



## **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**

**31 August 2017**

### **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.

Although the HTA found that Salisbury NHS Foundation Trust (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to the Governance and Quality System standards. The minor shortfalls relate to third party agreements and the retention of raw data for 10 years.

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.

'SLA' = Service level agreement; another licensed establishment carries out the activity on behalf of the establishment.

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

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell Haematopoietic, PBSC; PBSC	E	SLA	TPA	SLA	TPA		

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

Salisbury NHS Foundation Trust has been licensed by the HTA since 2008. The HTA licence includes the procurement, testing and distribution of autologous adult peripheral blood stem cells (PBSCs) under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Processing and storage activities are performed by another HTA licensed establishment under the terms of a service level agreement (SLA).

The establishment provides an autologous donor transplant service to patients and performs approximately fifteen PBSC procurements each year. Consultant haematologists, following diagnosis, identify patients as potential candidates for a stem cell transplant procedure.

Consent discussions, which are an Apheresis Clinical Nurse Specialist (CNS)-led process also include the provision of appropriate patient information. Apheresis CNSs also follow the patients throughout their treatment and provide a personalised plan, which includes a minimum of two appointments. Patients are given the opportunity during the consent discussions to also meet the transplant team at Southampton NHS Foundation Trust.

Blood samples for the mandatory serology testing are taken on the day of the consent and no earlier than 30 days before procurement of stem cells. Donor testing, including testing for HTLV takes place at a specialist laboratory, which is part of the Public Health England network, under the terms of a third party agreement (TPA). The serology test results are communicated directly to the processing laboratory/ storage establishment and to Southampton NHS Foundation Trust, where infusion of the PBSCs takes place. Serological testing is additionally performed by an on-site specialist laboratory, which is also part of the Public Health England network, for internal quality assurance purpose. Both laboratories are accredited under the UK Clinical Pathology Accreditation Scheme.

The establishment has one apheresis machine; however, further contingency arrangements are in place with Southampton NHS Foundation Trust. The apheresis machine is cleaned between procedures and additionally on a weekly basis, and is serviced regularly. Apheresis kits are stored in a secure, designated area and the anticoagulant Acid-Citrate-Dextrose Formula A (ACD-A) is stored in a temperature-monitored fridge.

On the day of the procurement, the sample is sent to the processing laboratory and results are phoned and faxed through to ensure that the target CD34 counts are reached. The Apheresis CNS reconfirms consent prior to apheresis. Each collection is assigned a unique code, which ensures traceability from procurement through to processing, storage, distribution and end-use or disposal. The labels with the unique code are provided by the processing establishment. Procured cells are packaged in validated transport boxes, collected on the apheresis ward by pre-arranged couriers and transported to the processing establishment.

Transplantation takes place at Southampton NHS Foundation Trust, where the cryopreserved cells are sent upon request.

This report describes the establishment's fifth routine inspection, which took place on 31 August 2017. Discussions were held with the Designated Individual (DI), the Consultant Haematologist, both of the Apheresis CNSs and the person involved with Quality Management. A review of documentation relevant to the establishment's licensable activities and a visual inspection of the premises where tissue procurement takes place, were also included as part of the inspection.

An audit was performed on five sets of patient records. The audit covered the signed Consent for Donation form, the request to Collect and Process Cells form, the Stem Cell Harvest and

Transplant Checklist, and the batch numbers and expiry dates of consumables used during apheresis. The following information, where applicable, was cross referenced against each of these documents: donor name, date of birth, unique harvest number and hospital number. Traceability was maintained throughout and no discrepancies were identified in the accompanying documentation.

### 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 and Quality

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.		
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.	<p>The establishment has written agreements with third parties. However, the agreements do not set out the responsibilities of each party in relation to:</p> <ul style="list-style-type: none"> <li>• serious adverse event and reactions (SAEARs) reporting procedure and the procedures to follow in the event of an incident.</li> <li>• retention of critical traceability records (30 years) and raw data (for 10 years).</li> </ul>	<b>Minor</b>
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.	Although the establishment retains raw data for 10 years after the use, expiry date or disposal of cells, there is no documented procedure.	<b>Minor</b>

## Advice

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

No.	Standard	Advice
1.	GQ1b	<p>The DI is advised to review the establishment's standard operating procedures (SOPs) to ensure that they reflect current practices. Examples of these include, but are not limited to:</p> <ul style="list-style-type: none"><li>• The SOP on planning for a stem cell harvest states that serology testing only takes place at the other laboratory. Current practice is for donor testing to be repeated at the establishment's onsite laboratory. The DI is also advised to consider the actions to be taken should there be a discrepancy between the results of the two testing laboratories.</li><li>• The SOP on testing for stem cell harvests states that "testing must take place within 30 days of last expected day of stem cell collection". The DI is advised to update the wording of the SOP to more closely reflect the wording of the testing requirements as set out in Annex II of Directive 2006/17/EC</li></ul>
2.	GQ2d	<p>The establishment annually re-validates the transportation boxes to ensure they continue to achieve the intended results.</p> <p>The DI is advised to put identifiers on the boxes. This will enable the establishment to identify the boxes used to transport PBSCs and to track their performance over the years.</p>
3.	GQ8a	<p>The establishment has carried out a number of risk assessments and has considered most of the risks associated with the procurement and distribution of PBSCs.</p> <p>The DI is advised to expand the scope of the risk assessments as they do not consider the failure of the apheresis machine and lack of bed space for apheresis patients.</p> <p>The DI is also advised to document the full range of control measures in place, which help to mitigate identified risks.</p>
4.	D1a	<p>The Disposal policy references the old Code of Practice on Disposal, which is now superseded by new HTA Codes of Practice and Standards.</p>

## Concluding comments

The HTA observed a number of good practices during the course of the inspection.

Licensable activities are undertaken by a small, but experienced and knowledgeable team of staff that provide a well-organised and co-ordinated service for patients.

Establishment staff have developed a Stem Cell Harvest checklist to ensure that patient records contain all applicable documentation, and also routinely make use of two-person check procedures for harvest identification and labelling procedures.

The establishment also uses competency assessments at the end of SOPs that contain multiple choice questions and open ended questions on the various procedures and

practices. The competency assessments are a useful tool and their use was further evidence that staff are committed to providing a high quality transplant service to their patients.

Two areas of practice were identified during the inspection that require improvement, resulting in two minor shortfalls. The HTA has given advice to the DI with respect to a number of the establishment's documents, the transport box validation process, risk assessments, and the disposal policy.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfall identified during the inspection.

**Report sent to DI for factual accuracy: 05/10/2017**

**Report returned from DI: 27/10/2017**

**Final report issued: 27/10/2017**

#### **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: 01 February 2018**

## 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

<b>Standard</b>
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.
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.
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.
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.
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.
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.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
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.

### Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
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.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
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.
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.