Inspection report on compliance with HTA licensing standards
Inspection date: **21 April 2022 and 9 June 2022**

St George's Hospital

HTA licensing number 12387

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
St George's Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Accident and emergency department	-	-	-
Maternity	-	*Carried out*	-

Summary of inspection findings

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

Although the HTA found that St George's Hospital ('the establishment') had met the majority of the HTA's standards, seven major and four minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. These related to incident management, disposal of post mortem tissue, long-term body storage procedures, document control, staff training and competency assessments and governance within the Maternity department.

Four of the shortfalls (three major and one minor) 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 current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and 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. However, in light of the establishment's lack of progress with addressing shortfalls from previous inspections, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Compliance with HTA standards

Major shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ2 There is a documented system of audit		
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	The establishment do not conduct audits of PM tissue stored in the block and slide archive. During the site visit, the inspection team carried out an audit of tissue taken during PM. One of the cases selected for review had been stored for over a year since the PM despite the family having requested for the tissue to be disposed of once the coroner's process had ended. There was no documented evidence that this	**Major**

	case had been followed up with the Coroner to establish whether tissue could be disposed of. This was identified as a shortfall at the previous inspection in December 2018.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	There are no competency assessments for mortuary staff carrying out licensable activities after their initial training and sign off. This was identified as a shortfall at the previous inspection in December 2018.	**Major**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA.	Persons Designated do not know how to report incidents in the absence of the DI which has led to delayed HTARI reporting.	**Major**
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.	There are no clearly assigned responsibilities for incident management and the establishment staff fail to carry out suitable investigations and root cause analysis.	**Major**
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.	Investigations and follow up actions are not carried out promptly. The establishment has failed to submit sufficient follow up reports for three open HTA reportable incidents within the required timescales.	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of Practice		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is no procedure for following up with the Coroner to determine when the Coroner's authority has ended. This means that the establishment staff cannot assure themselves that tissue is not kept for longer than necessary. During the site visit, the inspection team carried out an audit of tissue taken during PM. One of the cases selected for review had been stored for over a year since the PM despite the family having requested for the tissue to be disposed of once the coroner's process had ended. There was no documented evidence that this	**Major**

	case had been followed up with the Coroner to establish whether tissue could be disposed of. This was identified as a shortfall at the previous inspection in December 2018.	
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
a) Storage arrangements ensure the dignity of the deceased	There is no procedure for the following-up of bodies in storage. There is no procedure for following up with Funeral Directors when bodies are ready for collection which results in bodies staying at the establishment for longer than necessary. During the site visit the HTA audited a body that had been stored in the freezer for over one year with no documented evidence for following up the case with appropriate persons. The lack of procedure is having a direct impact on freezer capacity which in turn is resulting in bodies being stored in refrigerated storage for over 30 days.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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 of the establishments SOPs and risk assessments are written and reviewed by the same person.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	Licensable activity is carried out in the establishments Maternity Department however this area is not within the governance framework and no Persons Designated (PDs) have been nominated for this area.	**Minor**

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.	There is no refresher training for mortuary staff carrying out licensable activities after their initial training and sign off.	**Minor**
g) Visiting/ external staff are appropriately trained and receive an induction which includes the establishments policies and procedures	Although visiting/ external mortuary staff (such as locums) receive an induction, it is not mandatory for them to read the establishments policies and SOPs relating to licensable activities. This was advised at the previous inspection in December 2018.	**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(c)	Although consent is always taken from the appropriate persons in the hierarchy of qualifying relationships, the hospital PM consent form references the Next of Kin (in relation to keeping a copy of the document). The DI is advised to update this reference.
2.	C2(a)	Due to the COVID pandemic the consent training schedule for perinatal consent seekers has been disrupted. The DI is advised to have the relevant staff members attend refresher training at the earliest convenience.
3.	GQ1(a)	The *'Receipt of deceased adults'* SOP (MORT43) states that the mortuary is accessed using a key. The DI is advised to update this reference as now all access is via swipe card only.

Background

St George's Hospital has been licensed by the HTA since February 2007. This was the sixth inspection of the establishment; the most recent inspection took place in December 2018.

Since the previous inspection, there has been some significant changes to the licence arrangements including the change of Designated Individual (DI) in April 2019 and a change in Corporate Licence Holder contact in January 2020.

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI and Mortuary Manager. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation, and equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs was also reviewed.

Visual inspection

The inspection team undertook an unannounced site visit inspection of the premises which included the mortuary body storage areas, the PM suites as well as the storage arrangements for relevant material held within the facilities.

Audit of records

The inspection team undertook audits of traceability for three bodies in storage. This included community and hospital cases in the fridge and freezer, as well as one long stay body. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. Although no traceability discrepancies were identified one body had been stored in the freezer for over one year with no documented evidence for following up the case with appropriate persons. See shortfall for PFE2(a).

Audits were conducted of stored tissue taken at PM examination. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. One case in storage was audited and the family had requested disposal. The blocks and slides had been stored for over one year subsequent to the request with no documented evidence of the following up of the case with the Coroner. See shortfall for T2(b).

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the Mortuary Manager, an Anatomical Pathology Technologist (APT), a senior porter, staff involved in the consent seeking processes, the Bereavement Midwife, and a pathologist who holds the position of DI.

Report sent to DI for factual accuracy: 1 August 2022

Report returned from DI: 12 August 2022

Final report issued: 18 August 2022

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: 28 September 2023

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.