



## **Site visit inspection report on compliance with HTA minimum standards**

**Salisbury NHS Foundation Trust**

**HTA licensing number 11102**

**Licensed for the**

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

**17 September 2013**

### **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.

The HTA found that Salisbury NHS Foundation Trust (the establishment) had met all HTA standards. Advice has been given relating to the Consent (C), Governance and Quality Systems (GQS), Premises, Facilities and Equipment (PFE) and Disposal (D) 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 (DI), Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (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.

## 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
PBSC	E	-	TPA	-	TPA	-	-

## Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Salisbury NHS Foundation Trust (the establishment). This was the fourth site visit inspection of the establishment since it was issued an HTA licence in September 2006; the last inspection was in July 2011. It was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards.

The establishment currently undertakes donor selection, consent, procurement, distribution and end use of haematopoietic stem cells (HPCs) for patient treatment. The HPCs are peripheral blood stem cells (PBSCs). Approximately 75 units of PBSCs are procured each

year for autologous transplantation. The establishment carried out 8 autologous transplants in 2012.

Donor serological testing and sample sterility testing are carried out under a third party agreement (TPA) with a separate organisation.

Procured cells are transported by courier to an HTA-licensed establishment for processing and storage. This organisation also carries out immunophenotyping and cell counting of the cell samples. There is a Service Level Agreement (SLA) in place with this HTA-licensed establishment, and a TPA with the courier.

An agreement is in place with an HTA-licensed establishment both for the re-provision of service in an emergency and as a contingency for equipment failure (*see Advice item 1*).

Following the previous site visit inspection of the establishment, minor shortfalls were found in the areas of: inconsistencies and omissions in the quality management documentation; the formalising of TPAs and SLAs; incomplete Serious Adverse Event and Adverse Reaction (SAEAR) policies and standard operating procedures (SOPs); and, the creation and review of some risk assessments. All of these were assessed as being met following submission of evidence by the establishment in 2012.

The site visit inspection covered by this report included a visual inspection of the clinical areas, the 'consenting' rooms and the apheresis suite (which contains one apheresis machine). Meetings were held with the DI (Medical Director), the Persons Designated (PDs; Consultant Haematologist and Clinical Nurse Specialist – Haematology), the Haematology Quality Co-ordinator and the Corporate Licence Holder contact (Head of Clinical Effectiveness). A documentation review and audit trail were carried out. Details of the audit are provided below; no anomalies were found.

A vertical traceability audit was carried out from consent in patient notes through to distribution, return and transplantation for six patients. All samples were fully traceable.

### **Inspection findings**

The HTA found the DI 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:

<b>No.</b>	<b>Standard</b>	<b>Advice</b>
1.	N/A	The DI is advised to ensure all SLAs are in date and are signed. A hard copy should be kept in the establishment's records.
2.	C3(b)	The DI is advised to ensure that all haematology consultants undergo the consent training programme and that such training is recorded.
3.	GQ1(d)	The DI is advised to modify the statement that 'The review period for SOPs is not more than 12 months' and give it a

		definite timeframe.
4.	GQ1(p), GQ5(b)	The DI is advised to ensure that the TPA with the testing organisation is reviewed and signed, and that a hard copy is kept in the establishment's records.
5.	GQ2(b), GQ4(b)	The DI is advised to consider building on the existing system of audits by setting up a separate folder and spreadsheet for audits and the corresponding corrective and preventative action plans (CAPAs). It is suggested that a vertical audit of tissue and cell traceability is included in this.
6.	GQ3(b)-(d)	The DI is advised to ensure that the induction training programme, continuous professional development (CPD) and mandatory training apply to all clinical staff working under the licence.
7.	GQ3(e)	The DI is advised to ensure that all competency training (including apheresis training, where applicable) is recorded for all staff working under the licence.
8.	GQ3(g)	The DI is advised to ensure that the training programme on quality management and organisational structure is formalised.
9.	GQ3(k)	The DI may wish to consider identifying further dedicated time for a quality manager.
10.	GQ4(e), GQ6(b), (c), PFE4(b) - (d)	<p>Although information on the quantities of cells that are procured, tested, stored and distributed or otherwise disposed of is available, it is not in a single register. Notes, spreadsheets and records are kept in various places. The DI may wish to consider creating a single register, which is also reconciled with the register of cells held by the HTA-licensed storage organisation.</p> <p>The DI may also wish to consider setting up an individual 'patient folder', which includes details of all clinical and traceability records for each patient, as well as temperature records during transport.</p>
11.	GQ4(g)	The Trust Data Protection Policy is out of date and needs reviewing and updating.
12.	GQ4(h)	The DI is advised to modify the SOP on raw data to ensure that such data is kept for 10 years after the use, expiry date or disposal of cells.
13.	GQ4(m)	There is a plan and procedure for the transfer of traceability records and raw data in the event of termination of licensable activities. The DI is advised to ensure that a written agreement is now set up with the nominated HTA-licensed establishment.
14.	GQ5(d)	The testing organisation only informs the establishment if serology tests are 'positive' or 'negative', it does not provide details of each test performed. The DI is advised to ensure that the testing organisation provides a copy of the full serological test results for each patient.
15.	GQ8(b)	Although risk assessments of licensable activities are available, there is no evidence that they are reviewed on a

		regular basis.
16.	PFE5(e)	The DI is advised to ensure that copies of all documented agreements with maintenance companies are held locally to provide reminders to the DI of when they need to be reviewed.
17.	D2(a)	The DI is advised to consider creating a disposal folder to contain copies of records of disposal.

### Concluding comments

During the inspection of Salisbury NHS Foundation Trust, several areas of good practice were noted:

- The establishment has set up a consent training programme, which includes Good Clinical Practice (GCP) compliance training, HTA e-learning and in-house presentations.
- The establishment has set up an agreement for the 'Provision of an independent HTA compliance audit for haematology stem cell transplant establishments'. This audit is performed by a member of staff from an HTA-licensed PBSC establishment.
- All staff involved in the licensable activities function well together as a team under the DI.

The HTA has given advice to the DI in several areas, including consent, governance and quality systems, premises facilities and equipment and disposal.

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

**Report sent to DI for factual accuracy: 15 October 2013**

**Report returned from DI: 29 October 2013**

**Final report issued: 19 November 2013**

## 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.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
Q2 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.
Q3 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.
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.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of 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.
e) Testing of donor samples is carried out using CE marked diagnostic 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.
<b>GQ6</b> 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.
<b>GQ7</b> 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.
<b>GQ8</b> Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

### **Premises, Facilities and Equipment**

<b>Standard</b>
<b>PFE1</b> 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.
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.
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.

### Disposal

<b>Standard</b>
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
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.

## 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.