Site visit inspection report on compliance with HTA minimum standards

Chelsea and Westminster Hospital

HTA licensing number 11146

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)**

12 December 2018

Summary of inspection findings

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

Although the HTA found that the Chelsea and Westminster Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to Governance and Quality and Premises and Facilities and Equipment standards. These were in relation to the disposal of allograft skin and the storage temperature of allograft skin in the quarantine and contingency freezer.

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

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	-	-	-	E	-	-	-
Musculoskeletal, Tendon & Ligament	-	-	-	E	-	-	-
Membrane, Amniotic	-	-	-	E	-	-	-
Skin; Skin	-	-	-	E	-	-	-

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Chelsea and Westminster Hospital (the establishment). The establishment is licensed for storage under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. This was a routine site visit to assess whether the establishment is continuing to meet the required HTA standards. This was the sixth HTA site visit inspection of the establishment since it was issued a HTA licence in October 2006.

Chelsea and Westminster Hospital is a large referral centre for both adult and paediatric patients and is part of the burns care network providing specialist burns treatment to London and the South East of England. The establishment's Burns Unit is licensed to store packaged cryopreserved whole skin, bone and amniotic membrane from donors for use in burns and elective surgery. All three tissues are purchased from another HTA-licensed establishment. There is a service level agreement (SLA) between the establishment and tissue supplier. The

establishment has also previously purchased frozen femoral heads from a second HTA-licensed establishment.

Skin

The purchased skin, in its transport packaging, is received at the main reception of the Burns Unit. Only trained staff take delivery of the package and will place the skin into a dedicated -80°C freezer after checking the quality of the packaging and cross-referencing the tissue's unique identifier number and individual pack number. The unique identifier number, date and time of receipt, time of placement into the freezer, tissue expiry date and the name and signature of the staff member receiving the skin are entered into the skin register. Stock is rotated between shelves to ensure the oldest material is used first. There is a separate container in the freezer available for non-conforming units and this is stored on a separate shelf.

When required for engraftment, trained theatre staff remove the skin from the freezer and record the date of removal, patient number of the recipient and the theatre staff's name and signature in the skin register. The unique identifier number of the allograft to be used is also entered into a separate log book located in theatre and the tissue label is affixed to the patient's notes.

Other tissues

The establishment also stores packaged, frozen bone and tendons for use in burns and elective surgery. Bone is received directly at the theatre reception and is stored in the same -80°C freezer as the skin allografts, but on a dedicated shelf. The storage temperature requirement for the bone products is -40°C. Trained theatre staff from orthopaedics are responsible for storage and removal of the bone from the freezer. Amniotic membrane is also received but is used within 48 hours of receipt. Trained theatre staff from ophthalmology are responsible for the receipt of amniotic membrane. There are separate tissue registers for each tissue type where the tissue's unique identifier number, date and time of receipt, tissue expiry date and name and signature of staff storing and removing the tissue is recorded. When used in surgery, the unique identifier number is noted onto the appropriate tissue register as well as on an electronic database.

All tissue is stored at -80°C in a locked freezer in a temperature-controlled room located between the store room and the main theatre for convenient access. There is daily manual recording of the freezer temperature. There is also continuous temperature monitoring. If the temperature deviates outside of the set range (-75°C to -90°C), the freezer alarms locally and remotely to two different sites; the main Burns Department reception located nearby, and the Blood Transfusion unit situated on a separate floor, which operates around the clock to ensure staff are always alerted to any temperature excursion. The freezer has been temperature-mapped and is currently under warranty. There is a contingency freezer located in the same room which is manually temperature-monitored daily and alarmed remotely to the same sites as the main freezer. This freezer has been temperature-mapped and there are plans to also continuously monitor the temperature remotely. There is also a second contingency freezer located in a separate department.

If the tissue is to be disposed of, the reason and method for the disposal is noted alongside the name and signature details of staff in the same tissue register log. Tissue for disposal is placed into a disposal bin separate from other waste.

The inspection included interviews with the Designated Individual and other key staff. A review of documentation relevant to the establishment's activities was also conducted and the

visual inspection covered areas where the licensable activity of storage take place and the Blood Transfusion unit responsible for the 24-hour monitoring of storage temperatures.

An audit of three skin allografts and one bone allograft held in storage was performed during the visual inspection. Labelling details were compared to the details recorded in tissue registers. No discrepancies were found. During the document review, patient notes were reviewed and allograft labelling details were compared against the tissue register and electronic database. Full traceability was maintained.

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

Shortfalls

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.	The disposal of tissue standard operating procedures (SOPs) state that: *Where an allograft has been released for use, and has either been opened or remains at room temperature for longer than 30 minutes and is not required for a planned patient procedure, the disposal procedure should be followed*. The establishment did not have any validation or documented rationale to support the use of this timeframe. The DI should validate this time span for all stored tissues to ensure the safety and quality of the tissue has not been compromised when tissue has remained at room temperature for 30 minutes.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	The establishment has had the temperature of its storage freezers mapped on several occasions. On at least two occasions, these exercises have identified zones within the freezer which are not operating at the intended temperature. The establishment has not taken appropriate steps to remedy this or to amend storage locations of sensitive products accordingly.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The SOP which covers removing allograft skin from the freezer states that staff check the temperature of the freezer to ensure the temperature is above -80°C. The DI is advised to amend this to *below* -80°C to reflect current practice and storage requirements.
2.	GQ1(b)	On receipt of tissue, the level of dry ice in the transport container is assessed to ensure that the required temperature conditions have been maintained during transport. The DI is advised to update the relevant SOP to ensure this check is included in the documented procedure.
3.	GQ1(d)	As part of the quality management system, current documents that are in use are version controlled. The DI is advised to include all forms such as temperature monitoring records within this quality management system to ensure the most current forms are in use, or to include these forms as annexes to version-controlled SOPs.
4.	GQ3 (e)	Staff currently sign and date a training record to confirm that they have read and understood all the information in the establishment's SOPs. The DI is advised to include version numbers to record that the staff have read the up-to-date versions of the SOPs.
5.	GQ1(r)	The current agreement in place with the tissue supplier is due for renewal in March 2019. The DI is advised to update this agreement to include the requirements of the SEC.
6.	GQ2(b)	In addition to audits included in the annual audit schedule, the DI is carrying out further ad-hoc audits (e.g. tissue traceability). The DI is advised to add these to the schedule to reflect the level and scope of audit activity being performed.

7.	GQ4(e)	The establishment keeps a register of the types, expiry dates and quantities of tissues stored. The DI is advised to keep a back-up copy of this tissue register in case of loss or destruction of these paper records.
8.	GQ6(d)	The establishment keeps delivery records which detail the Single European Code (SEC) as a unique identifier and are keeping the original documentation in patient notes. The DI is advised to consider recording the SEC in the tissue register to ensure robust tissue traceability
9.	PFE3(c)	Tissue is stored in the small contingency freezer for short periods prior to clinical use or when the main freezer is undergoing maintenance. During these periods, the temperature is monitored manually every one to two hours. There are plans to continuously monitor this temperature remotely but, until this is implemented, the DI is advised to record maximum/minimum temperature ranges and review this data prior to use of the tissue. Any unexplained temperature deviations can then be investigated prior to tissue use.
10.	PFE5(b)	The contingency freezer is used to store tissue when the main freezer is under maintenance (i.e. defrosted). The DI is advised to challenge test the alarm systems on completion of maintenance to ensure all monitoring systems are performing as required.
11.	PFE5(c)	The temperature of the main freezer is continuously monitored and data are reviewed for trends. The DI is advised to annotate these records to map excursions to events. Any unexpected deviations therefore can be investigated as part of the review process.

Concluding comments

The HTA saw examples of good practice during the inspection.

There is clear commitment on the part of staff at the establishment, in particular the DI, for further developing quality processes and for driving up standards in relation to activities conducted under the licence.

There are a number of areas of practice that require improvement, including two minor shortfalls in relation to Governance and Quality and Premises, Facilities and Equipment standards. These are in relation to the storage temperature of allograft skin and the disposal of allograft skin when taken out of storage if not used. The HTA has given advice to the DI with respect to updating documentation and service level agreements to ensure they reflect current practice, to record all audit activity in the annual audit schedule, the back-up of paper records, the annotation of temperature monitoring data and to challenge test the freezers after maintenance.

The HTA requires that the DI 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: 14 January 2019

Report returned from DI: 28 January 2019

Final report issued: 1 February 2019

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.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
k) There is a procedure for handling returned products.
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.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
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.
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.
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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 002/2018.
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.
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.
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.

h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
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.

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.