

Inspection report on compliance with HTA licensing standards
Inspection date: **22 May 2024**



King's College Hospital
HTA licensing number 22702

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
King's College Hospital				E			

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Membrane, Amniotic; Amniotic membrane				Authorised			

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that King's College Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, six minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

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 inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
<p>GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.</p>		
<p>b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.</p>	<p>The establishment has a single document outlining procedures for the storage and release of tissue. It does not, however, describe practices for:</p> <ul style="list-style-type: none"> • checking the tissue's expiry date before releasing it for end use; • reporting serious adverse events and reactions (SAEARs) to the HTA within 24 hours of discovery; • transporting tissue to other sites for emergency use within King's College Hospital NHS Foundation Trust (the Trust) and ensuring traceability is in place, including for unused/disposed tissue; • staff procedures and the recording of information in the traceability log when tissue is released but not used; and • reporting any storage temperature deviations to the DI so that the DI may consider whether any further action is required. <p>In addition, the procedure has not been reviewed within the last two years and the document control system was found to be not operating effectively.</p>	<p>Minor</p>
<p>d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.</p>		

GQ2 There is a documented system of quality management and audit.

<p>b) There is an internal audit system for all licensable activities.</p>	<p>The scope of the internal audit does not include a review of patient notes to ensure traceability is maintained. One example was identified where tissue traceability could not be confirmed for a patient.</p>	<p>Minor</p>
<p>GQ4 There is a systematic and planned approach to the management of records.</p>	<p>There has been no documented auditing of records to ensure they are complete and legible. A small number of temperature monitoring records showed, for example, that: two temperature readings could not be deciphered, one record had not been signed as required and for two entries where either a “Y/N” (Yes/No) response was required, a different response had been recorded.</p>	
<p>b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.</p>	<p>A process was described for the investigation and management of internal audit findings. However, corrective and preventative actions are not documented and assessed for effectiveness after their implementation.</p>	

GQ2 There is a documented system of quality management and audit.

<p>c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.</p>	<p>The establishment has not undertaken an independent audit since the licence was granted.</p>	<p>Minor</p>
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GQ4 There is a systematic and planned approach to the management of records.		
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	The establishment could not produce evidence of appropriate temperature monitoring for the tissue storage area for several periods in 2023.	Minor

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes.	<p>The establishment's documented procedure contains a section about the risks and control measures for the storage and use of tissue. However, this assessment has not been updated within the past year, is not available to all relevant staff and is limited in scope. For example, there is no assessment of the risk for:</p> <ul style="list-style-type: none"> • packing, moving, receipting and recording traceability information when tissue is sent to another site for emergency use within the Trust; and • the storage unit where tissue might be held over a weekend. 	Minor
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.		
c) Staff can access risk assessments and are made aware of local hazards at training.		

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.

<p>a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.</p>	<p>The establishment was unable to demonstrate that the thermometer used to record the temperature of the tissue storage cupboard has been maintained and calibrated in accordance with the manufacturer’s instructions.</p>	<p>Minor</p>
<p>b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.</p>		

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 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.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1b	The DI is advised to update the signed agreement with the tissue supplier to reflect that tissue is being stored beyond 48 hours.
2.	GQ2b	The DI should consider devising a schedule for use in internal audits.

3.	GQ4h GQ4i	<p>The DI is advised to ensure that there is a robust system in place, outlined in an appropriate procedure, explaining how the following data will be retained:</p> <ul style="list-style-type: none"> • raw data critical to the safety and quality of tissues and/ or cells for 10 years after the use, expiry date or disposal of tissue; and • traceability data for 30 years after the use, expiry or disposal of tissue.
4.	GQ6c	<p>The DI should ensure that for patients who receive an allograft:</p> <ul style="list-style-type: none"> • the unique identifiable number of the allograft is included in the recipient's notes; and • an appropriate "smart phrase" is documented in the recipient's notes to confirm they have received an allograft and the size of the tissue product used.
5.	GQ7a	<p>To provide assistance in complying with HTA standards and reporting any SAEARs to the HTA, the DI should appoint at least one Person Designated (PD).</p> <p>It is understood that the loss of temperature monitoring records for the tissue storage area has been logged as an internal incident. The DI should ensure that any corrective or preventative actions identified from the investigation are implemented and the loss of raw data is reported to the tissue supplier if necessary.</p>
6.	PFE3a	<p>To strengthen traceability procedures, the DI should consider expanding the scope of the information recorded in the tissue logbook, for example including:</p> <ul style="list-style-type: none"> • the name of the staff member who received the tissue; • the name of the staff member who released the tissue for end use; and

		<ul style="list-style-type: none"> where tissue is sent to another department/hospital within the Trust, the name of the person who received the tissue for onward emergency use, the recipient's details and the date of use or disposal.
7.	PFE4b	The DI may wish to consider defining the minimum stock criteria to help manage stock levels and avoid a consignment being held in transit or elsewhere, over the weekend.
8.	PFE5k	To ensure the continuous temperature monitoring of the tissue storage cupboard, the DI should consider if they have not done so already, keeping a suitably calibrated and maintained back-up thermometer available in case the 'in-use' thermometer fails.
9.	N/A	The DI is advised to review the establishment's documentation to ensure they include up-to-date references to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

Background

The establishment stores dry amniotic membrane tissue from a HTA-licensed supplier for use in ophthalmic procedures.

The establishment has been licensed by the HTA since August 2022. This was the establishment's first inspection.

There have been no significant changes to the licence arrangements or the activities carried out under the licence since the licence was granted.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

Review of governance documentation

The inspection included a review of the establishments documented procedure for storing and handling tissue, which included a section on risk assessment, SAEARs, traceability and internal auditing. These topics were discussed. The inspection team reviewed a small sample of temperature monitoring records for the tissue storage area, discussed expectations around the maintenance and calibration of temperature monitoring equipment and reviewed security arrangements for the stored tissue. Minutes of governance meetings were reviewed and discussed, as well as the process for reporting and investigating internal incidents and undertaking independent audits. Staff training and induction was discussed and the associated documentation for one training session reviewed.

Visual inspection

The inspection team visited the location where the tissue is stored.

Audit of records

The traceability audit included a review of five records randomly selected from the traceability log. One discrepancy was identified within one of the patient's electronic notes, whereby full traceability could not be assured. In addition, three stored tissue products were selected during the visual inspection and crossed referenced against the traceability log.

Meetings with establishment staff

Meetings were held with the DI who is a Consultant Ophthalmologist and key staff working under the licence.

Report sent to DI for factual accuracy: 21 June 2024

Report returned from DI: 26 June 2024

Final report issued: 12 July 2024

Completion of corrective and preventative actions (CAPA) plan

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

Date: 4 October 2024

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard 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 standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard 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 expected standard, 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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

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:

- A notice of proposal being issued to revoke the licence
- 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.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- 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 safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

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 the quality and safety of the tissues and cells.

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 inspection 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 on-site inspection.

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 inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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

Appendix 3: HTA standards

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.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards (as amended)

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.

i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.

c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.

c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.

GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.

a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.

b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.

c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.

e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.

f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.

a) There are documented risk assessments for all practices and processes.

b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.

c) Staff can access risk assessments and are made aware of local hazards at training.

d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.

c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.

c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.