Site visit inspection report on compliance with HTA minimum standards

University Hospitals Coventry and Warwickshire NHS Trust

HTA licensing number 30019

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen.**

3 November 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.

University Hospitals Coventry and Warwickshire (UHCW) NHS 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 (DI), 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.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at the University Hospitals Coventry and Warwickshire NHS Trust (the establishment), where the West Midlands Surgical Training Centre (WMSTC) is located. This was the second routine site visit inspection of the establishment by the HTA. The previous inspection took place in 2009. The latest inspection included: a visual inspection of the areas where tissue is received and stored; a visual inspection of the training room; meetings with members of staff, and a review of documentation. An audit trail was also conducted. Details are included in the report below.

The DI under the licence is a Consultant Pathologist and Clinical Lead for Cellular Pathology. The Corporate Licence Holder is the University Hospitals Coventry and Warwickshire NHS Trust. The Surgical Skills Training Centre Manager is the Persons Designated (PD) under the licence. Other staff working under the licence are a Senior Technician, a Trainee Technician, and a Course Organiser. There is also a Medical School Anatomy Lead for Warwick Medical School.

The WMSTC facilitates approximately 250 different courses for a wide range of students, including health care professionals. The WMSTC uses plastinated specimens for anatomical training and education of UHCW and Warwick Medical School Students. They also use fresh frozen specimens for training various professionals from the UK and abroad. Before working

with the specimens, all course participants must read and sign a code of conduct and attend a presentation, both of which cover working with human tissue, and dignity and respect for the donors.

Currently, staff at the establishment do not seek consent - all material is either imported or received from other institutions within the UK. However, the establishment is moving towards creating its own donor programme within the next couple of years (see Advice, item 2).

The establishment imports fresh frozen specimens from the USA and plastinated material from Germany. With regards to consent for the imported specimens, the establishment requires proof from the exporting establishments that consent was sought appropriately for each donation. The establishment also receives surplus tissue from the Birmingham Heart Valve Bank where consent is in place to use this tissue for the scheduled purpose of education and training. In addition, the establishment stores skeletons that pre-date the Human Tissue Act 2004 (HT Act).

The establishment checks the qualifications and suitability of the course leaders before permitting a course to take place. Each course has a course leader and demonstrators or other staff supervise the participants. The layout of the training room is set up according to the requirements of the course. Each group of participants are assigned to a table with at least one member of staff. The training room has a total of eight tables, all of which can be moved to access drainage and suction.

The establishment rarely receives frozen whole bodies. When they do, bodies are delivered by contracted funeral director to the mortuary and stored there prior to use.

Deliveries of body parts are arranged in advance and the reception area is in a secluded part of the hospital site, with CCTV monitoring. The reception area is adjacent to the training room. Staff receiving a delivery of material will sign for it and fill out a delivery note with the following details: the time and date of delivery; descriptions of the items, and; where the delivery has come from. Packages are then hand-delivered directly to WMSTC staff, who must sign to confirm receipt.

All specimens arrive labelled with a unique ID number, which the establishment uses for traceability purposes. The establishment shares a storage space with the mortuary, which has its own HTA licence. When fresh frozen parts are received, they are either stored in the mortuary or taken straight into the WMSTC, where they are placed on surgical tables to thaw for at least 24 hours, depending on the size of the specimen. Within the mortuary, there is a dedicated -80° C freezer for storage of the fresh frozen specimens. This freezer is managed under the anatomy licence. The freezer is linked to a computerised temperature monitoring system, which has a call out system that contacts a person on call when the temperature deviates outside the specified operating range. The establishment has an agreement with the mortuary to use their freezer space when needed, and only if the mortuary is under 80 per cent capacity. There is also contingency storage at another HTA-licensed establishment.

There is a separate storage room for plastinated specimens. In order to access the room, staff must input a key code and use their swipe card, which purposely limits access to certain staff. As described earlier, each plastinated part has a unique ID number. There is also a security tag attached to each part, which is linked to a call out phone system that alerts staff if the specimen is moved outside the designated zone. The establishment occasionally loans plastinated specimens to the Warwick Medical School and have appropriate Material Transfer Agreements (MTAs) in place.

When fresh frozen specimens are ready to be disposed of, they are packaged appropriately and taken by courier for disposal. Details of the disposal are recorded.

A traceability audit was conducted by the inspection team on:

- heart tissue in the -80˚ freezer that was received from the Birmingham Heart Valve Bank;
- two fresh frozen specimens in the -80˚ freezer that were imported from the USA; and
- three plastinated specimens in the storage room that were imported from Germany.

Labels on the specimens/packaging were checked against information on relevant paperwork, MTAs, consent forms, and computer records. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

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.	GQ2	There are audits covering all licensable activities, which are carried out by the DI and Centre Manager. The DI is advised to also consider using auditors who are not closely associated with the work, which may provide more independent assessments.
2.	GQ7	The establishment currently shares a storage space with the mortuary in the hospital. The DI is advised to risk assess the capacity of this storage to determine whether it is adequate to support the storage of material for the number of courses offered, and whether it is adequate to support the storage of bodies if the body donor programme is started.

Concluding comments

One strength was observed:

- the training centre appears well managed, with a high standard of cleanliness being maintained. Plastinated specimens are well maintained and in excellent condition, which results in all specimens being treated with the utmost dignity and respect.

In addition, a number of areas of good practice were observed on the inspection. These included:

- staff from the establishment including the Surgical Skills Training Centre Manager have visited the companies that provide services to them to ensure that they are suitable. This included: a visit to the company which disposes of material at the end of use, and a visit to the company from which they obtain fresh frozen material (where they also observed the consent-seeking process);
- the centre manager has set up an online sharing network with other professionals, to share information and good practice;
- the establishment reviews professional qualifications of course leaders to make sure they are suitable before allowing a course to take place; and

- each plastinated specimen has a security tag that connects to the call out system if it is moved outside its designated zone

The HTA has given advice to the Designated Individual about audits and contingency storage.

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

Report sent to DI for factual accuracy: 21 November 2016

Report returned from DI: 19 December 2016

Final report issued: 22 December 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.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Independent interpreters are available when appropriate • Information is available in suitable formats
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all licensable activities • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • Complaints system
GQ2 There is a documented system of quality management and audit
• A document control system, covering all documented policies and standard operating procedures (SOPs).

- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom

GQ6 There are systems to ensure that all adverse events are investigated promptly

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Appropriate separation of relevant material • Air classification system and maintenance of air quality, including control and monitoring of environmental conditions • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis
PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transportation • Records of transportation and delivery • Records are kept of transfer agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies • Users have access to instructions for equipment and receive training in use and maintenance where appropriate • Staff aware of how to report an equipment problem • Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

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 risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   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 that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

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, but which indicates a departure from expected standards.

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 or site visit.

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.