Site visit inspection report on compliance with HTA minimum standards

Torbay District General Hospital

HTA licensing number 11088
Licensed for the

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

27 March 2012

Summary of inspection findings

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

Although the HTA found that Torbay District General Hospital (the establishment) had met the majority of the HTA standards, a minor shortfall was found in relation to risk assessments.

Particular examples of strengths and 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 Paragraph 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.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone				**E**			

Background to the establishment and description of inspection activities undertaken

Torbay District General Hospital, HTA licensing number 11088, is licensed to store bone and tendons for patient treatment under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The South Devon Healthcare NHS Trust is the licence holder.

The establishment buys femoral heads, bone struts and tendons for use in surgical procedures from another HTA licensed establishment. Couriers deliver the items to the theatre suite, where they are received by nursing staff who have received training in bone banking procedures. Nursing staff place the tissues in the dedicated bone bank freezer, which is located in the recovery room near the operating theatres. Routine stock checks take place to ensure that sufficient material is available and that all material stored in the freezer is within expiry dates. The freezer temperature is continuously recorded on a built in chart recorder and also displayed on two digital displays. Charts are changed each week, scanned and saved as a pdf file so that temperature records can be stored in a digital format. The freezer has an alarm system which alarms locally and is also linked to the switchboard. This alarm system is tested regularly. The bone bank has access to a freezer in the Blood Bank which is used as a back-up freezer.

Staff record the receipt, storage, end use or disposal of tissues in the 'Femoral Heads' notebook or the 'Bone Graft and Bone Struts' notebook as appropriate. The tissue supplier provides a unique identifier for each tissue and these details (including the expiry date of the tissue) are recorded in the notebooks when tissues are delivered. Delivery notes are also stored for each item.

A site visit inspection of the establishment was carried out on 27 March 2012. This was the third site-visit inspection of the establishment and was classified as routine.

The inspection included interviews with a Consultant Orthopaedic Surgeon, the Divisional General Manager who is the corporate licence holder contact, a Senior Theatre Practitioner and a Surgical Care Practitioner who both act as persons designated under the licence. A document review was carried out. Documents reviewed included: standard operating procedures (SOPs) relating to storage of bone and tendons and incident reporting; audit reports, temperature monitoring records and the agreement with the supplier of bone products.

Five audit trails were undertaken. The records relating to a femoral head stored in the freezer were traced from the delivery note to records in the 'Frozen Femoral Heads' notebook. Audit trails of femoral heads and bone struts used for patient treatment were traced from the recipient's clinical notes to storage and receipt records in the 'Frozen Femoral Heads' notebook and the 'Bone Grafts and Bond Struts' notebooks and to the delivery notes. Relevant electronic records used to record implants and consumables used during surgical procedures were also audited. The findings confirmed that the establishment has a system to record the unique identifier of each graft in the recipient's clinical notes, thus ensuring traceability. A minor discrepancy was noted in the unique ID number of one bone product entered into the relevant electronic record and one delivery note had been misfiled.

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

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Risk assessments of practices and procedures have not been undertaken. The HTA acknowledges that many of the SOPs in use have been drafted following consideration of some of the risks to patients and tissues. However, risk assessments have not been formally documented which means that they are not subject to review and cannot be accessed by staff.	**Minor**
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.		

Advice

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

No.	Standard	Advice
1.	GQ 1d	The DI is advised to control the number of copies of each SOP in circulation by including the copy number as part of the current system of document control. Several copies of each SOP are in use and staff use printed copies which are available. The inclusion of copy numbers will help the DI to ensure that all current copies are removed and replaced whenever new versions of the SOPs are issued, minimising the risk of staff following out of date procedures.
2.	GQ 2b	The DI is advised to include the dates when actions are to be completed on the form used to summarise findings from internal audits and corrective actions. This will help the DI to monitor progress on actions to be taken following audits.
3.	GQ 2c	The DI is advised to extend the scope of the external audit undertaken by the Clinical Effectiveness Department to include audits of procedures and audits of records such as patient files, temperature monitoring records etc. The external audit covers electronic records and details corrective actions. However, no other records have been audited.
4.	GQ 6c	The DI is advised to liaise with the supplier to determine whether it would be possible to obtain several barcode labels for each tissue supplied, in order to strengthen the current system of traceability. The labels can then be affixed to the 'femoral head' notebook and the 'bone graft and bone struts' notebook, clinical notes and other records as required. This will reduce the risk of transcription errors when recording digits and letters into paper records.
5.	GQ 7a	The DI is advised to update SOP9 on incident reporting. The SOP covers reporting adverse reactions in patients, but does not explicitly state that adverse events such as freezer break down, resulting in the loss of a large number of allografts, must be reported to the HTA. The SOP also does not state that the DI or another member of staff must report all Serious Adverse Events and Reactions to the HTA within 24 hours of discovery.
6.	PFE 3c	The DI is advised to have a system in place, at least in the short term, to check the accuracy of the chart recorder used to record the freezer temperature. During the inspection it was observed that the temperature recording on the chart was -42^{o}C, whereas the digital displays showed – 37^{o}C. The HTA understands that the establishment will arrange for the chart recorder to be recalibrated. However, since the chart recorder has required adjustment since the freezer was commissioned a year ago, and because the establishment relies on the chart recorder to record the temperature of the freezer, it will be helpful for the DI to assure himself that accurate records are being kept.

Concluding comments

There is good communication between the DI and staff who work under the licence who meet formally and informally on a regular basis. The corporate licence holder contact engages with the DI and other staff who work under the licence, and so they work well together as a team.

The use of the electronic records to store information relating to the use of bone for patient treatment ensures that there is an effective way to retrieve records relating to end use of tissues.

The HTA has given advice to the Designated Individual with respect to document control, audits, traceability, Serious Adverse Events and Reactions reporting procedure and advice on ensuring the accuracy of the freezer temperature records.

The HTA requires that the Designated Individual addresses the shortfall 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 the corrective and preventative action being implemented to meet the shortfall identified during the inspection.

Report sent to DI for factual accuracy: 13 April 2012

Report returned from DI: 2 May 2012

Final report issued: 8 May 2012

Completion of corrective and preventative actions (CAPA) plan

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

Date: 14 May 2012

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.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
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.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.

c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
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.
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 shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

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 breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures 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.

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.