Site visit inspection report on compliance with HTA minimum standards

Bart’s and the London, Queen Mary's School of Medicine and Dentistry

HTA licensing number 12004

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.**

27 and 28 November 2012

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.

Bart’s and the London, Queen Mary's School of Medicine and Dentistry (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 DI are set down in Paragraph 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 by Bart's and the London, Queen Mary's School of Medicine and Dentistry (the establishment). Before the Human Tissue Act came into force, previous inspections of this establishment were carried out by HM Inspector of Anatomy; the last one of these was in 2006. This was the first site-visit HTA inspection of the establishment since it was issued an HTA licence in 2007.

The establishment's licensing arrangements cover the Mile End Campus (Turnbull Centre; the hub) and two satellites (St Bartholomew's Hospital Pathology Museum Upper Galleries, West Smithfield; Royal London Hospital Pathology Museum Galleries, Whitechapel).

The storage and anatomical examination of human cadavers is carried out at the hub (Turnbull Centre; TC). Approximately 50 donated embalmed bodies are accepted for undergraduate and postgraduate courses each year. All consent procedures, consent information and consent training are organised by the London Anatomy Office (LAO), which is contracted to and overseen by the London and South East Committee of Anatomists (LSECA). The LAO consent form covers bequeathal of the body for anatomical examination, education, training and research. The form also records whether donors consent to storage and use for a specified period or indefinitely, and whether photographs may or may not be

taken.

The deceased are embalmed prior to being transported to the TC. There is an agreement between the LAO and Dignity Caring Funeral Services for the safe transport of cadavers and their eventual cremation (if required). There is also an agreement between the establishment and an individual at St George's, University of London for the embalming of donors. Prosected specimens, consented to be retained for longer than the corresponding cadaver, are sensitively disposed of by the disposal contractor (SITA UK) under an agreement with the establishment.

Cadavers and prosected material are used for teaching human anatomy to medical and dental students in years 1 and 2. Approximately 280 medical students, 90 dental students and a smaller number of biomedical sciences, physiological science and sports science students use the TC. Qualified surgeons also use the facility for professional training.

Embalmed cadavers and large prosections are stored at room temperature on trays in the well ventilated body store, which has a capacity for 20 cadavers. Smaller prosections and those requiring wet storage are in plastic boxes. The dissecting room contains 36 dissecting tables. The dissecting room and adjacent teaching room (anatomy practical laboratory) also hold a labelled and (paper) catalogued tissue collection of preserved pathological specimens (approximately 500) for teaching anatomy to medical and dental students. This collection includes foetuses, bones, potted specimens, specimens from children and tissue blocks and slides. A locked side-room also contains a collection of skeletons and bones (bone collection; approximately 100 specimens).

The site-visit inspection of the hub included a visual inspection of the dissection room, body store and anatomy practical laboratory. Interviews were conducted with the DI, the TC Manager and the two TC Technicians. A documentation review and audit trails were also carried out. Details of the hub forward and reverse audits are provided below, there were no discrepancies noted.

In the body store, details on the identity tags (attached to ear, finger, toe) for three cadavers were checked against each unique index number in the relevant computer and hard copy records (the Cadaver Register). The records contained details of the donor, consent information and acceptance criteria. A similar reverse vertical audit was completed for three prosections in the dissection room. Each prosection was matched in the Parts Register to its original cadaver, and matched to records of cremation for one cadaver. Additionally, a forward audit was performed, where two consent forms were used to track prosections. One prosection had been correctly disposed of and one was correctly located in the dissecting room.

A records audit was also completed on the inventory of existing holdings of five randomly chosen potted preserved specimens in the tissue collection; no discrepancies were found.

The bone collection in the side-room has yet to be catalogued for use.

The satellite at St Bartholomew's Hospital holds approximately 4000 preserved and potted specimens for the education and training of medical students (years 1 and 2) and qualified pathologists. All specimens are currently being preserved, photographed, labelled with a bar code and catalogued onto an electronic catalogue. Access to this database is restricted to students and staff.

The site-visit inspection of this satellite included a visual inspection of the galleries and the

preservation/photographic workshop. The HTA provided advice on the workshop environment *(see Advice item 8)*. Interviews were conducted with the Assistant Curator and the Curator of the Pathology Collection. A documentation review and audit trails were also carried out. For the records audit the inventory of existing holdings of five randomly chosen potted preserved specimens in the galleries were traced; no discrepancies were found.

The satellite at the Royal London Hospital consists of three separate galleries holding, in total, approximately 1100 preserved specimens for the education and training of medical students (years 1 and 2) and qualified pathologists and, for one gallery, for education of outside audiences by invitation only. The galleries are the Doniach Gallery (40 skeletal specimens), the Thompson Yates Gallery (500 pathological specimens) and the Dorothy Russell Gallery (500 pathological specimens). One of these galleries (Thompson Yates) has been electronically catalogued onto the database, one has a local paper catalogue, and one (Dorothy Russell) has yet to be labelled and catalogued. It is envisaged, in due course, that all specimens will be placed on the electronic catalogue, as will the tissue and bone collections at the TC.

The site-visit inspection of this satellite included a visual inspection of the galleries. An interview was conducted with the Learning Resources Manager. A documentation review and audit trails were also carried out. For the records audit the inventory of existing holdings of five randomly chosen potted preserved specimens in each of the Thompson Yates and Doniach Galleries were traced; no discrepancies 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.	GQ1	Licensable activities are covered by a range of documented policies, codes of conduct and procedures, though there is some inconsistency in the format of each of them. The DI is advised to consider the addition of the following features to each document to create a more robust system: - document control information, such as a revision history and version number - review date (at least annual) - issue date - pagination - the names of both the author and the reviewer who has authorised the content of the document (the reviewer should have knowledge of the relevant procedure/process but need not be more senior than the author). The DI is advised to ensure that all governance and record documentation is placed on an intranet site with restricted access so that all relevant staff are

		familiar with the most up-to-date documents.
2.	GQ1	Governance meetings occur regularly and there is a standing item at these meetings for HTA-related matters. The DI is advised to emphasise this to all staff working under the licence. This will ensure that nominated Persons Designated (PDs) and other staff can discuss and feed back on issues such as adverse events, changes to SOPs, audits, risk assessments, HTA training and updates from the HTA at these meetings.
3.	GQ1, PFE2	The DI is advised to document all cleaning and decontamination procedures and to record when cleaning and decontamination has taken place.
4.	GQ2	The DI requested guidance on the format of a quality manual, which was given as follows: The Quality Manual (QM) should be understood and followed by all members of staff at the establishment. It is an overarching document, containing high-level information which gives a practical "snapshot" of the establishment's structure and ways of working. The QM should act as a resource and can either highlight the practices and processes for which there are policies and standard operating procedures (SOPs) in place or include specific references to policies and SOPs. It should be focused, generally keeping the detail to a minimum to reduce the frequency of revisions. The QM can either be in paper or electronic format and could include the following: • An introduction, outlining the features of the establishment's quality systems and the purpose of the QM • A general outline of the establishment, which could include: o A section akin to a "mission statement", including main responsibilities o An overview of current arrangements/activities e.g. body donations/enquiries, acceptance of cadavers, embalming arrangements, use of cadavers and relevant material, respect and dignity for the deceased, disposal, thanksgiving arrangements o Organisational/staffing structure • Demonstration of intent to conform to the requirements of regulatory and professional bodies, for example by detailing relevant governance meetings, audit programme, etc. • Reference to training and appraisal processes • Reference to staff employment/HR documents (grievance, complaints, disciplinary procedures)
5.	GQ2	The DI is advised to implement a formal schedule of procedural horizontal audits. This will help to ensure that SOPs accurately reflect the practices being carried out. Vertical audits of records and specimens could also be carried out on a scheduled basis. The results of audit findings, and actions taken, should be formally recorded.
6.	GQ6	Adverse events are dealt with on an individual basis and the DI makes recommendations for preventative actions. Where the requirement for action has been identified, the DI is advised to consider whether this should be

		reflected in an SOP detailing how an adverse event is logged, reported, addressed and monitored. The adverse events should be those relating to licensable activities that fall outside of the RIDDOR reporting system. Such adverse events could be defined as event that: -caused harm or had the potential to cause harm to staff or visitors. -led to or had the potential to lead to a breach of security of the premises and the contents contained therein. -caused harm or had the potential to cause harm to stored human tissue (including loss) and resulting loss of dignity. -breached the HT Act or the HTA Code of Practice on Anatomical Examination (Code 4).
7.	GQ7	Assessments have been made of the risks to health and safety of staff, students and visitors. The DI has also identified areas where problems may arise and identified solutions to these problems; for example, the actions to take if the body of a deceased person arrives without appropriate paperwork. The DI is advised to document these as formalised risk assessments, which should be reviewed regularly and updated if necessary.
8.	PFE2	The DI is advised to provide equipment to measure and record the environmental levels of formaldehyde in the workshop area.
9.	D2	The method and reason for disposed tissue are the same for all cases. The DI is advised that these could be incorporated into an SOP.

Concluding comments

During the inspection of the Bart's and the London, Queen Mary's School of Medicine and Dentistry, several areas of good practice were noted. These were:

- To ensure that the dignity of the deceased is always upheld the DI has put a number of safeguards in place
    - a review of the security of the premises, documented in an SOP
    - a registration system to monitor student attendance and also to record dissecting table cleanliness. The DI and other persons working under the licence are aware of who is in the establishment at any given time, students and staff are given restricted access on their swipe cards and students are not permitted into the anatomy suite before 9am or after 5pm
    - a local code of conduct reflecting the requirements of the HT Act and the HTA Code of Practice on Anatomical Examination. This is given as a handout (in the dissection manual) and as a presentation by the DI before all dissections begin.
    - a declaration to be signed by all relevant visitors to confirm that they have read and understood the local code of conduct
    - prominent signs relating to important aspects of the local code of conduct
- Staff are knowledgeable and are encouraged to further their academic qualifications (e.g. one Technician is sitting the Diploma in Anatomical Technology and Science).
- The Cadaver Register and corresponding spreadsheet are clearly laid out. Columns include: index number, Funeral Director number, full donor details, date/place of death, consent and retention details (including consent for photographs) and details of

cadaver release and cremation/burial.

- Individual loose leaf folders on each cadaver are filed in chronological order with all the above details as well as with all Funeral Director documents and copies of the consent forms.

- The Parts Register and corresponding Excel spreadsheet contain a similar detailed account. The Register is divided into separate sections for: head and neck, thorax, abdomen, pelvis and limbs.

- A colour coding system in the records (and on a corresponding white board in the body store) indicates which cadaver is: waiting to come in, arrived, released. There is a similar system for prosections.

- At the satellites the electronic catalogue system logs all specimen details, including specimen number, dimensions, acquisition date, barcode number and photograph. Images are watermarked and cannot be copied.

- At the hub there is a high awareness of the need for security and the premises are well secured with key and code locks, an alarm, and CCTV cameras. There are variable entry rights and there is a published list of key holders. Students are limited to a maximum of 140 at any one time to ensure that there is sufficient space for anatomical examination to be carried out safely and efficiently.

- At the satellites all galleries are locked, with programmable ID cards and restricted access. There is a 24 hour wireless callout facility for all the galleries. Entrant photographs are recorded on CCTV and saved as image to Email/memory card for one month.

No shortfalls were identified during the inspection. The establishment has been provided with advice in a number of areas, which the DI is advised to consider.

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

Report sent to DI for factual accuracy: 21 December 2012

Report returned from DI: 15 January 2013

Final report issued: 25 January 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.

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

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.