Inspection report on compliance with HTA licensing standards
Inspection date: **26 September 2023**

St Peter's Hospital
HTA licensing number 12542

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem 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 the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site St Peter's Hospital	Licensed/Not licensed	Licensed/Not licensed	Licensed/Not licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	-

Summary of inspection findings

Whilst the HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation, the LH is advised to consider a change of DI as the current DI has clinical commitments in an area

not associated with licensable activities. The current DI took on the role as a temporary arrangement until a suitable individual with more direct oversight of licensable activity could be identified.

Although the HTA found that St Peter's Hospital ('the establishment') had met the majority of the HTA's standards thirteen major and eight minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

Shortfalls against HTA standards C2(b), C2(d), GQ1(a), GQ2(a), GQ3(g), GQ6(a), T1(c), T1(d), PFE2(e), and PFE2(f), relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

Concerns were discussed with the establishment as part of this inspection. The establishment completed a series of HTA compliance audits leading up to this inspection and self-identified most of the shortfalls detailed in this report. Action plans had been implemented to address non-compliance with HTA standards at the time of inspection and progress with these plans was evident. Had this not been the case, some standards where major shortfalls have been identified would have been assessed as critical findings. The current DI and the CLHc provided assurance that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Records did not provide assurance that staff involved in seeking consent for adult post mortem examination had up to date training due to records not being maintained sufficiently.	**Major (Cumulative)**
d) Competency is assessed and maintained	Competency in consent seeking was not assessed or maintained for both adult and perinatal consent seekers.	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	SOPs do not always include sufficient detail of procedures for traceability of bodies or tissue or reflect current practice. These include but are not limited to: • The SOP for management of tissue taken at PM examination details that only two identifiers of the deceased, name and mortuary reference number are to be written onto containers for both tissue and organs retained at PM. • The SOP for receipt and release of bodies does not contain sufficient detail of the number and type of identifiers of the deceased that should be crosschecked with information provided by the funeral director to information on the body to determine the correct body is being released. • The SOP for viewing of the deceased does not include detail of how identification of the body is established with families using three points of identification at the point of arrival to ensure the correct body has been prepared for the correct family. • The SOP for PM examination does not detail when bodies should be moved into the PM room prior to PM examination. Furthermore, it does not detail how identification of a body is established using three points of identification cross referenced to the Coroner authorisation or consent form. • The SOP for admission of bodies to the mortuary by funeral directors details that funeral service staff collect keys from the porters office to gain access to the mortuary unsupervised. This is not current practice as portering staff now provide access and supervision to the mortuary. • The SOP for visitors to the mortuary does not detail how oversight of contractors and maintenance staff entering the mortuary is	**Major**

	managed. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail, are reflective of current practice and cover all mortuary and laboratory procedures relevant to licensed activity.	
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Many documents provided to the inspection team for review did not include the document review date, provide detail of the author and authoriser of the document or the version number. Therefore, the inspection team could not be assured staff were using the latest versions.	**Major**
e) There is a system for recording that staff have read and understood the latest versions of these documents	At the time of the inspection there was no assurance that staff working in the mortuary including locum and visiting staff had read and acknowledged SOPs relevant to their work.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst the establishment have recently implemented an audit schedule and have made progress with the audits on the schedule, including an audit of all HTA standards, there was no assurance that regular audits had been undertaken since the previous inspection as evidence to support this was not provided to the inspection team.	**Major (Cumulative)**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Whilst the establishment provided several audits completed in the preparation for this inspection, which provided some evidence of compliance with this standard, the standard was unable to be assessed fully due to the shortfall against GQ2(a).	

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Lists of tissue retained at PM were provided to the inspection team for review rather than audits which identify any nonconformities in tissue retention and traceability procedures. The format could not be interpreted in a manner that provided assurance of compliance with this standard.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Due to a recent significant change in staffing and oversight of the mortuary, this standard could not be fully assessed for assurance all staff involved in mortuary duties were appropriately trained and qualified for the roles undertaken. The establishment however, had action plans in place to address staffing and senior management were providing direct supervision of the mortuary at the time of inspection. This meant that HTA standards GQ3(c), GQ3(d), GQ3(e) and GQ3(f) could also not be assessed fully as part of this inspection.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Risk assessments in place had not been subject to regular review. Furthermore, they did not consider risks relating to all procedures as outlined in HTA standard GQ1(a) or fully consider risks to mitigate the occurrence of HTA reportable incidents (HTARIs).	**Major (Cumulative)**

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Whilst risk assessments reviewed included some control measures in place to mitigate risks, not all control measures had been considered for inclusion. (see *Shortfall* against HTA standard GQ1(a)).	
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
a) Bodies are tagged/labelled upon arrival at the mortuary	Whilst bodies were labelled upon admission to the mortuary and no discrepancies in identity were seen during the inspection team audit, it was noted that identification bands on the ankles of bodies were not routinely crosschecked to ensure they match the wristbands and the notice of death form during the admission procedure. This poses a risk as any discrepancies in the information on the body may not be identified to prevent a misidentification incident.	**Major**
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Whilst the establishment had recently adopted the use of a viewing form so three identifiers of the deceased could be recorded and crosschecked to the body at the point of preparation and upon entry of visitors, the inspection team were not fully assured that viewing of bodies, both in and out-of-hours occurred using three identifiers routinely as the procedure is not adopted into SOPs or embedded into practice. Tissue and organs retained at post mortem examination were only labelled with two identifiers of the deceased; name and post mortem number.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment did not get confirmation of receipt for tissues and organs sent off site for analysis. This poses a risk should tissues or organs not arrive at the intended destination as staff would be unaware of any issues in a timeframe that could prevent total loss of traceability.	**Major (Cumulative)**

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The procedure for managing transportation of tissue and organs outside of the mortuary for analysis did not adequately detail how traceability is maintained. Furthermore, the records of tissue and organs sent off site, whilst kept, did not provide sufficient detail of who has removed material from the mortuary as only the initials of those removing material were recorded.	
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Whilst the mortuary was mainly secured with swipe card access and CCTV was in use to monitor access, there are some external doors which used key access locks only. The establishment could not provide assurance of the number of keys in operation which means some access doors may not be controlled as expected.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	There was no assurance of consistent oversight or supervision of funeral directors accessing the mortuary out of hours to admit bodies. Access to the PM room and changing rooms was on internal swipe access, however, staff with general access to the mortuary can also swipe into the PM room area which may mean that staff not authorised to access this area may gain admittance. Furthermore, at the time of inspection, security audits to monitor access to the mortuary had not been undertaken. The establishment however, provided assurance to the inspection team that security audits were in the process of completion.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The bariatric storage unit is not linked to the remote alarm system therefore staff will not be alerted if temperatures deviate from within set ranges. Furthermore, at the time of the inspection, whilst a recent alarm test had been completed, there was no evidence to support alarms had been tested regularly to ensure they would alarm as expected in the event of a temperature deviation.	**Major (Cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	At the time of the inspection, there was no assurance that temperatures of fridges and freezers had been monitored on a regular basis or that trend analysis of the temperatures had been completed. Furthermore, temperatures of fridges and freezers were not monitored over weekends or long bank holiday periods.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst requests for adult post mortem examination are rare, a Standard Operating Procedure (SOP) for the seeking of consent was not provided to the inspection team for review. This means there was no assurance that staff would seek consent if required in line with the HT Act and HTA Codes of Practice.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst the bodies in storage audited were in a good condition, the SOP for consideration of movement of bodies to freezer storage indicates that condition checks are only performed after a body has been in storage for a period of three weeks. This may pose a risk to bodies starting to show signs of deterioration not being identified in a timeframe that would allow action to be taken to prevent deterioration becoming advanced.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst a HTA governance meeting had been held just prior to the inspection and there were action plans in place to ensure meetings are held going forward, there was no assurance that regular governance meetings involving staff working under the licence had been held since the previous inspection.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Whilst the establishment had created a checklist for visiting and external staff to demonstrate that an induction had been received, this did not provide sufficient detail of the induction and training provided or include sufficient assurance of sign off of the establishment's policies and procedures.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	The system for flagging up same or similar name deceased was not completed in accordance with the SOP for admission of bodies to the mortuary. Whilst bodies audited with a same or similar names were flagged on the whiteboards, the SOP stated that orange bands were to be attached to bodies to highlight to staff the presence of bodies with a same or similar name, however, at the time of the inspection, these bands were not available.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Whilst the premises were clean at the time of the inspection, there was no schedule of cleaning in place and records of cleaning and decontamination had not been maintained.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE	Whilst face masks are available for staff to use in the PM room, there is no record that staff have received face fit testing for use of this personal protective equipment.	**Minor**
e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation	The maternity unit routinely use chemicals for preservation of placental material. The room used for this purpose has a small window which is opened for ventilation. Staff informed the inspection team the arrangements for ventilation in this area can be inadequate.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1(a)	The consent policy and the information leaflet for relatives for adult PM examination contain links to the HTA website which are broken. The DI is advised to review the consent policy and associated documentation to ensure links to external information are up to date and are working as expected.

2.	C1(g)	The consent form in use for perinatal PM examination is listed as an appendix of the consent policy. There is an additional part of the form for families to consent to whole organ retention. The DI is advised to add this separate whole organ consent form as an appendix in the policy also. This will aid with regular review of all consent documents in operation.
3.	GQ1(h)	The DI is advised to invite portering supervisors, contracted funeral directors and all PDs to HTA governance meetings for assurance and oversight of training and competency assessment of staff undertaking licensable activities.
4.	GQ5(a)	Whilst staff undertaking activity in areas outside of the mortuary were aware of incident reporting, the DI is advised to include reference to other staff members in the HTARI SOP such as porters and maternity staff and share the SOP with these staff groups for reference.
5.	T1(b)	Systems in place to manage traceability of bodies, tissue and organs through the mortuary are heavily reliant on paper-based systems. Due to the number of storage areas and movements of bodies between these storage areas, the DI is advised to consider the use of an electronic tracking system. This may also assist with traceability of tissue and organs sent off site for analysis.
6.	T1(c)	The DI is advised to review the process for release of bodies from the mortuary. Funeral directors collect release of deceased forms from the bereavement office which are then cross checked to the body in the mortuary. Whilst these forms contain three identifiers of the deceased, the use of internal paperwork and not independent information supplied by the funeral director at the point of release may pose a risk of release of the wrong body should the incorrect internal form be given.
7.	T1(g)	The DI is advised have agreements in place with visiting pathologists for the management of traceability of tissue slides sent off site for analysis. The DI is advised to review the following information provided by the HTA: Management and traceability of tissue samples retained by independent pathologists.
8.	PFE2(i)	Whilst there is a documented contingency plan in place which covers the management of mortuary capacity during peak periods, the DI is advised to include reference in this SOP to the contingency

		arrangements to be made by staff in the event of a power failure or failure of fridge and freezer units for clarity.

Background

St Peter's Hospital has been licensed by the HTA since April 2009. This was the fifth inspection of the establishment; the most recent previous inspection took place in January 2019.

Since the previous inspection, the following changes have been made to the licensing arrangements: a change to the list of Persons Designated under the licence was completed in May 2020, August 2020, August 2022 and September 2023. A change of DI was completed in October 2021.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

68 of 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards GQ3(c), GQ3(d), GQ3(e) and GQ3(f) could not be assessed due to a significant restructure of staffing within the mortuary just prior to inspection.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included records of servicing of equipment, recent fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, security audit templates to be used, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and some staff training records. The consent seeking policy, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, PM room, viewing room and the maternity department body storage area.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar names, and a body stored longer term. Traceability details were crosschecked between the identification bands on the body, information on the door of the storage unit, the mortuary register, associated paperwork, and the electronic mortuary database. Whilst no discrepancies with traceability were identified, the inspection team noted that bodies with a same / similar name were not managed in line with the admissions SOP due to a lack of same/similar name bands that are attached directly to the body. (see *Shortfall* against T1(b))

As the establishment send relevant material to another HTA licensed establishment for processing and storage, an audit was conducted of tissue taken at PM examination for one case where the tissue had been returned to the department for return to a family at a later date. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, the family wishes form, and the tissue blocks and slides being stored. Whilst no discrepancies with this case were identified, the records for managing traceability require improvement (see *Shortfall* against T1g)).

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, Persons Designated for the mortuary, portering staff, staff involved in the consent seeking process for both adult and perinatal PM examination, a pathologist undertaking PM examination, the mortality lead with oversight of the SUDIC process and the DI.

Report sent to DI for factual accuracy: 31 October 2023

Report returned from DI: 13 November 2023

Final report issued: 30 November 2023

A further inspection was undertaken 27-06-2024. A new inspection report will be issued and new corrective and preventative actions will be carried out to address the identified shortfalls.

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 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. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.