Site visit inspection report on compliance with HTA minimum standards

Epsom Hospital

HTA licensing number 22539

Licensed for the

- **storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

2 October 2018

Summary of inspection findings

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

Although the HTA found that Epsom Hospital South West London Elective Orthopaedic Centre (SWLEOC; the establishment) had met the majority of the HTA standards, one major and ten minor shortfalls were found in relation to governance and quality and premises, facilities and equipment standards. The major shortfall was in relation to the monitoring of storage temperatures and freezer maintenance. The minor shortfalls were in relation to the requirement for documents to reflect current practice, the requirement to record the Single European Code, internal and independent audits, staff competency records and the scope of risk assessments.

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual 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.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone	-	-	-	E	-	-	-
Musculoskeletal, Bone; Bone Strut	-	-	-	E	-	-	-
Musculoskeletal, Tendons & Ligament; Tendons, Ligaments	-	-	-	E	-	-	-

Background to the establishment and description of inspection activities undertaken

Epsom Hospital SWLEOC was formed out of a partnership of four local NHS Trusts. Representatives from each Trust make up a governance board which oversees the activity of the Centre. The establishment is licensed for the storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Regulations).

Frozen femoral heads, femoral strut grafts, tendons and ligaments are stored for use in elective hip and knee revision and reconstruction surgery. The products are purchased from other HTA-licensed establishments through a managed service. The establishment also carries out the procurement of femoral heads on behalf of NHSBT; this is carried out under a satellite licence of NHSBT and did not form part of this inspection. The femoral heads

procured under the satellite licence were strictly segregated in a separate freezer in the same location from the tissue stored under HTA licence number 22539.

The Senior Sister for Theatres is responsible for purchasing and receiving bone products from an HTA-licensed establishment. The products are initially received by the establishment's stores department who will alert the Senior Sister when the consignment has arrived. The products, in their transport packaging, are received along with their dispatch notes in the theatre stores department. Staff there check for any damage to the packaging and then deliver the package to the theatre. The Senior Sister is then responsible for checking the integrity of the product. The dispatch note is reviewed and the unique donor number, along with the date of receipt and respective expiry date, which is no more than three months from the date of receipt, is documented in the tissue freezer diary located near the freezer. The details from the tissue freezer diary are transferred onto an electronic database, which is backed-up as part of the establishment's Information Technology system.

The tissue is stored in a secure -34°C freezer located in a lockable room adjacent to the Orthopaedic Theatres (see shortfall against PFE3(c)). The temperature of the freezer is recorded daily, from Monday to Saturday, in the tissue freezer diary as well as in a separate temperature log document. The freezer has a local audible local alarm. The orthopaedic department is only staffed during normal working hours (see shortfall against standard PFE3(c)).

Theatre staff are trained in handling bone products and are responsible for completing the tissue freezer diary when a bone product is required for surgery (see shortfall against standard GQ3(e)). The bone product closest to its expiry date is used first. The date of removal from the freezer, along with a patient label which includes the recipient's full name, hospital and NHS number, are added into the tissue freezer diary. These details are transferred onto a database.

A traceability audit was carried out on two femoral heads and one bone strut in storage and included a review of the tissue freezer diary and the traceability database. No discrepancies were noted. Three sets of recipient notes were examined for presence of the donor number within the record of the operation. These records were traced through the paper and electronic records. There was one discrepancy; one recipient of tissue could not be found on the patient database (see shortfall against standard GQ4(b)).

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	All documents should reflect current practice. For example, relevant standard operating procedures (SOPs) and tissue records have not been updated to include steps for recording the Single European Code (SEC). The SWLEOC SOP states that the temperature of the freezer is maintained at -40°C. If temperature excursions reach -25°C, bone will be disposed of. However, the SOP does not state the procedure to follow in the event of temperature excursions between -25°C and -40°C which impact on the expiry date of the tissue.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The internal audits carried out by the establishment were limited to the traceability of the tissue and there was no schedule for internal audits.	**Minor**
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.	Although an independent audit has been carried out, a full independent audit to verify compliance with all relevant HTA standards has not been performed since the previous inspection.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Theatre staff are involved in the release of tissue from freezer storage for use in surgery. At the time of inspection, competency records were available for only two members of theatre staff.	**Minor**

GQ4 There is a systematic and planned approach to the management 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.	Records are not regularly audited. During the traceability audit, one recipient of tissue was not traceable on the electronic database.	**Minor**
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.	The SOPs for receipt and storage of tissue states that two expiry dates are recorded in the tissue record book. These dates are three months from the receipt of the tissue and the expiry date stated on the tissue label. This was inconsistently recorded in practice.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and 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.	The establishment is not currently recording the SEC for each tissue product in paper or electronic records.	**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.	Although risk assessments for some licensable activities are in place, these did not cover all licensable activities. In addition, the risk assessments are not reviewed annually.	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
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.	A risk assessment has not been carried out of the storage area to ensure it is fit for purpose.	**Minor**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	There is a local audible alarm system which alerts staff to temperature excursions outside of acceptable limits. The department is not continuously staffed. Outside of working hours and during bank holidays, there is no call-out system to alert the DI of failure in storage conditions. Freezer temperature monitoring is not continuous and maximum/minimum temperatures are not recorded. This poses a risk to the quality and safety of the tissues in storage in the event of storage failure out-of-hours, or at weekends and bank holidays. The temperature at which frozen tissue was stored (-34°C) was not in accordance with the product labelling (-40°C). The establishment had not taken steps to assess the impact this may have on the expiry date of these tissues. See *Advice*, item 9	**Major**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The freezer has undergone maintenance approximately every two years and is now overdue. A review of the temperature of the freezer over the last three maintenance periods showed a gradual drift of temperature from -40°C to the current -34°C. This poses a risk to the quality and safety of stored tissue if not rectified or if appropriate steps are not taken to manage the expiry dates of the products in accordance with the manufacturer's recommendations.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The DI is advised to ensure that the level of dry ice contained in the transport box on receipt of bone and ligaments is checked and recorded and that this procedure is included in the relevant SOP.
2.	GQ1(d)	The DI is advised to include a procedure for a two-person check when transferring the SEC for each product into the tissue records to prevent any transcription errors and to include this in the relevant SOP.
3.	GQ1(r)	The service level agreement (SLA) with one of the tissue suppliers has not been reviewed since 2012 and therefore does not reflect the requirements for recording the SEC. The DI is advised to review and amend this agreement and to also ensure the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) are stipulated such as incident reporting.
4.	GQ2(c)	The DI has now made provision for an independent audit. The DI is advised to ensure that the audit verifies compliance with all relevant HTA standards including the requirements for the SEC.
5.	GQ4(a)	The DI is advised to implement a consistent approach to the amendment of written records, for example, ensure all amendments are dated and signed.
6.	GQ4(h)	The DI is advised that the requirements for keeping raw data which are critical to the safety and quality of tissues and cells for 10 years after the use, expiry date or disposal of tissues and / or cells is documented in the storage SOP.
7.	GQ7(a)	Although the requirement to report all incidents that can potentially affect the quality and safety of tissues to the HTA within 24 hours of discovery is included in an overarching SOP, the DI is advised to ensure this requirement is included in the SOP entitled 'What constitutes an adverse event in relation to activities under the HTA licence'.
8.	GQ8(a)	Although some risk assessments are in place that cover licensable activities, the DI is advised to ensure they are sufficiently robust to identify and mitigate all relevant risks and include specific references to relevant SOPs.
9.	PFE3(c)	Records of storage of frozen tissue are currently recorded in the tissue diary. Temperature monitoring is also included in this record. The DI is advised to keep a separate record of temperature monitoring to aid the review of trends. The DI is advised to review the temperature monitoring data for trends to ensure preventative action can be undertaken if necessary. The DI is also advised to manually challenge the freezer alarm system and to document this.

Concluding comments

There are a number of areas of practice that require improvement, including one major shortfall and ten minor shortfalls. The major shortfall relates to the monitoring of storage conditions and freezer maintenance. The minor shortfalls relate to the documentation, the requirement to record the SEC, internal and independent audits, staff competency records and the scope of risk assessments.

The HTA has given advice to the DI with respect to monitoring of dry ice on receipt of tissues, recording the SEC, amendment of records, updating documentation, the scope of risk assessments, temperature monitoring and challenging the freezer alarm system.

The HTA requires that the Designated Individual 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 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.

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.

Report sent to DI for factual accuracy: 6 November 2018

Report returned from DI: 19 November 2018

Final report issued: 20 November 2018

Appendix 1: 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

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.
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.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
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.
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 002/2018.
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 002/2018 are kept for 30 years after the use, expiry or disposal of 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.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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.
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.

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.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
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.
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.
e) There are documented agreements with maintenance companies.
i) Staff are aware of how to report an equipment problem.
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.

Appendix 2: Classification of the level of shortfall (HA)

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 HT Act 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:

   (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 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 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 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 both the draft and final inspection 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

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