Licence application desk-based assessment report on compliance with HTA licensing assessment criteria
Virtual meeting date: 16 March 2021

The London Clinic
Proposed HTA licensing number 40080

Application for a licence under the Human Tissue Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

Proposed licensed activities – Procurement

Organ type	**Kidney**
Adult (living donor)	*Applied to be licensed: DC, OC, P, 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)

Proposed licensed activities – Transplant

Organ type	**Kidney**
Adult recipient	*Applied to be licensed: OC, P, I*

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)

Summary of desk-based assessment findings

The London Clinic (the establishment) was found to have met all HTA assessment criteria. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

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 practice:

Number	Assessment Criterion	Advice
1.	CT3	The establishment is advised to review SaBTO and BTS guidance and consider adding additional questions to the potential live donor questionnaire, specifically to address IV drug use, tattoos, and piercings.
2.	R4	The establishment is advised, with the donor's consent, to include a reminder to the donor's GP in the discharge letter making clear that contact should be made with the transplant unit should the donor present with any medical conditions which may have a potential consequence for the organ recipient. This is to ensure the recipient can be followed up.
3.	General Advice	The establishment is advised to contact the HTA for further advice if arrangements to transport an organ may need to be made.

Background

The London Clinic is making an application to be licensed for the procurement from, and transplantation of, adult living donors.

The London Clinic was previously licensed by the HTA between August 2012 and May 2018, but requested the licence be revoked due to no licensed activities taking place.

Description of audit activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The audit team reviewed the following areas during the audit:

Criteria assessed against during the audit

Standards CT1, TP1 – 5 and TC3 were not assessed as they are not applicable to the activities undertaken. The remaining 23 HTA licensing standards were assessed.

Review of governance documentation

The audit included a review of the establishment's governance documentation relating to licensed activities. This included procedural documents relating to licensed activities, procurement and retention policies and accreditation certificates for relevant laboratories.

Visual inspection

No visual inspection of areas has taken place as this was a desk-based application assessment.

Audit of records

No audit of records was conducted as this is a licence application assessment.

Meeting with establishment staff

A meeting was held with staff who would be carrying out processes under the licence e.g. renal transplant consultant, medical director (CLH Named Contact), senior nurse involved in the living donor pathway, head of nursing and head of clinical governance (ODT Named Individual).

Report sent for factual accuracy: 5 May 2021

Report returned: 14 May 2021

Final report issued: 14 May 2021

Appendix 1: 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 (as amended) 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; and
- 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 2 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.

Appendix 2: 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 the 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 (as amended)** 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 the final audit report. The establishment 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 site-visit audit;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site-visit audit.

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