Site visit inspection report on compliance with HTA minimum standards

Wrightington Hospital

HTA licensing number 11089

Licensed for the

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

4 February 2015

Summary of inspection findings

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

Although Wrightington Hospital (the establishment) was found to have met the majority of the HTA standards, one shortfall was found in relation to the Governance and Quality standards which was addressed following the inspection. In 2014, the establishment procured chondrocytes in the absence of an HTA licence for procurement. The HTA is satisfied that in this case, the quality and safety of the material was not compromised by having taken place on premises not licensed for the purpose. The HTA has been assured that no such procurement will take place again.

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**			
cartilage and tendons				**E**			

Background to the establishment and description of inspection activities undertaken

Wrightington Hospital has been licensed by the HTA since May 2009 for storage of tissues for human application. The corporate licence holder is Wrightington, Wigan & Leigh NHS Trust and the corporate licence holder contact is the Acting Chief Executive of the Trust.

Wrightington Hospital is a specialist centre for the treatment of musculo-skeletal disease, and pioneered hip-replacement surgery in the UK. The hospital receives femoral heads, bone chips, cartilage, tendons and acellular demineralised bone matrix from HTA licensed establishments within the UK, that supply material for use in several hundred orthopaedic surgical procedures which take place each year. Patients who undergo hip replacement surgery at the hospital also donate around 500 femoral heads each year. The activities undertaken by the establishment in relation to procurement and storage of procured bone, do not fall under this licence, but are under the satellite licence of another HTA licensed establishment, which collects the procured bone for processing.

Tissues are stored in a secure room with a keypad lock. The room has a dedicated freezer as well as a back up freezer for storing bone. Daily checks of freezer temperatures take place

and these are recorded. On the day of the inspection, the temperature of the freezer where bone is stored was -42^{0}C which was within the acceptable temperature range for storage of bone. Freezers are linked to alarms, which are connected to the switchboard. The alarm and the response from the staff based at the switch board are tested each week.

Staff record the receipt, storage and use of bone in the Bone Bank Register. Details recorded include the product type, its barcode, the date it was placed in the freezer, the name of the staff member who signed the bone out of the freezer, the date and time when the bone was removed from the freezer and the named recipient, as appropriate. Theatre staff have been trained to access the room out of hours, remove bone from the freezer and record its use. Once the bone has been implanted, theatre staff record the use of bone on the tissue transplant reporting form and on the theatre computer system.

In 2014, the establishment conducted a 'one-off' procurement of a knee biopsy for autologous patient treatment (see advice item 2). The biopsy was transported to another establishment outside the UK (accredited under the EU Tissues and Cells Directives in another Member State), where the cartilage was processed to isolate and expand chondrocytes. A representative of the establishment outside the UK was present during the procurement and was responsible for packaging and transporting the biopsy and the blood sample (required for donor testing). The expanded chondrocytes are designated as Advanced Therapy Medicinal Products (ATMPs) and the HTA only regulates the procurement and donor testing of the process; the manufacturing distribution is regulated by the Medicine and Healthcare Products Regulatory Agency (MHRA). The product was sent back to Wrightington Hospital and implanted into the patient**.**

A consultant orthopaedic surgeon took the consent to procure the chondrocytes for autologous patient treatment. The surgeon and relevant staff who were involved in seeking consent, procurement of the biopsy and taking of donor blood samples had received training in the relevant procedures.

The activity of procurement is subject to licensing by the HTA under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The HTA has obtained assurances from the Designated Individual that no such procurement will take place again and is satisfied that the quality and safety of the material was not compromised by having taken place on premises not licensed for the purpose.

This was the fourth routine site visit inspection of Wrightington Hospital and included a visual inspection of the premises and interviews with the Consultant Orthopaedic Surgeon who is the DI, the Bone Bank Manager who is the person designated under the licence, a service manager and a member of the theatre staff.

A document review was carried out. Standard operating procedures (SOPs) covering receipt, storage and transfer of bone products to the theatres and he procedures relating to the one-off procurement of chondrocytes were reviewed.

Audit trails relating to four transplanted tissue products (three femoral heads and an achilles tendon) were traced from the patient files, tissue transplant reporting form, care plan within the theatre computer system and the bone bank registry as appropriate. There were no discrepancies. Staff training records, temperature records, the establishment's audit reports, which included findings and corrective actions, and the Bone Bank Divisional risk assessments were reviewed. Calibration records of the freezer alarms and maintenance records relating to the freezers temperature monitoring were also reviewed.

An audit of the one-off procurement was also carried out. Staff training records and the donor file were reviewed. This included the consent form, patient information leaflet, which formed part of the consent process undertaken by the clinician, the procurement report for the knee biopsy, taking of the blood sample for donor testing, the transport kit with transport medium

(including expiry date) and transport records. Details relating to traceability, such as the unique number of the expanded product which was returned and implanted, were also checked. No anomalies were found.

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 Quality Standards

Standard	Inspection findings	Level of shortfall
GQ1c- There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	The establishment undertook procurement of a knee biopsy for autologous patient treatment, in the absence of a licence for procurement from the HTA. The existing governance arrangements do not identify other areas within the hospital which intend to undertake activities licensable by the HTA under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The governance arrangements increase the risk of unlicensed activities taking place, which could impact on the quality and safety of tissues for patient treatment. *Following the inspection, the HTA was provided with evidence that new governance arrangements require all new requests to perform new procedures, therapies, techniques or drugs to be submitted to the Divisional New Procedures Committee which is responsible for evaluation, management of risks and monitors effectiveness. In addition, the DI has informed all clinical staff and relevant managers that official approval is required for procurement of chondrocytes.* *Based on the information provided, the HTA is satisfied that the establishment has taken sufficient action to address this shortfall.*	**Minor** **(not applicable - addressed following the inspection)**

Advice

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

No.	Standard	Advice
1.	GQ1b	In the future, the establishment may wish to undertake procurement and testing of femoral heads under its own licence, instead of working under the satellite licensing arrangement where responsibilities for these activities fall under the HTA licence held by another establishment. If so, the DI must inform the HTA in order to extend the number of licensable activities, and put in place appropriate governance arrangements, including updating risk assessments, training and documented procedures before making this significant change to licensing arrangements.

2.	GQ1p	The DI should ensure that it is licensed for procurement of tissues and cells in the event that further procurements of knee biopsies should take place. In this regard, the DI is also advised to review and update the agreement with the ATMP manufacturer based in the EU Member State, which should include the responsibilities of both organisations in relation to training of staff involved in procurement and packaging, donor testing and transport of the biopsies, and should update SOPs as appropriate.
3.	GQ2b	The DI is advised to review and update the SOP – Bone bank internal audit schedule. Staff undertake a wide range of audits, some of which may no longer be required following the implementation of the tissue transplant reporting form and the theatre computer system.

Concluding comments

The DI, the Bone Bank Manager and the Bone Bank Assistant work well together as a team. There are good systems for managing the receipt, storage and use of bone products. The comprehensive audit schedule helps to ensure traceability of bone products.

The establishment has a comprehensive range of detailed SOPs, which cover bone bank activities and training of theatre staff. All theatre staff receive annual training in handling bone products; theatre links, who access the freezer room to remove bone for surgical procedures, are trained and competency assessed.

There are robust systems in place to monitor freezer temperatures and respond to any freezer alarms, both during and after working hours. Bone which has been allocated for a named patient or category of patient, for example bone from a Rhesus negative donor allocated for women of child bearing age, is kept in a designated area of the freezer.

The establishment took action to address one minor shortfall relating to systems in place to ensure that licensing arrangements cover all licensable activities. All applications for new procedures have to be submitted to a Divisional New Procedures Committee for evaluation and approval. There are a number of areas of practice that require improvement, including. During the inspection the HTA was informed that the establishment is considering extending its activities to include procurement of femoral heads and associated donor testing. The HTA has given advice to the Designated Individual on this issue and on ensuring that the agreement with the ATMP manufacturer is updated prior to further procurements of chondrocytes.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 3 March 2015

Report returned from DI: 17 March 2015

Final report issued: 7 April 2015

Completion of corrective and preventative actions (CAPA) plan

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

Date: 4 March 2015

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

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.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
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.
q) There is a record of agreements established with third parties.
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.

k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
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.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
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.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.

b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
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.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
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.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
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.