Site visit inspection report on compliance with HTA minimum standards

Blackpool Fylde and Wyre NHS Foundation Trust

HTA licensing number 12133

Licensed for the

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

9 June 2016

Summary of inspection findings

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

Blackpool Fylde and Wyre NHS Foundation Trust (the establishment) was found to have met all HTA standards.

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 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.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'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
PBSC	**E**				**E**		

Background to the establishment and description of inspection activities undertaken

The establishment undertakes the clinical assessment and collection and transplantation of peripheral blood stem cells (PBSC) from adults for autologous treatment of cancers, principally lymphomas and myelomas. These activities are carried out within the department of haematology at Blackpool Victoria Hospital

In addition to its HTA licence, the establishment holds JACIE accreditation (Joint Accreditation Committee-International Society for Cellular Therapy (Europe)) and is a member of the European Group for Blood and Marrow Transplantation.

Clinical assessment of patients for whom treatment methodologies are suitable follows referral into the department and discussion at multi-disciplinary team meetings. During initial meetings with the patient about possible treatment types, information is provided in order to help inform subsequent consent discussions.

A defined cohort of trained clinical staff, being Consultants, Specialist Registrars, Speciality Doctors and the Clinical Nurse Specialist are responsible for seeking informed consent, following a specific standard operating procedure. Medical staff undertake training on informed consent as part of Good Clinical Practice training, and the Clinical Nurse Specialist has been trained in seeking informed consent.

Consent is taken for each element of the procedure, with separate forms used for; apheresis, storage, testing and discard, transplantation and data collection. Patients are given the opportunity to ask questions and are provided with relevant patient information leaflets.

Cells are procured by apheresis in a temperature monitored apheresis suite which is part of the day unit at the establishment. Apheresis kits and reagents are stored in a secured area within the apheresis suite.

Procured cells are transferred to another HTA licensed establishment for processing and storage, under the terms of a service level agreement (SLA). The responsibilities of each HTA licensed establishment in relation to labelling, packaging, transport, testing, processing and reporting are clearly defined in the SLA, which also clarifies how serious adverse events or reactions are to be reported.

Traceability is ensured by the establishment using pre-printed labels, supplied by the processing laboratory, containing the patient's details together with a unique donation number. Serology testing of donor blood samples, taken initially during pre-collection outpatient appointments within 30 days of the planned collection date, is updated by samples being taken during the cell collection procedure.

Records of transport to and from the processing lab are retained, with transport being carried out under the terms of a service agreement with a contracted taxi firm. Staff at each establishment sign to acknowledge release and receipt of cells.

Following the patient's cancer treatment, cells for transplantation are requested from storage and are supplied in a dry shipper, with traceability being recorded as above. Ward staff thaw and infuse the cells and provide confirmation of this, as well as detailing any issues or reactions, to the processing establishment.

This was the establishment's fourth, routine site-visit inspection. The inspection consisted of a visual inspection of the area where apheresis procedures take place, interviews with the DI and key staff members working under the licence and a review of relevant documentation.

Those activities carried out by the HTA licensed establishment which carries out activities under an SLA, were not covered within this site visit.

An audit of three sets of patient records was undertaken as part of the inspection. In each case the patient file was reviewed for the presence of transplant plans, signed consents for each stage of the process, transport records, serology results and traceability details.

Serology results were not stored within patient files, instead being held in electronic record files, as they were e-mailed to the establishment. The results were reviewed separately.

No discrepancies were noted, other than some inconsistency in the way staff completed check-box elements of the consent form detailing what risks had been discussed with the patient. Advice has been provided below.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C3a	The HTA notes that medical staff refresh their training on seeking informed consent as part of training in Good Clinical Practice. The DI is advised to ensure that training for other staff involved in seeking informed consent is refreshed periodically.
2.	GQ2a,b	The DI is advised to ensure that the quality manager is supported in efforts to bring review of governance documentation and the carrying out of audits back on schedule. During the inspection, the HTA noted that staffing problems during the quality manager's maternity leave meant the schedule of review of documentation and carrying out of audits slipped behind schedule but that efforts are being made to address this on an on-going basis.
3.	GQ2a	The DI is advised to press the Trust governance department to complete the review of out of date overarching Trust policies and procedures. These were noted during an audit carried out by establishment staff and this has been raised within the Trust.
4.	GQ2b	The DI is advised to audit completed consent documentation to determine whether the inconsistency in completion of the check-box elements provided to record risks discussed with patients is widespread. The DI should use the results of the audit to inform staff training or review of the format of the consent forms.
5.	GQ2c	The DI is advised to ensure that all HTA standards are covered by the audit in an independent manner carried out by staff from another department of the Trust. The HTA noted that other audits within the department dealt with those standards which had not been included in the last such audit, but including all standards in one audit will help to ensure that the meeting of this standard is more easily evidenced.
6.	GQ3e	The DI is advised to ensure that refresher or update training in relation to matters relevant to apheresis is made available to the Clinical Nurse Specialist,

		so that this can be cascaded to other staff within the department. As the establishment uses “Train the trainer” methods to cascade training throughout the department, it is important that those training others have opportunities to keep their own knowledge and training up to date.
7.	GQ3k	The DI is advised to risk assess staffing levels in light of the likelihood of an increase in the number of stem cell transplants carried out by the establishment in the future. The HTA noted that staff shortages during periods of illness or leave have necessitated the Clinical Nurse Specialist taking part in apheresis sessions. As the role is critical to the administration of the other elements of the stem cell transplant programme, this may increase the risk of system failure.
8.	PFE3a	The DI is advised to regularly review the temperature logs produced by the data-logger in the apheresis suite, also used for the storage of consumables, in order to determine the risk of the advised maximum temperature of storage of consumables (25oC) being exceeded. On review of data from this year, the HTA noted that the temperatures logged approached this figure on a few occasions. In the event that the DI considers there is a risk of the maximum storage temperature being exceeded, he is advised to request the Trust estates department to adjust the air conditioning unit appropriately. He is also advised to incorporate contingency storage arrangements in the Standard Operating Procedure “Storage and Control of Reagents and Equipment for Apheresis” (HAEM/HSCT/COLL/SOP/008). The DI is further advised to have staff check the temperatures recorded by the data-logger on a regular basis to ensure that there have been no out of range events before using consumables stored for use in apheresis. The DI should consider documenting such checks in the procurement records kept by the establishment.

Concluding comments

The HTA saw various elements of good practice during the inspection.

- The establishment has incorporated the use of well-designed checklists to support staff in their roles. With regard to the checklist of requirements for apheresis, in the event that any requirements have not been met, this is recorded as a deviation from procedure and requires sign-off by one of the consultants prior to apheresis commencing.

- The procedure record form used is comprehensive and includes details of pre and post procedure room temperatures, consumable batch numbers and records of release and receipt as well as intervening transport.

- When cells are being transported, the driver of the taxi supplied by the contracted company is provided with a sheet detailing responsibilities and also providing contact details for both the establishment and the processor. The documented procedure which drivers must follow also includes these responsibilities and has detailed route maps as well as turn by turn instructions for the route between the two establishments involved in the licensed activity.

- The establishment has a defined contingency arrangement for situations where it may be unable to carry out apheresis, and this is reflected in an SLA entered into with another licensed establishment, to enable continued provision of apheresis service.

The HTA noted that staff pressures, including the absence of the quality manager for a period in the last year, have led to some elements of governance review and audit falling behind schedule, but that steps are in place to rectify this. The HTA also noted that the increased number of treatments being carried out by the establishment puts greater pressure on staff, particularly during periods of leave or staff illness. The HTA has given advice to the DI with regard to this and to elements of governance documentation, risk assessment and audit.

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

Report sent to DI for factual accuracy: 20 June 2016

Report returned from DI: No comments received

Final report issued: 12 September 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

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.
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.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
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.
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.
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.

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
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.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
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.

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.