Site visit inspection report on compliance with HTA minimum standards

Bart's Pathology Museum

HTA licensing number 12625

Licensed under the Human Tissue Act 2004 for the

- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **use, for the purpose of public display, of the body of a deceased person or relevant material which has come from the body of a deceased person**

2-3 December 2014

Summary of inspection findings

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

Although the HTA found that Bart's Pathology Museum (the establishment) had met the majority of the HTA standards, four minor shortfalls were found against the Governance and Quality Systems (GQS) standards. The shortfalls were in relation to standard operating procedures, governance meetings, audits and the investigation of adverse events. Advice has also been given relating to the GQS, Premises, Facilities and Equipment (PFE), and Disposal (D) standards.

Particular examples of 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 (LH), premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Bart's Pathology Museum (the establishment), which applied for an HTA licence in July 2014 in order to facilitate public engagement through wider participation in unticketed events. In the first instance, it is planned that some of the facilities will be open to the public for such unticketed events, whereas other areas will have restricted access. This is described under each section below.

The establishment's licensing arrangements cover Bart's Hospital Pathology Museum (the hub site) and the Royal London Hospital Pathology Museum Galleries (two satellite sites). The satellites are the Doniach Gallery and the Thompson Yates Gallery. The hub and satellites are covered by one nominated Person Designate (PD), who reports to the DI.

The Corporate LH (CLH) is Queen Mary University of London, which rents the premises from Bart's Health NHS Trust. The Trust itself has two separate public museums - St Bartholomew's public museum and the Royal London public museum. These are not covered by the licence as they do not display human tissue specimens.

In the public display sector, it is HTA policy to undertake a full site visit inspection before material of human origin is put on display, to ensure that the HTA's standards are being met.

<u>The hub</u>

Bart's Pathology Museum holds approximately 4,000 skeletal and preserved potted human pathological specimens from both living and deceased donors. The museum consists of a

ground floor and first and second floor galleries. It is planned that the ground floor will be open to the public and that the galleries will continue to be used for teaching purposes.

The ground floor is already being used for public seminars and school visits. The seminars have a medical-humanities theme and attendance is restricted to online registration. Only human tissue specimens over 100 years old are displayed. Examinations for medical and dental students are also held on the ground floor.

The first and second floor galleries contain approximately 3,400 specimens. These are currently used for teaching medical and dental students and trainee pathologists. Most of the specimens are less than 100 years old and are arranged in modules in line with the teaching curriculum. There is a spiral staircase leading from the ground floor to the galleries. During public events on the ground floor, the staircase is blocked by a 'No Entry' sign and is cordoned off with display boards.

All doors are kept locked when no one is present in the museum. Staff access to the museum is via swipe cards. Movement of the doors is recorded by closed-circuit television (CCTV). If the doors are forced open, central security (which is available on a 24-hour basis) receives an alert (*see Advice item 12, below*).

Outside the galleries, there is a locked cupboard where uncatalogued specimens are kept, a locked office where records (and some uncatalogued human skeletal specimens) are kept, and a preservation and photographic workshop (*see Advice item 6*).

Specimen labelling and cataloguing at the hub. Specimens have individual labels with a unique reference number identifying each specimen. Specimen details are kept in paper records and are then transcribed onto a backed-up electronic spreadsheet.

As part of its ongoing conservation programme, the establishment has set up an online database ((VPathMuseum). Each specimen is currently being assessed, described, photographed, bar code-labelled and electronically catalogued on the database. Access to this is restricted to students, staff and external applicants who are assessed by staff and who have temporary access rights

Acquisition, loan and disposal. All samples are existing holdings. There are no plans for collecting further specimens so the consent standards do not apply. Specimens are occasionally loaned to other HTA-licensed organisations. There has been no specimen disposal to date.

The site visit inspection of the hub included a visual inspection of the museum ground floor and galleries, the preservation and photographic workshop and the office area. Meetings were held with the PD (Resources Manager) and the Museum Technical Curator. A documentation review and horizontal and vertical audits were carried out.

Four specimens were selected at random from the galleries and the specimen descriptions, and their reference numbers and locations, were compared to information contained in the paper records and on the electronic database; there were no anomalies. The records for the loan and return of a batch of eight specimens were also examined; there were some anomalies (*see Standard GQ3, below*).

The sateliite sites

The satellites hold approximately 510 skeletal and preserved potted human pathological specimens from both living and deceased donors. The Doniach Gallery holds ten skeletal specimens and the Thompson Yates Gallery 500 pathological specimens. Both galleries contain some specimens of less than 100 years old. It is planned that the galleries will continue to have restricted access and will not be open to the public in the short term.

The Doniach Gallery contains three full human skeletons in glass cases. Access is restricted

to individuals or small groups who must apply to the PD to visit the gallery. Guests must sign a register. They are generally accompanied by the PD during the visit. The room is locked when not in use.

The Thompson Yates Gallery is used for teaching medical and dental students and trainee pathologists, as well as being used for school visits. There is swipe card access for staff and students. For school groups, teachers supply a list of students' names and a register is signed on the day.

Specimen labelling and cataloguing at the satellites. Specimens have individual labels with a unique reference number identifying each specimen. In the Doniach Gallery, specimen details are kept as a local paper record. In the Thompson Yates Gallery, specimen details are kept within the gallery on the paper records and some are also on the VPathMuseum database. It is envisaged, in due course, that details of all specimens will be recorded on the database.

Apart from specimens in the two galleries, there are approximately 500 uncatalogued pathological specimens of less than 100 years old stored on the Common Room first floor balcony ('Dorothy Russell Gallery'). The room is locked but is still in use as a common room.

Although the Trust Royal London public museum does not come under the licence (as there are no human specimens on public display), it stores blocks and slides (approximately 500). These are from deceased donors, and are mostly less than 100 years old. They are famous cases and are occasionally used for identity testing and criminal investigation (*see Advice item 6*).

The site visit inspection of the satellites included a visual inspection of the galleries and the Trust Royal London public museum. Meetings were held with the DI (Professor of Pathology Education) and the CLH Contact (Medical School Chief Operating Officer). A documentation review and horizontal and vertical audits were carried out.

Three specimens were selected at random in the Thompson Yates Gallery; the specimen descriptions, reference numbers and locations were compared with information in the paper records and on the electronic database. There was one anomaly (*see Standard GQ3, below*).

Inspection findings

The HTA found the DI and the CLH 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 The establishment's work on public display is supported by ratified documented policies and procedures as part of an overall governance process.	There are no Standard Operating Procedures (SOPs) to cover the following activities: • conducting audits • admission and curating of the Doniac Gallery • specimen preservation and monitoring (including the checking of preservative levels of exhibits) • control of environmental conditions and housing • transport of specimens between sites. *See Advice item 1*.	**Minor**
GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of an overall governance process.	There is no regular forum where staff working under the licence can discuss regulatory issues. *See Advice item 2*.	**Minor**
GQ3 There is a systematic and planned approach to the management of records.	There is currently no regular audit of record content to check for completeness, legibility and accuracy. During the inspection it was found that: (i) The records for the loan and return of a batch of eight specimens from the hub had discrepancies. The loan documents were incomplete and were missing the signatures of staff at the establishment and staff at the organisation which had received the loan. It was difficult to ascertain if the specimens had been returned to the establishment. (ii) One of the specimens selected for audit at the Thompson Yates satellite was not described in the bound shelf guide, although it was described in the VPathMuseum database. *See Advice items 6 and 7*.	**Minor**
GQ5 There are systems to ensure that all adverse events are investigated promptly.	There is no formal system for capturing adverse events relating to human specimens. *See Advice item 8*.	**Minor**

Advice

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

No.	Standard	Advice
1.	Principally GQ1 but also relevant to standards PFE1, PFE2 and PFE4	There is inconsistency in the current format of SOPs. The DI is advised to consider the inclusion of the following features, to create a more robust system and to ensure that the most up-to-date documents are being used: • document control information, such as a revision history and version number • 'effective from' date • review date (at least every three years) • pagination • author and reviewer names.
2.	GQ1	In other establishments, similar meetings have covered items such as: adverse incidents, changes to SOPs, audits and their findings, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). It is advised that these meetings are governed by an agenda and that minutes are recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings. The DI may wish to consider incorporating this meeting into the programme of Pathology Museum Management Committee meetings.
3.	GQ1	The DI may wish to consider setting up meetings with other DIs working both within and outside the organisation, to share information and experience with them and their PDs. This may help facilitate learning and understanding of staff at the establishment as well as being a forum for the discussion of good practices.
4.	GQ2	The DI may wish to consider using the HTA 'Code of Practice on Public Display (Code 7)' as part of its training programme.
5.	GQ2	The DI may wish to consider that induction and refresher training for examiners and volunteers managing public events could include signing off familiarity with the 'code of conduct' (see *Concluding comments, below*), relevant SOPs and relevant risk assessments. The DI may then wish to consider extending this to all relevant staff.
6.	GQ3	The DI is advised to formalise a schedule of audits carried out by different members of staff. It could include regular process audits to ensure that SOPs accurately reflect current practices, vertical human specimen traceability audits, from records of receipt to storage, display, loan or disposal, and horizontal audits. The DI may also wish

		to consider implementing a regular audit against HTA standards. The initial audits should cover specimens in the records office, locked cupboard and the Trust Royal London public museum. The results of all audit findings, and actions taken, should be formally recorded to ensure continuing improvement of processes and practices.
7.	GQ3	The DI is advised to ensure that paper copies of loan documents are scanned to ensure that they can be permanently retained. The DI is also advised to amend the loan form to include a box to record date and signature for return of specimens.
8.	GQ5	The DI is advised to keep a central log of all adverse events relating to human specimens. These could include: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • specimen transport between sites under this licence or to other licensed establishments • inappropriate disposal The results of all actions taken (root cause analysis and corrective and preventative actions) should be formally recorded.
9.	GQ6	The DI has created risk assessments relating to the Control of Substances Hazardous to Health (COSHH) regulations for the workshop procedures. They have also created risk assessments for 'risks to the specimens during a public event' (including theft and vandalism) and their mitigation by the use of CCTV. Although not exhaustive, the DI should consider further risks to specimens, such as: • all premises (satellites, Dorothy Russell Gallery and the Trust Royal London public museum) • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • specimen transport between sites under this licence or to other licensed establishments • inappropriate disposal Risk assessments should be reviewed regularly and also after changes to key procedures.

10.	PFE1	The DI may wish to consider using signage to indicate potentially sensitive (i.e. foetal) specimens during public exhibitions.
11.	PFE1	The DI is advised to introduce a system to record the maximum and minimum temperature in all areas used for the storage and public display of human specimens and to review these temperature readings periodically. This will ensure that staff are alerted to temperature deviations promptly and they will be able to minimise the effect of adverse temperatures on specimen quality.
12.	PFE1	The DI is advised to carry out regular testing of the security alarm system at the hub site to ensure that the callout procedure is functioning correctly.
13.	D2	The DI is advised to make the disposal SOP clearer. It should include the following: • the date, reason (e.g. poor condition of specimen) and method (incineration) of disposal. • the sign off process for who authorises the disposal. • a reference to the HTA 'Code of Practice on Disposal of Human Tissue (Code 5)'.

Concluding comments

During the site visit inspection of the establishment, several areas of good practice were noted:

- The DI and her team have created a 'location agreement' for the museum. This acts as a 'code of conduct' for visitors (e.g. for those attending or filming public events) and specifies appropriate behaviour.
- Management and staff are committed to making better use of this valuable and unique resource of human tissue at both the hub and satellite sites. The staff are dedicated and enthusiastic, and the organisation is taking note of this in its funding arrangements by providing a permanent curatorial position in the near future.
- The establishment aims to obtain Arts Council England accreditation for the collections in due course.

There are a number of areas of practice that require improvement, including four minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality Systems, Premises, Facilities and Equipment, and Disposal standards.

The HTA requires that the DI 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 2 January 2015

Report returned from DI: 13 January 2015; Final report issued: 6 February 2015

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: 26 October 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment highlighted as grey text.

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 Codes of Practice • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 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 • Agreements with third parties who provide material for public display contain information about consent requirements
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 • There is 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 The establishment's work on public display is supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, governing the storage and public display of bodies and relevant material • There is a system of risk management in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • There is a complaints system in place

GQ2 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training is recorded
- There are orientation and induction programmes for new staff
- There is a documented training programme (e.g. health and safety, fire, risk management, infection control), including developmental training

GQ3 There is a systematic and planned approach to the management of records

- There are documented procedures for the creation, amendment, retention and destruction of records
- There is regular audit of record content to check for completeness, legibility and accuracy
- There is a back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ4 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 specimen, and to each of the products associated with it

GQ5 There are systems to ensure that all adverse events are investigated promptly

- There is a system for reporting adverse events
- Corrective and preventive actions are taken where necessary and improvements in practice are made

GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- There are 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 licensed activities
- There are policies in place to review and maintain the safety of staff, students and visitors
- Where appropriate, policies are in place to ensure that the premises are of a standard that ensures the dignity of the deceased
- 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 Equipment is appropriate for use and environmental controls are in place to avoid potential contamination
• There are documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • There is a contingency plan for equipment failure
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells.
• Bodies and relevant material are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Critical storage conditions are monitored and recorded • There are systems to deal with emergencies out of hours
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
• A system is in place to ensure that traceability of specimens is maintained during transport • Records of transportation and delivery are maintained • Records are kept of any agreements with courier or transport companies

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• There is a documented disposal policy • There is compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• There is a system for tracking the disposal of relevant material, including recording 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.