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**

9 November 2016

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder and the premises 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, six shortfalls were found in relation to Governance and Quality systems and Premises, Facilities and Equipment. The shortfalls are related to the absence of accurate documentation of procedures, internal audits covering the full scope of activities, independent audits, risk assessments of the establishment's practices and procedures for reporting a serious adverse event or reaction to the HTA. A further shortfall was found relating to the lack of premises risk assessments.

Particular examples of good practice 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 type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Amniotic membrane	-	-	-	**E**	-	-	-
Bone	-	-	-	**E**	-	-	-
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 fifth 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 stores packaged cryopreserved whole skin, bone and amniotic membrane from donors for use in burns and elective surgery. All three tissues are routinely purchased from another HTA-licensed establishment. The establishment has also recently started purchasing whole skin from a second HTA-licensed establishment as a trial. There is a service level agreement between the establishment and both tissue suppliers.

Skin

The purchased skin, in its transport packaging, is received at the main reception of the burns unit. Staff at the reception will take delivery of the package and only trained staff 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 shelf in the freezer available for non-conforming units. A discrete section of the same shelf is used to store skin allografts purchased from different tissue suppliers as a means to distinguish them.

When required for engraftment, trained theatre staff will 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, fresh-frozen amniotic membrane and bone for use in burns and elective surgery. Both bone and amniotic membrane are received directly at the theatre reception and are stored in the same -80°C freezer as the skin allografts, but on a dedicated shelf. Trained theatre staff from orthopaedics and ophthalmology are responsible for the receipt, storage and removal of the bone and amniotic membrane respectively, from the freezer. 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 a daily temperature recording of the freezer temperature that is backed up monthly. If the temperature deviates outside of the set range, the freezer alarms locally and remotely to two different sites; the main Burns 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 upon installation and is currently under warranty. There is an uninterruptible power supply in place for the freezer but in the event of freezer failure, there is a back-up 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, Corporate Licence Holder contact 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 took place, the back-up freezer and the Blood Transfusion unit responsible for the 24 hour monitoring of storage temperatures.

An audit of three skin allografts 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 document review, patient notes were reviewed where allograft labelling details were compared against the tissue register and electronic database. Although full traceability was maintained a number of discrepancies related to record keeping were noted.

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.	Although the staff are able to describe procedures for receipt, storage and disposal of tissue, the procedures are not accurately reflected in the establishment's documentation. For example, • the SOPs covering receipt of tissue do not include the criteria for tissue acceptance and steps to take when tissue does not conform to the standard required. The SOPs also do not reflect practices when storing tissue from different suppliers in separate compartments. • the SOPs covering disposal of tissue do not document the criteria that would warrant disposal of tissue before its expiry date.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	At the time of the inspection, an internal audit system encompassing the full range of licensable activities had not been implemented. Completed audits were restricted to reviewing tissue identifiers in tissue registers and patient records. Although a schedule of audits was produced at the inspection aimed at assessing the establishment's compliance the timetable does not include clearly defined agendas to cover the full scope of all HTA relevant activities.	**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.	The establishment has not undertaken an independent audit aimed at assessing the establishment's compliance against all applicable HTA standards.	**Minor**
GQ7 There are systems to ensure that all adverse events 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.	The establishment's SOP relating to reporting serious adverse events and adverse reactions (SAEARs) does not state that SAEARS must be reported to the HTA within 24 hours from the point of discovery as set out in the "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment" which forms the Annex to Directions 003/2010.	**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 the establishment has in place a basic risk assessment focused on storage freezer failure, this was limited in scope and did not reflect the full range of control measures that are in place. The establishment has no risk assessments to capture all risks associated with other activities being carried out under the licence and factors that may affect the quality and safety of tissues and cells.	**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.	The establishment has no formal documentation to capture all risks associated with premises, facilities and equipment.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1d	The DI should ensure all documents are version controlled so only the most up-to-date versions are in use.
2.	GQ2b	Once having implemented a robust auditing system, the DI should ensure that findings, and actions arising, from the audits are well documented and regularly disseminated at HTA governance meetings. The DI may wish to consider using standardised internal audit forms for all tissue types. By having a standard form that can be completed by staff undertaking the audits, provided there are entry fields to capture findings and actions taken, this may help provide a more consistent approach to documenting follow up actions from the audits.
3.	GQ3e	Although the establishment has implemented a systematic approach to recording training, there is no formalised system for recording staff who have read and understood the current versions of SOPs and risk assessments to support this training. Records will help ensure the DI can identify staff training needs for additional training or refreshers, when documents are amended or when changes in practices occur.
4.	GQ7a	The DI is advised to appoint Persons Designated who are able to report SAEARs to the HTA in the DI's absence. All staff should be made familiar with the 24 hour time stipulation and the chain of personnel involved for reporting SAEARs in the absence of the DI. The amended procedures for SAEARs reporting should be included in the staff training programme.
5.	GQ8a	Once risk assessments for HTA licensable activities have been completed, the DI should review them annually or when there is a change in practice.
6.	PFE5c	During the inspection, the computer system responsible for 24 hour monitoring of storage facilities displayed the alarm status as 'disabled'. The HTA is satisfied that the alarm is functioning as required through discussions with the DI and alarm tests performed by the establishment. However, the DI is advised to contact the service team responsible for maintenance of the alarm to ascertain why the software registered the alarm as disabled when evidence suggest the alarm is operational.
7.	PFE5c	The DI is advised to regularly review alarm status records and challenge the 24 hour alarm system to ensure staff are alerted during any temperature excursions. The DI is advised to include such mitigating practices in the establishment's risk assessment so the continual suitability of the remote alarm can be assessed. **Since the inspection the establishment has submitted evidence to show implementation of practices to regularly test and review the alarm systems in place.**
8.	PFE5d	Temperature mapping of the establishment's storage freezer identified hot-spots which did not meet the required -80˚C for storing allografts. The DI is advised to risk assess the use of those areas to minimise the risk of any deterioration of stored tissue through exposure to higher temperatures or to

		undertake further validation to provide assurances that the areas are appropriate to store tissue at conditions defined by the supplier.
9.	PFE5e	The DI is advised to ensure maintenance contracts for storage facilities and calibration of equipment are in place before the warranty for the storage freezer ends.
10.	D2a	The DI is advised to implement the new system for documenting allograft disposal as soon as possible to ensure the method and reason for disposal is clearly logged.

Concluding comments

The HTA saw examples of good practice during the course of the inspection.

There is clear commitment on the part of staff at the establishment, in particular the DI, for further developing working practices and for driving up standards in relation to work conducted under the authority of the licence. The establishment has given thought to improving contingency plans and streamlining tissue ordering, which serves to safeguard their quality and safety in the future.

Six areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. These relate to a number of aspects absent in the establishment's Governance and Quality systems and Premises, Facilities and Equipment, which present a risk of failure in management systems which ensure the quality and safety of the tissues and cells. The HTA has given advice to the DI in relation to practices and procedures with the view to help the establishment further develop their working practices and governance systems.

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: 1 December 2016

Report returned from DI: 13 December 2016

Final report issued: 19 December 2016

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.
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.

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 003/2010.
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 003/2010 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.
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.
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.
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.
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.
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.
b) Disposal arrangements reflect (where applicable) the consent given 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.