively, issued by NHSBT in December 2016.	**Minor**

Assessment Criteria	Audit findings	Level of Shortfall
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. **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. **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. **GN3**) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	The establishment does not have operating procedures in place which cover: • the process by which the surgeon is made aware of the latest information on EOS immediately prior to implanting a kidney as described in NOP 002; this could be by means of a printout of EOS or direct review of EOS by the surgeon; • the return of HTA A and B forms to NHSBT as described in NOP 006; • management of serious adverse events and reactions; • reporting of serious adverse events and reactions to NHSBT within 24 hours as stated in NHSBT SOP 3888/2 – reporting an organ donation or transplantation incident to NHSBT; • the requirement that medical activities are performed under the guidance of a registered medical practitioner as described in NOP 005. (see advice item 5)	**Minor**
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.	The Trust employs one surgical transplant registrar and several locum surgical registrars who receive offers of kidneys from NHSBT and transfer information to surgeons and nephrologists as required. There is no formal system of training on the requirements of the role or documented assessments of competency before they commence this role.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT4	The establishment is advised to include data relating to the kidney perfusion device and identification of the batch of consumables used during machine perfusion when storing data for 30 years as required by paragraph 86 in the HTA Framework document – Quality and Safety of Organs intended for Transplantation updated November 2016. Traceability data must be kept in a manner so that it can easily be traced to each transplanted organ and recipient. The establishment is advised to adopt or adapt NOP 006 'Transfer and storage of donor and organ characterisation information and storage of traceability data' issued in December 2016.
2.	R4	The establishment is advised to include a statement in the discharge letter for living donors which states that the GP, or other referral centres including those outside the UK, should inform RLH if, post donation, the donor develops a condition such as a malignancy, which may have implications for the wellbeing of the recipient. This is particularly important in cases of non-directed altruistic or paired and pooled donations, where the absence of a direct relationship between the living donor and the recipient means that the recipient may not be aware of any change to the health status of the donor.
3.	P1	The establishment is advised to document the procedure for monitoring and recording the storage of perfusion fluids.
4.	S1	The establishment is advised to increase staff awareness of the requirement to report incidents including damage to organs and other serious adverse events and reactions to NHSBT within 24 hours.
5.	I1, I2, TC1, S1, S2, GN3	The establishment is advised to consider adapting or adopting NOP 002, NOP 003, NOP 005, NOP 006 and SOP 3888/2 issued by NHSBT in December 2016.

Concluding comments

The establishment provides information to potential donors in several formats and languages and is sensitive to the needs of the multi-ethnic population in East London. Donors are repeat tested for HIV, HBV and HCV two weeks before donation in order to confirm that the donors are free from those diseases. Staff from the Clinical Transplantation Laboratory attend MDTs and play a key role in decision making.

There are a number of areas of practice that require improvement, including seven minor shortfalls relating to several operating procedures, formal training of locum on-call surgical transplant registrars who receive offers of kidneys from NHSBT, documentation of checks carried out on the integrity of the kidney box and levels of ice within the box and living donor assessment relating to travel history to help inform the risk of transmission of diseases from

donor to recipient The HTA has given advice to the establishment with respect to reviewing discharge letters, adapting and adopting the NOPs issued by NHSBT, implementing a proforma which can be used by surgical transplant registrars when they receive an offer of an organ from NHSBT and increase awareness of the requirement to report incidents to NHSBT.

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: 5 September 2017

Report returned with comments: No comments received

Final report issued: 26 September 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the organisation has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Audit Report.

Date: 18 June 2020

Appendix: Classification of the level of shortfall

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

1. Critical shortfall:

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

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

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

3. Minor shortfall:

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

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

Follow up actions

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

 a follow-up audit

 a request for information that shows completion of actions

 monitoring of the action plan completion

 follow up at next desk-based or site-visit audit.

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

Compliance with HTA assessment criteria

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

Donor Characterisation and Organ Characterisation
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.

CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.
Retrieval of Organs for transplantation
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.
Organ preservation
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.
Making arrangements to transport an organ
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP2) The organ shipping container is suitable for transport of the specified organ.
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.
Implantation
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.

I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.
I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.
Traceability – (*these criteria apply to all licensed activities*)
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.
Serious adverse events and adverse reactions (SAEARs) – (*these criteria apply to all licensed activities*)
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.
General – (*these criteria apply to all licensed activities*)
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.
GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.