Site visit inspection report on compliance with HTA licensing standards
Inspection date: **10 October 2019**

Royal Stoke University Hospital
HTA licensing number 22593

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

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

Licensed activities

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Royal Stoke University Hospital	E				E*		

Tissue types authorised for licensed activities

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, PBSC; PBSC	Authorised				Authorised		

Summary of inspection findings

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

Although the HTA found that Royal Stoke University Hospital (the establishment) had met the majority of the HTA's standards, seven minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment. These related to the content of establishment procedures, raw data retention and the retention of records in the event of termination of activities, risk assessments, monitoring of storage areas, the agreement with the courier undertaking transport of cells to another establishment for processing and storage, and the lack of evidence to demonstrate that transportation boxes had been validated to ensure they were fit for purpose.

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.

Compliance with HTA standards

Minor Shortfalls

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.	During the inspection, examples were identified where establishment procedures did not reflect current practice. For example: • the procedure for obtaining consent does not set out the requirement to seek consent for mandatory serological testing and the future disposal of cells; • the procedure for the collection of PBSCs by apheresis does not include	**Minor**

	instructions to break the frangible on each bag of ACD-A solution, and check that this is flowing correctly; • the establishment's threshold CD34 measurement, below which stem cell collection would not take place, is not documented in establishment procedures; and, • the procedure for the transportation of cells does not define the temperature at which the cool packs used need to be conditioned prior to use.	
GQ4 There is a systematic and planned approach to the management of records.		
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.	The establishment does not have procedures in place to ensure that temperature monitoring records are retained in accordance with the regulatory requirement.	**Minor**
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.	The establishment does not have contingency arrangements in place to ensure that records are retained in accordance with the regulatory requirement in the event of termination of activities.	**Minor**
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's risk assessments do not consider the risks associated with the storage of reagents and consumables.	**Minor**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	ACD-A solution is stored in a secure area of the pharmacy, which is adjacent to the haematology day ward. The area is continuously monitored and alarmed using a wireless web-based system. Responsibility for the system lies with the pharmacy team. Establishment staff do not routinely review the captured data, and were not familiar with the current alarm settings. There were no documented procedures in place to ensure establishment staff were made aware of incidents or excursions, and would be kept informed of any subsequent investigations. ***The establishment submitted evidence that this shortfall has been addressed prior to issue of the report. The HTA has assessed this information as satisfactory and considers this standard to be met.***	**Minor**
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.	The agreement with the courier undertaking transportation of cells to the establishment responsible for processing and storage has not been signed.	**Minor**
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	The establishment was not able to provide evidence to demonstrate that the boxes used to transport cells to the processing and storage establishment have been validated to ensure that they are fit for purpose.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

Advice

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

Number	Standard	Advice
1.	GQ1b	The DI is advised to update the reference to the HTA Directions in the quality manual, and anywhere else they occur, to reflect the most up to date version (currently 02/2018). References to superseded HTA Codes of Practice should be replaced by references to the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, as this is the applicable reference for establishments licensed under the Human Tissue (Quality and Safety for Human Application) Regulations, 2007.
2.	GQ2b	The DI is advised to work with the Quality Manager to devise a series of audit templates covering all licensable activities. This will support establishment staff in undertaking scheduled audits in a timely and efficient manner, and provide assurance to the DI that the scope of audits is consistent and appropriate to the activities undertaken under the licence.
3.	GQ4b	During the inspection it was noted that records of consent and procurement dating from 2017 onwards had not yet been audited. Examples were noted where electronic copies of records were not present in the assigned file location, and there were some minor omissions from paper procurement records. The DI is advised to consider aligning the frequency of audits of consent and procurement records with the annual frequency stipulated for other internal audits. This will help ensure that records are completed and retained as required, and that any omissions are detected.

4.	GQ2c	The most recent independent audit of licensable activities occurred less than one month prior to the routine site inspection by the HTA. The DI is advised to ensure that the independent audit is conducted in the interim year between site inspections by the HTA. This would provide assurance that there has been an independent assessment of compliance each year, and enable sufficient time to resolve any findings prior to the next regulatory inspection.
5.	GQ4i	Stickers are placed into patient notes to identify those records applicable to licensable activities. The sticker states that records must be kept for 30 years. The DI is advised to update this sticker to clarify that records must be stored for 30 years after use, expiry or disposal of the cells, to help ensure compliance with the regulatory requirement.
6.	PFE4f	The DI is advised to update the agreement with the courier to reflect the correct details for the DI, and ensure the correct Trust is referenced throughout.
7.	PFE5j	The establishment that undertakes the processing and storage of procured cells provides a worksheet, upon which the identification of the apheresis machine used is recorded. The establishment does not retain a copy of this sheet, and the identification of the machine is not captured elsewhere within the establishment's own records. The DI is advised to introduce a method to ensure that the identification of the machine used is captured in establishment records, to support routine evaluation procedures and help identify any equipment-related issues.

Background

Royal Stoke University Hospital has been licensed by the HTA since September 2009. This was the sixth site visit inspection of the establishment; the most recent previous inspection took place in October 2017.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

There are a total of 121 standards in the Human Application Sector, and establishment compliance against 102 of these standards was assessed during the inspection. Standards C1b, C2b, GQ1f, l and n, GQ4k, GQ5c and e, GQ7g and h, PFE1d, PFE2a and b, PFE3d and D1a, b and c were not applicable. Compliance against standards GQ1k and GQ1o was not assessed.

Review of governance documentation

The inspection included a review of documentation relevant to the establishment's licensable activities. This included the quality manual, standard operating procedures, patient information booklets, controlled forms, records of servicing and calibration, temperature monitoring records, agreements with third parties, meeting minutes, reported incidents and adverse events, audits, risk assessments, and staff training records.

Visual inspection

The inspection team visited the haematology day unit (Ward 202) where apheresis takes place, and the areas where consumables and reagents are stored. The team also visited the inpatient facility (Ward 201), where cells are returned to the establishment for thawing and reinfusion.

Audit of records

Donor assessment, consent, procurement, serological and microbiological testing, storage and reinfusion records for two apheresis patients were audited during the inspection. Records were a combination of paper forms stored within the patient file and electronic records stored on Trust servers. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with the DI (who is the Collection Facility Director and lead consultant for the myeloma transplant pathway), the lead consultant for the lymphoma transplant pathway, and staff undertaking key activities under the licence. These included the Quality Manager, the Haematology Transplant Nurse Specialist, the Lead Apheresis Nurse and the Data Manager.

Report sent to DI for factual accuracy: 07 November 2019

Report returned from DI: 22 November 2019

Final report issued: 12 December 2019

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI 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.

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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007, 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 the final inspection report. Establishments 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 routine site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.